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DEPARTMENT OF HOMELAND SECURITY

6 CFR Part 29

Protected Critical Infrastructure Information: Technical Amendments

AGENCY: Cybersecurity and Infrastructure Security Agency, DHS.

ACTION: Final rule; technical amendment.

SUMMARY: This final rule amends the Protected Critical Infrastructure Information regulations to provide non-substantive technical, organizational, and conforming updates that are intended to improve the accuracy of these provisions. This action is editorial in nature and does not impose any new regulatory requirements on affected parties.

DATES: This final rule is effective December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Phillip Boggs, Protected Critical Infrastructure Information Program Manager, (202) 878–2859, *Phillip.Boggs@cisa.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to the Critical Infrastructure Information Act of 2002 [1] (CII Act), the Department of Homeland Security (DHS) established uniform procedures for the receipt, care, and storage of critical infrastructure information voluntarily provided to the Federal government by the public. (69 FR 8074, Feb. 20, 2004; 71 FR 52262, Sep. 1, 2006). Today, these procedures are known as the Protected Critical Infrastructure Information (PCII) regulations outlined in Title 6, part 29 of the Code of Federal Regulations (6 CFR part 29). In 2007, DHS transitioned the responsibility to carry out the functions and responsibilities of the PCII Program from the DHS Preparedness Directorate to the National Protection and Programs Directorate (NPPD).[2] In 2018, Congress passed the Cybersecurity and Infrastructure Security Agency Act of 2018 which redesignated NPPD as the Cybersecurity and Infrastructure Security Agency (CISA) and established it as a new agency within DHS.[3] This technical amendment is intended to account for the organizational changes related to responsibility for the PCII Program within DHS and improve the regulation's accuracy through non-substantive, technical, and editorial updates. See the Description of Technical Amendments section below for a more detailed discussion of the updates included in this action.

II. Description of Technical Amendments

Technical amendments are made through this final rule to apply throughout the entirety of 6 CFR part 29. A majority of the changes made throughout 6 CFR part 29 are intended to reflect that CISA is the agency responsible for operating the PCII Program within DHS and providing the public with accurate information regarding how CISA currently operates the program. Specifically, the part is amended to accurately identify the names of offices and titles of personnel responsible for operating the PCII Program within CISA and to update legal citations and cross-references. This rule also creates several new definitions and amends existing definitions to clarify terms, titles, and acronyms used throughout the part that are specific to CISA's operation of the PCII Program. For example, some new definitions include ''CISA'', ''Director'', ''Executive Assistant Director'', and ''PCII Program Manager'' and do not create substantive changes to the regulations. Other definitions such as ''Critical Infrastructure'', ''Information Sharing and Analysis Organization'', and ''Voluntary or Voluntarily'' are amended through this rule to align the definitions with the exact statutory text of the CII Act or to update outdated legal citations.

This final rule also makes changes throughout the entirety of 6 CFR part 29 to correct typographical and grammatical errors and to clarify the regulation through stylistic wording and organizational changes. Some of these changes in the wording of the regulation are to align the regulatory text with the statutory text of the CII Act by incorporating the exact statutory language instead of cross-references to the CII Act or to add words from the statutory language of the CII Act which were initially erroneously omitted from 6 CFR part 29. Other wording and organizational changes are editorial in nature and intended to improve the clarity of the regulatory text. An example of such changes in wording includes the deletion of ''tribal'' used throughout the PCII regulations in the interest of brevity and ease of reading. Deleting ''tribal'' does not change the scope or substance of the rule because the definition of ''Local government'' in Section 29.2 expressly includes ''Indian tribe or authorized tribal organization, or in Alaska, a Native village or Alaska Regional Native Corporation.'' Overall, none of the technical amendments made through this final rule should be construed as modifying or creating any new substantive requirements.

A. Significant Changes to Regulatory Text

Some of the most significant changes to the regulation include changes to:

Section 29.3 Effect of Provisions

The section title has been replaced with ''FOIA Exemptions and Restrictions on Regulatory Use of PCII'' to more accurately describe the content provided in this section which relates to FOIA exemptions for PCII and other restrictions on the use of PCII.

Section 29.5 Requirements for Protection

In section 29.5(a)(3)(iii)(A) & (B), the ''and'' inserted between subparagraphs (A) & (B) has been replaced with ''or'' to correct a technical drafting error. As currently written, the ''and'' between both subparagraphs suggests that submitters must provide identical electronic and non-electronic express statements to CISA in order to receive PCII protection for electronically

[1] 6 U.S.C. 671–674.

[2] Notices of Implementation of the Post-Katrina Emergency Reform Act of 2006 and of Additional Changes Pursuant to Section 872 of the Homeland Security Act of 2002, to Michael B. Enzi, U.S. Senate Committee on Health, Education, Labor and Pensions (Jan. 28, 2007) and to Bennie G. Thompson, U.S. House of Representatives Committee on Homeland Security (Sep. 11, 2007) (on file with the Department of Homeland Security).

[3] 6 U.S.C. 652(a).

submitted information. However, the statute only requires, and PCII Program only needs, one express statement to accompany written information or records seeking PCII protection regardless of the method used to submit the information to CISA (*e.g.,* documentary, oral, or electronic submission formats). This change aligns the regulatory text with the legal requirements for PCII protection of information under the CII Act and eliminates the technical drafting error suggesting that submitters must follow a duplicative and more burdensome process for electronic submissions to receive PCII protection.

Section 29.6 Acknowledgment of Receipt, Validation, and Marking

Throughout this section, the term ''calendar'' has been added throughout the section to areas describing deadlines where it was erroneously omitted. This change is made to improve consistency and clarity throughout the section and to reflect the PCII Program's longstanding practice of using calendar days for all deadlines related to this section.

In section 29.6(e)(2)(ii), the paragraph was reorganized and revised to improve clarity on the chronological steps that CISA follows to return to the submitter information that is not eligible for PCII protection. The changes to this paragraph are editorial in nature to reflect a chronological sequence. They do not change any of the steps that CISA will follow to return information to submitters.

B. Amendatory Instructions

Amendatory instructions are the standard terms that the Office of the Federal Register uses to give specific instructions on how to change the CFR. Due to the extensive number of technical and conforming amendments made through this final rule, CISA is utilizing the Office of the Federal Register's new amendatory instruction ''revise and republish'' to codify the revisions set out in this regulatory action.[4] Use of the combined instruction allows CISA to republish 6 CFR part 29 in its entirety instead of using piecemeal amendments to revise the full unit of the CFR. Because piecemeal amendments are not used in this rule to signal where changes have been made, CISA intends to publish an unofficial, informal document showing what changes CISA made through this final rule to assist industry and other stakeholders in reviewing the changes that this final rule makes to the regulatory text. CISA will make the unofficial, informal document showing edits available on its website at *https://www.cisa.gov/pcii-program.*

[4] The Office of the Federal Register's Document Drafting Handbook (Chapter 2, 2–39) explains that agencies ''use [r]epublish to set out unchanged text for the convenience of the reader, often to provide context for your regulatory changes.'' *https://www.archives.gov/federal-register/write/handbook.*

III. Exemption From Public Notice and Delayed Effective Date Requirements

DHS has determined that this rulemaking is exempt from notice-and-comment rulemaking requirements under 5 U.S.C. 553(b)(A) and 5 U.S.C. 553(b)(B). Many of the amendments made through this action pertain solely to the organizational change in responsibility for the PCII Program within DHS and constitute ''rules of agency organization, procedure, or practice'' not subject to the Administrative Procedure Act's (APA) notice and comment requirements under 5 U.S.C. 553(b)(A). All of the amendments made through this action are technical or editorial non-substantive corrections, which are intended to provide the public with more accurate and current regulatory information about the PCII Program. These changes are necessary to correct errors and grammatical language, update definitions and titles, provide current legal citations, and make other non-substantive amendments that improve the clarity of the CFR. None of the amendments included in this action will have a substantive impact on the public and nor will they alter the regulatory requirements in the affected part. Accordingly, CISA finds for good cause that this final rule is exempt from public notice-and-comment rulemaking procedures under 5 U.S.C. 553(b)(B) because such procedures are unnecessary.

For the same reasons that this rule is exempt from notice-and-comment rulemaking requirements, and because affected parties will not need time to adjust to the amendments to the regulation made through this action, CISA finds that good cause exists to make this final rule effective upon publication in the **Federal Register** under 5 U.S.C. 553(d)(3).

This final rule constitutes final agency action under the APA and is issued under the authority of 5 U.S.C. 552(a), 5 U.S.C. 553, and 6 U.S.C. 673.

IV. Regulatory Flexibility Act and Executive Order 12866

Because CISA has determined that this rule is exempt from notice and comment rulemaking requirements, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply to this action. This technical amendment also does not meet the criteria for a ''significant regulatory action'' as specified in Executive Order 12866.

V. Paperwork Reduction Act

There is no new or amended collection of information required by this document; therefore, the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) are inapplicable.

List of Subjects in 6 CFR Part 29

Confidential business information, Reporting and record keeping requirements.

■ For the reasons set forth in the preamble, the Department of Homeland Security amends 6 CFR part 29 as follows:

PART 29—PROTECTED CRITICAL INFASTRUCTURE INFORMATION

Sec.
29.1 Purpose and scope.
29.2 Definitions.
29.3 FOIA exemptions and restrictions on use of PCII.
29.4 PCII program administration.
29.5 Requirements for protection.
29.6 Acknowledgement of receipt, validation, and marking.
29.7 Safeguarding of PCII.
29.8 Disclosure of PCII.
29.9 Investigation and reporting of violation of PCII procedures.

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

Authority: 6 U.S.C. 671–674; Section 2222–2225 of the Homeland Security Act of 2002, Pub. L. 107–296, 116 Stat. 2135, as amended by Subtitle B of the Cybersecurity and Infrastructure Security Act of 2018, Pub. L. 115–278, 132 Stat. 4184. 5 U.S.C. 301.

■ 2. Revise and republish §§ 29.1 through 29.9 to read as follows:

§ 29.1 Purpose and scope.

(a) *Purpose of this part.* This part implements the Critical Infrastructure Information Act of 2002 (CII Act) by establishing uniform procedures for the receipt, care, and storage of Critical Infrastructure Information voluntarily submitted to the Department of Homeland Security through CISA. Consistent with the statutory mission of DHS to prevent terrorist attacks within the United States and reduce the vulnerability of the United States to terrorism, CISA will encourage the voluntary submission of CII by safeguarding and protecting that information from unauthorized disclosure and by ensuring that such information is, as necessary, securely shared with State and Local governments pursuant to the CII Act. As

required by the CII Act, this part establishes procedures regarding:

(1) The acknowledgment of receipt by CISA of voluntarily submitted CII;

(2) The receipt, validation, handling, storage, proper marking, and use of information as PCII;

(3) The safeguarding and maintenance of the confidentiality of such information and appropriate sharing of such information with State and Local governments or government agencies pursuant to 6 U.S.C. 673(a)(1)(E); and

(4) The issuance of advisories, notices, and warnings related to the protection of critical infrastructure or protected systems in such a manner to protect, as appropriate, from unauthorized disclosure the source of critical infrastructure information that forms the basis of the warning, and any information that is proprietary or business sensitive, might be used to identify the submitting person or entity, or is otherwise not appropriately in the public domain.

(b) *Scope.* This part applies to all persons and entities that are authorized to handle, use, store, or otherwise accept receipt of PCII.

§ 29.2 Definitions.

For purposes of this part:

Critical Infrastructure has the same meaning stated in 6 U.S.C. 101(4) (which cross references the term used in 42 U.S.C. 5195c(e)) and means systems and assets, whether physical or virtual, so vital to the United States that the incapacity or destruction of such systems and assets would have a debilitating impact on security, national economic security, national public health or safety, or any combination of those matters.

Critical Infrastructure Information or CII has the same meaning stated in 6 U.S.C. 671(1) and means information not customarily in the public domain and related to the security of critical infrastructure or protected systems, including documents, records or other information concerning:

(1) Actual, potential, or threatened interference with, attack on, compromise of, or incapacitation of critical infrastructure or protected systems by either physical or computer-based attack or other similar conduct (including the misuse of or unauthorized access to all types of communications and data transmission systems) that violates Federal, State, or Local law, harms interstate commerce of the United States, or threatens public health or safety;

(2) The ability of any critical infrastructure or protected system to resist such interference, compromise, or incapacitation, including any planned or past assessment, projection, or estimate of the vulnerability of critical infrastructure or a protected system, including security testing, risk evaluation thereto, risk-management planning, or risk audit; or

(3) Any planned or past operational problem or solution regarding critical infrastructure or protected systems, including repair, recovery, reconstruction, insurance, or continuity, to the extent it is related to such interference, compromise, or incapacitation.

CII Act means the Critical Infrastructure Information Act of 2002 in 6 U.S.C. 671–674; Sections 2222–2225 of the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135, as amended by Subtitle B of the Cybersecurity and Infrastructure Security Act of 2018, Public Law 115–278, 132 Stat. 4168.

CISA means the Cybersecurity and Infrastructure Security Agency.

Department or DHS means the Department of Homeland Security.

Director means the Director of the CISA, any successors to that position within the Department, or any designee.

Executive Assistant Director means the Executive Assistant Director for the Infrastructure Security Division of the CISA, any successors to that position within the Department, or any designee.

Information Sharing and Analysis Organization or ISAO has the same meaning stated in 6 U.S.C. 671(5) and means any formal or informal entity or collaboration created or employed by public or private sector organizations for purposes of:

(1) Gathering and analyzing CII, including information related to cybersecurity risks and incidents, in order to better understand security problems and interdependencies related to critical infrastructure and protected systems, so as to ensure the availability, integrity, and reliability thereof;

(2) Communicating or disclosing CII, including cybersecurity risks and incidents, to help prevent, detect, mitigate, or recover from the effects of an interference, compromise, or an incapacitation problem related to critical infrastructure or protected systems; and

(3) Voluntarily disseminating CII, including cybersecurity risks and incidents, to its members, Federal, State, and Local governments, or any other entities that may be of assistance in carrying out the purposes specified in paragraphs (h)(1) and (2) of this section.

In the public domain means information lawfully, properly, and regularly disclosed generally or broadly to the public. Information regarding system, facility, or operational security is not ''in the public domain.'' Information submitted with CII that is proprietary or business sensitive, or which might be used to identify a submitting person or entity will not be considered ''in the public domain.'' Information may be ''business sensitive'' for this purpose whether or not it is commercial in nature, and even if its release could not demonstrably cause substantial harm to the competitive position of the submitting person or entity.

Local government has the same meaning stated in 6 U.S.C. 101(13) and means:

(1) A county, municipality, city, town, township, local public authority, school district, special district, intrastate district, council of governments (regardless of whether the council of governments is incorporated as a nonprofit corporation under State law), regional or interstate government entity, or agency or instrumentality of a Local government;

(2) An Indian tribe or authorized tribal organization, or in Alaska, a Native village or Alaska Regional Native Corporation; and

(3) A rural community, unincorporated town or village, or other public entity.

Protected Critical Infrastructure Information or PCII means validated CII, including information covered by § 29.6(b) and (h), including the identity of the submitting person or entity and any person or entity on whose behalf the submitting person or entity submits the CII, that is voluntarily submitted, directly or indirectly, to CISA, for its use regarding the security of critical infrastructure and protected systems, analysis, warning, interdependency study, recovery, reconstitution, or other appropriate purpose. PCII also includes any information, statements, compilations or other materials reasonably necessary to explain the CII, put the CII in context, or describe the importance or use of the CII when accompanied by an express statement as described in § 29.5.

PCII Program Manager means the federal employee within the Infrastructure Security Division of CISA appointed as responsible for the administration of the PCII Program pursuant to this part, any successors to that position within the Department, or any designee.

PCII Program Manager's Designee means a federal employee outside of the PCII Program Office, whether employed by CISA or another federal agency, to whom certain functions of the PCII

Program Office are delegated by the PCII Program Manager, as determined on a case-by-case basis.

Protected Critical Infrastructure Information Program Office or PCII Program Office means the personnel organized within the Infrastructure Security Division of CISA who carry out the operational and administrative functions of the PCII Program pursuant to the direction of the PCII Program Manager.

PCII Program Officer means a Federal, State, or Local government employee appointed by their respective agency or entity and, upon approval of the PCII Program Manager, carries out the responsibilities described in 6 CFR 29.4(d) to ensure the proper use, storage, and handling of PCII within their respective agency or entity.

Protected Critical Infrastructure Information Program or PCII Program means the program implementing the CII Act within the Infrastructure Security Division of the CISA, including the maintenance, management, and review of the information provided in furtherance of the protections provided by the CII Act.

Protected Critical Infrastructure Information Management System or PCIIMS means the electronic database and platform used to record the receipt, acknowledgement, validation, storage, dissemination, and destruction of PCII. PCIIMS also enables CISA to manage and train individuals authorized to view, handle, and access PCII.

Protected system has the same meaning stated in 6 U.S.C. 671(6) and means any service, physical or computer-based system, process, or procedure that directly or indirectly affects the viability of a facility of critical infrastructure; and includes any physical or computer-based system, including a computer, computer system, computer or communications network, or any component hardware or element thereof, software program, processing instructions, or information or data in transmission or storage therein, irrespective of the medium of transmission or storage.

Purposes of the CII Act has the meaning set forth in the CII Act and includes the security of critical infrastructure and protected systems, analysis, warning, interdependency study, recovery, reconstitution, or other informational purposes.

Regulatory proceeding, as used in 6 U.S.C. 671(7) and this part, means administrative proceedings in which DHS is the adjudicating entity, and does not include any form or type of regulatory proceeding or other matter outside of DHS.

State has the same meaning stated in 6 U.S.C. 101(17) and means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any possession of the United States.

Submission as referenced in these procedures means any transmittal, either directly or indirectly, of CII to the CISA PCII Program Office or the PCII Program Manager's Designee, as set forth herein.

Submitted in good faith means any submission of information that could reasonably be defined as CII or PCII under this section. Upon validation of a submission as PCII, CISA has conclusively established the good faith of the submission. Any information qualifying as PCII by virtue of a categorical inclusion identified by the PCII Program Manager pursuant to this part is submitted in good faith.

Voluntary or voluntarily, when used in reference to any submission of CII, means the submittal thereof in the absence of an exercise of legal authority by DHS to compel access to or submission of such information. Voluntary submission of CII may be accomplished by (*i.e.,* come from) a single State or Local governmental entity; private entity or person; or by an ISAO acting on behalf of its members or otherwise. There are two exclusions from this definition:

(1) In the case of any action brought under the securities laws—as is defined in 15 U.S.C. 78c(a)(47)—the term ''voluntary'' or ''voluntarily'' does not include:

(i) Information or statements contained in any documents or materials filed pursuant to 15 U.S.C. 78l(i) with the U.S. Securities and Exchange Commission or with federal banking regulators; or

(ii) A writing that accompanied the solicitation of an offer or a sale of securities; and

(2) Information or statements previously submitted to DHS in the course of a regulatory proceeding or a licensing or permitting determination are not ''voluntarily submitted.'' In addition, the submission of information to DHS for purposes of seeking a federal preference or benefit, including CII submitted to support an application for a DHS grant to secure critical infrastructure will be considered a voluntary submission of information. Applications for Support Anti-terrorism by Fostering Effective Technologies Act of 2002 filed pursuant to 6 U.S.C. 441 *et seq.,* or SAFETY Act Designation or Certification under 6 CFR part 25, will also be considered a voluntary submission.

Used directly by such agency, any other Federal, State, or Local authority, or any third party, in any civil action arising under Federal or State law in 6 U.S.C. 673(a)(1)(C) means any use in any proceeding other than a criminal prosecution before any court of the United States or of a State or otherwise, of any PCII, or any drafts or copies of PCII retained by the submitter, including the opinions, evaluations, analyses and conclusions prepared and submitted as CII, as evidence at trial or in any pretrial or other discovery, notwithstanding whether the United States, its agencies, officers, or employees is or are a party to such proceeding.

§ 29.3 FOIA exemptions and restrictions on use of PCII.

(a) *Freedom of Information Act disclosure exemptions.* Information that is separately exempt from public disclosure under the Freedom of Information Act (5 U.S.C. 552) or applicable State, or Local law does not lose its separate exemption from public disclosure due to the applicability of these procedures or any failure to follow them.

(b) *Restriction on use of PCII by regulatory agencies and other Federal, State, and Local agencies.* A Federal, State, or Local government agency that receives PCII may utilize the PCII only for purposes appropriate under the CII Act, including securing critical infrastructure or protected systems. Such PCII may not be utilized for any other collateral regulatory purposes without the written consent of the PCII Program Manager and of the submitting person or entity. The PCII Program Manager or the PCII Program Manager's Designee will not share PCII with Federal, State, or Local government agencies without instituting appropriate measures to ensure that PCII is used only for appropriate purposes.

§ 29.4 PCII Program administration.

(a) *Cybersecurity and Infrastructure Security Agency.* The Secretary of the Department of Homeland Security hereby designates the Director as the senior DHS official responsible for the direction and administration of the PCII Program. The Director administers this program through the Executive Assistant Director.

(b) *Appointment of a PCII Program Manager.* The Director will:

(1) Appoint a PCII Program Manager serving under the Executive Assistant Director who is responsible for the administration of the PCII Program;

(2) Commit resources necessary for the effective implementation of the PCII Program;

(3) Ensure that sufficient personnel, including detailees or assignees from other federal national security, homeland security, or law enforcement entities, as the Director deems appropriate, are assigned to the PCII Program to facilitate secure information sharing with appropriate authorities; and

(4) Promulgate implementing directives and prepare training materials, as appropriate, for the proper treatment of PCII.

(c) *Appointment of PCII Program Officers.* The PCII Program Manager will establish procedures to ensure that each DHS component and each Federal, State, or Local agency or entity that works with PCII appoints one or more employees to serve as a PCII Program Officer in order to carry out the responsibilities stated in paragraph (d) of this section. Persons appointed to serve as PCII Program Officers must be fully familiar with these procedures.

(d) *Responsibilities of PCII Program Officers.* PCII Program Officers:

(1) Oversee the handling, use, and storage of PCII;

(2) Ensure the secure sharing of PCII with appropriate authorities and individuals, as set forth in § 29.1(a), and paragraph (b)(3) of this section;

(3) Establish and maintain an ongoing self-inspection program including periodic review and assessment of compliance with handling, use, and storage of PCII;

(4) Establish additional procedures, measures, and penalties, as necessary, to prevent unauthorized access to PCII; and

(5) Ensure prompt and appropriate coordination with the PCII Program Manager regarding any request, challenge, or complaint arising out of the implementation of these regulations.

(e) *Protected Critical Infrastructure Information Management System or PCIIMS.* The PCII Program Manager will develop, for use by the PCII Program Office and the PCII Manager's Designees, an electronic database to be known as PCIIMS to record the receipt, acknowledgement, validation, storage, dissemination, and destruction of PCII. This compilation of PCII must be safeguarded and protected in accordance with the provisions of the CII Act. The PCII Program Manager may require the completion of appropriate background investigations of an individual before granting that individual access to any PCII.

§ 29.5 Requirements for protection.

(a) CII receives the protections of the CII Act when:

(1) Such information is voluntarily submitted, directly or indirectly, to the PCII Program Office or a PCII Program Manager's Designee;

(2) The information is submitted for protected use regarding the security of critical infrastructure or protected systems, analysis, warning, interdependency study, recovery, reconstitution, or other appropriate purposes including, without limitation, for the identification, analysis, prevention, preemption, disruption, defense against and/or mitigation of terrorist threats to the homeland;

(3) The information is labeled with an express statement as follows:

(i) *Documentary submissions.* In the case of documentary submissions, a written marking on the information or records substantially similar to the following: ''This information is voluntarily submitted to the federal government in expectation of protection from disclosure as provided by the provisions of the Critical Infrastructure Information Act of 2002, as amended by the Cybersecurity and Infrastructure Security Act of 2018'';

(ii) *Oral submissions.* In the case of oral submissions:

(A) Through an oral statement, made at the time of the oral submission or within a reasonable period of time thereafter, indicating an expectation of protection from disclosure as provided by the provisions of the CII Act; and

(B) Through a written statement substantially similar to the one specified above in paragraph (a)(3)(i) of this section accompanied by a document that memorializes the nature of the oral submission initially provided to the PCII Program Office or the PCII Program Manager's Designee within a reasonable period of time after making the oral submission; or

(iii) *Electronic submissions.* In the case of electronic submissions:

(A) Through an electronically submitted statement made within a reasonable period of time after making the electronic submission, indicating an expectation of protection from disclosure as provided by the provisions of the CII Act; or

(B) Through a non-electronically submitted written statement substantially similar to the one specified in paragraph (a)(3)(i) of this section accompanied by a document that memorializes the nature of the electronic submission initially provided to the PCII Program Office or the PCII Program Manager's Designee within a reasonable period after making the electronic submission; and

(4) The documentary, electronic, or oral submission is accompanied by a statement, signed by the submitting person or an authorized person on behalf of an entity identifying the submitting person or entity, containing such contact information as is considered necessary by the PCII Program Office, and certifying that the information being submitted is not customarily in the public domain.

(b) Information that is not submitted to the PCII Program Office or the PCII Program Manager's Designees will not qualify for protection under the CII Act. Only the PCII Program Office or a PCII Program Manager's Designee are authorized to acknowledge receipt of information submitted for consideration of protection under the CII Act.

(c) All Federal, State, and Local government entities must protect and maintain information as required by this part and by the provisions of the CII Act when that information is provided to the entity by the PCII Program Manager or a PCII Program Manager's Designee and is marked as required in § 29.6(c).

(d) All submissions seeking PCII status are presumed to have been submitted in good faith until validation or a determination not to validate is made pursuant to this part.

§ 29.6 Acknowledgment of receipt, validation, and marking.

(a) *Authorized officials.* Only the PCII Program Manager is authorized to validate and mark information submitted for protection outside of a categorical inclusion as PCII. The PCII Program Manager or a Program Manager's Designee may mark information qualifying for protection under categorical inclusions pursuant to paragraph (f) of this section as PCII.

(b) *Presumption of protection.* All information submitted in accordance with the procedures set forth in § 29.5 of this part will be presumed to be and will be treated as PCII, enjoying the protections of the CII Act, from the time the information is received by the PCII Program Office or a PCII Program Manager's Designee. The information must remain protected unless and until the PCII Program Office renders a final decision that the information is not PCII. The PCII Program Office will, with respect to information that is not properly submitted, inform the submitting person or entity within thirty calendar days of receipt, by a means of communication to be prescribed by the PCII Program Manager, that the submittal was procedurally defective. The submitter will then have an

additional thirty calendar days to remedy the deficiency from the date of receipt of such notification by the PCII Program Office. If the submitting person or entity does not cure the deficiency within thirty calendar days after the date of receipt of the notification provided by the PCII Program Office in this paragraph, the PCII Program Office may determine that the presumption of protection is terminated. Under such circumstances, the PCII Program Office may cure the deficiency by labeling the submission with the information required in § 29.5 or may notify the applicant that the submission does not qualify as PCII. No CII submission will lose its presumptive status as PCII except as provided in paragraph (g) of this section.

(c) *Marking of information.* All PCII must be clearly identified through markings made by the PCII Program Office. The PCII Program Office will mark PCII materials as follows: ''This document contains PCII. In accordance with the provisions of 6 CFR part 29, this document is exempt from release under the Freedom of Information Act (5 U.S.C. 552(b)(3)) and similar laws requiring public disclosure. Unauthorized release may result in criminal and administrative penalties. This document is to be safeguarded and disseminated in accordance with the CII Act and PCII Program requirements.'' When distributing PCII, the distributing person must ensure that the distributed information contains this marking.

(d) *Acknowledgement of receipt of information.* The PCII Program Office or a PCII Program Manager's Designee will acknowledge receipt of information submitted as CII and accompanied by an express statement, and in so doing will:

(1) Contact the submitting person or entity, within thirty calendar days of receipt of the submission of CII, by the means of delivery prescribed in procedures developed by the PCII Program Manager. In the case of oral submissions, receipt will be acknowledged in writing within thirty calendar days after receipt by the PCII Program Office or a PCII Program Manager's Designee of a written statement, certification, and documents that memorialize the oral submission, as referenced in § 29.5(a)(3)(ii);

(2) Enter the appropriate data into the PCIIMS as required in § 29.4(e); and

(3) Provide the submitting person or entity with a unique tracking number that will accompany the information from the time it is received by the PCII Program Office or a PCII Program Manager's Designee.

(e) *Validation of information.* (1) The PCII Program Manager is responsible for reviewing all submissions that request protection under the CII Act. The PCII Program Manager will review the submitted information as soon as practicable. If a final determination is made that the submitted information meets the requirements for protection, the PCII Program Manager must ensure that the information has been marked as required in paragraph (c) of this section, notify the submitting person or entity of the determination, and disclose it only pursuant to § 29.8.

(2) If the PCII Program Office makes an initial determination that the information submitted does not meet the requirements for protection under the CII Act, the PCII Program Office will:

(i) Notify the submitting person or entity of the initial determination that the information is not considered to be PCII. This notification also will, as necessary:

(A) Request that the submitting person or entity complete the requirements of § 29.5(a) or further explain the nature of the information and the submitting person or entity's basis for believing the information qualifies for protection under the CII Act;

(B) Advise the submitting person or entity that the PCII Program Office will review any further information provided before rendering a final determination;

(C) Advise the submitting person or entity that the submission can be withdrawn at any time before a final determination is made;

(D) Notify the submitting person or entity that until a final determination is made the submission will be treated as PCII;

(E) Notify the submitting person or entity that any response to the notification must be received by the PCII Program Office no later than thirty calendar days after the date of the notification; and

(F) Request the submitting person or entity to state whether, in the event the PCII Program Office makes a final determination that any such information is not PCII, the submitting person or entity prefers that the information be maintained without the protections of the CII Act, returned to the submitting person or entity, or destroyed. If a request for return is made, all such information will be returned to the submitting person or entity.

(ii) If the information submitted has not been withdrawn by the submitting person or entity, the PCII Program Office will return the information to the submitter in accordance with the submitting person or entity's written preference and the procedures set forth in paragraph (e)(2)(i) of this section within thirty calendar days of making a final determination that the information submitted is not eligible for protections under the CII Act. If the submitting person or entity cannot be notified or the submitting person or entity's response is not received within thirty calendar days of the date of the notification as provided in paragraph (e)(2)(i) of this section, the PCII Program Office will make the initial determination final and return the information to the submitter. If return to the submitter is impractical, the PCII Program Office will destroy the information within thirty calendar days. This process is consistent with the appropriate National Archives and Records Administration-approved records disposition schedule.

(f) *Categorical Inclusions of Certain Types of CII as PCII.* The PCII Program Manager has discretion to declare certain subject matter or types of information categorically protected as PCII and to set procedures for receipt and processing of such information. Information within a categorical inclusion will be considered validated upon receipt by the PCII Program Manager or any of the PCII Program Manager's Designees without further review, provided that the submitter provides the express statement required by § 29.5(a)(3). The PCII Program Manager's designees will provide to the PCII Program Office information submitted under a categorical inclusion.

(g) *Changing the status of PCII to non-PCII.* Once information is validated, only the PCII Program Manager may change the status of PCII to that of non-PCII and remove its PCII markings. Status changes may only take place when the submitting person or entity requests in writing that the information no longer be protected under the CII Act; or when the PCII Program Office determines that the information was, at the time of the submission, customarily in the public domain. Upon making an initial determination that a change in status may be warranted, but prior to a final determination, the PCII Program Office, using the procedures in paragraph (e)(2) of this section, will inform the submitting person or entity of the initial determination of a change in status. Notice of the final change in status of PCII will be provided to all recipients of PCII received under § 29.8.

§ 29.7 Safeguarding of PCII.

(a) *Safeguarding.* All persons granted access to PCII are responsible for safeguarding such information in their possession or control. PCII must be protected at all times by appropriate

storage and handling. Each person who works with PCII is personally responsible for taking proper precautions to ensure that unauthorized persons do not gain access to it.

(b) *Background checks on persons with access to PCII.* For those who require access to PCII, CISA will, to the extent practicable and consistent with the purposes of the CII Act, undertake appropriate background checks to ensure that individuals with access to PCII do not pose a threat to national security. These checks may also be waived in exigent circumstances.

(c) *Use and storage.* When PCII is in the physical possession of a person, reasonable steps must be taken, in accordance with procedures prescribed by the PCII Program Manager, to minimize the risk of access to PCII by unauthorized persons. When PCII is not in the physical possession of a person, it must be stored in a secure environment.

(d) *Reproduction.* Pursuant to procedures prescribed by the PCII Program Manager, a document or other material containing PCII may be reproduced to the extent necessary and consistent with the need to carry out official duties, provided that the reproduced documents or material are marked and protected in the same manner as the original documents or material.

(e) *Disposal of information.* Documents and material containing PCII may be disposed of by any method that prevents unauthorized retrieval, such as shredding or incineration.

(f) *Transmission of information.* PCII will be transmitted only by secure means of delivery as determined by the PCII Program Manager, and in conformance with appropriate federal standards.

(g) *Automated Information Systems.* The PCII Program Manager will establish security requirements designed to protect information to the maximum extent practicable, and consistent with the CII Act, for Automated Information Systems that contain PCII. Such security requirements will be in conformance with the information technology security requirements in the Federal Information Security Management Act and the Office of Management and Budget's implementing policies.

§ 29.8 Disclosure of PCII.

(a) *Authorization of access.* The Director, the Executive Assistant Director, or either's designee may choose to provide or authorize access to PCII under one or more of the paragraphs in this section when it is determined that access supports a lawful and authorized government purpose as enumerated in the CII Act or other law, regulation, or legal authority.

(b) *Federal, State, and Local government sharing.* The PCII Program Office or a PCII Program Manager's Designee may provide PCII to an employee of the federal government, provided, subject to paragraph (f) of this section, that such information is shared for purposes of securing the critical infrastructure or protected systems, analysis, warning, interdependency study, recovery, reconstitution, or for another appropriate purpose including, without limitation, the identification, analysis, prevention, preemption, and/or disruption of terrorist threats to the homeland. PCII may not be used, directly or indirectly, for any collateral regulatory purpose. PCII may be provided to a State or Local government entity for the purpose of protecting critical infrastructure or protected systems, or in furtherance of the investigation or prosecution of a criminal act. The provision of PCII to a State or Local government entity will normally be made only pursuant to an arrangement with the PCII Program Manager providing for compliance with the requirements of paragraph (d) of this section and acknowledging the understanding and responsibilities of the recipient. State and Local governments receiving such information will acknowledge in such arrangements the primacy of PCII protections under the CII Act; agree to assert all available legal defenses to disclosure of PCII under State or Local public disclosure laws, statutes, or ordinances; and will agree to treat breaches of the agreements by their employees or contractors as matters subject to the applicable criminal code or employee code of conduct for the jurisdiction.

(c) *Disclosure of information to Federal, State, and Local government contractors.* Disclosure of PCII to Federal, State, and Local government contractors may be made when necessary for an appropriate purpose under the CII Act, and only after the PCII Program Manager or a PCII Program Officer certifies that the contractor is performing services in support of the purposes of the CII Act. The contractor's employees who will be handling PCII must sign individual nondisclosure agreements in a form prescribed by the PCII Program Manager, and the contractor must agree by contract, whenever and to whatever extent possible, to comply with all relevant requirements of the PCII Program. The contractor must safeguard PCII in accordance with these procedures and may not remove any ''PCII'' markings. An employee of the contractor may, in the performance of services in support of the purposes of the CII Act and when authorized to do so by the PCII Program Manager or a PCII Program Manager's Designee, communicate with a submitting person or an authorized person of a submitting entity about a submittal of information by that person or entity. Contractors will not further disclose PCII to any other party not already authorized to receive such information by the PCII Program Manager or a PCII Program Manager's Designee, without the prior written approval of the PCII Program Manager or a PCII Program Manager's Designee.

(d) *Further use or disclosure of information by State and Local governments.* (1) State and Local governments receiving information marked ''Protected Critical Infrastructure Information'' will not share that information with any other party not already authorized to receive such information by the PCII Program Manager or a PCII Program Manager's Designee, with the exception of their contractors after complying with the requirements of paragraph (c) of this section, or remove any PCII markings, without first obtaining authorization from the PCII Program Manager or a PCII Program Manager's Designee, who is responsible for requesting and obtaining written consent from the submitter of the information.

(2) State and Local governments may use PCII only for the purpose of protecting critical infrastructure or protected systems, or as set forth elsewhere in these rules.

(e) *Disclosure of information to appropriate entities or to the general public.* PCII may be used to prepare advisories, alerts, and warnings to relevant companies, targeted sectors, governmental entities, ISAOs, or the general public regarding potential threats and vulnerabilities to critical infrastructure as appropriate pursuant to the CII Act. Unless exigent circumstances require otherwise, any such warnings to the general public will be authorized by the Secretary of the Department of Homeland Security, the Director, the Executive Assistant Director for Infrastructure Security of CISA, or the Executive Assistant Director for Cybersecurity of CISA. Such exigent circumstances exist only when approval of the Secretary, the Director, the Executive Assistant Director for Infrastructure Security for CISA, or the Executive Assistant Director for Cybersecurity for CISA cannot be obtained within a reasonable time necessary to issue an effective advisory,

alert, or warning. In issuing advisories, alerts, and warnings, DHS will consider the exigency of the situation, the extent of possible harm to the public or to critical infrastructure, and the necessary scope of the advisory, alert, or warning; and take appropriate actions to protect from disclosure any information that is proprietary, business sensitive, relates specifically to or might be used to identify the submitting person or entity or any persons or entities on whose behalf the CII was submitted, or is not otherwise appropriately in the public domain. Depending on the exigency of the circumstances, DHS may consult or cooperate with the submitter in making such advisories, alerts, or warnings.

(f) *Disclosure for law enforcement purposes and communication with submitters; access by Congress, the Comptroller General, and the Inspector General; and whistleblower protection.*

(1) Exceptions for disclosure.

(i) PCII will not, without the written consent of the person or entity submitting such information, be used or disclosed for purposes other than the purposes of the CII Act, except:

(A) In furtherance of the investigation or prosecution of a criminal act by the federal government, or by a State, Local, or foreign government, when such disclosure is coordinated by a federal law enforcement official;

(B) To communicate with a submitting person or an authorized person on behalf of a submitting entity, about a submittal of information by that person or entity when authorized to do so by the PCII Program Manager or a PCII Program Manager's Designee; or

(C) When disclosure of the information is made by any officer or employee of the United States;

(1) To either House of Congress, or to the extent of matter within its jurisdiction, any committee or subcommittee thereof, any joint committee thereof or subcommittee of any such joint committee; or

(2) To the Comptroller General, or any authorized representative of the Comptroller General, in the course of the performance of the duties of the Government Accountability Office.

(ii) If any officer or employee of the United States makes any disclosure pursuant to these exceptions, contemporaneous written notification must be provided to CISA through the PCII Program Manager.

(2) Consistent with the authority to disclose information for any of the purposes of the CII Act, disclosure of PCII may be made, without the written consent of the person or entity submitting such information, to the DHS Office of Inspector General.

(g) *Responding to requests made under the Freedom of Information Act or State and Local government information access laws.* PCII will be treated as exempt from disclosure under the Freedom of Information Act and any State or Local government law requiring disclosure of records or information. Any Federal, State, or Local government agency with questions regarding the protection of PCII from public disclosure must contact the PCII Program Office, who will in turn consult with the CISA Office of the Chief Counsel.

(h) *Ex parte communications with decision-making officials.* Pursuant to 6 U.S.C. 673(a)(1)(B), PCII is not subject to any agency rules or judicial doctrine regarding ex parte communications with a decision-making official.

(i) *Restriction on use of PCII in civil actions.* Pursuant to 6 U.S.C. 673(a)(1)(C), PCII will not, without the written consent of the person or entity submitting such information, be used directly by any Federal, State, or Local authority, or by any third party, in any civil action arising under Federal, State, or Local law.

§ 29.9 Investigation and reporting of violation of PCII procedures.

(a) *Reporting of possible violations.* Persons authorized to have access to PCII must report any suspected violation of security procedures, the loss or misplacement of PCII, and any suspected unauthorized disclosure of PCII immediately to the PCII Program Manager or a PCII Program Manager's Designee. Suspected violations may also be reported to the DHS Office of Inspector General. The PCII Program Manager or a PCII Program Manager's Designee will in turn report the incident to the appropriate security officer and to the DHS Office of Inspector General.

(b) *Review and investigation of written report.* The PCII Program Manager, or the appropriate security officer must notify the DHS Office of Inspector General of their intent to investigate any alleged violation of procedures, loss of information, and/or unauthorized disclosure, prior to initiating any such investigation. Evidence of wrongdoing resulting from any such investigations by agencies other than the DHS Inspector General must be reported to the United States Department of Justice, Criminal Division, through the CISA Office of the Chief Counsel. The DHS Office of Inspector General also has authority to conduct such investigations and will report any evidence of wrongdoing to the United States Department of Justice, Criminal Division, for consideration of prosecution.

(c) *Notification to originator of PCII.* If the PCII Program Manager or the appropriate security officer determines that a loss of information or an unauthorized disclosure of PCII has occurred, the PCII Program Manager or a PCII Program Manager's Designee must notify the person or entity that submitted the PCII, unless providing such notification could reasonably be expected to hamper the relevant investigation or adversely affect any other law enforcement, national security, or homeland security interest.

(d) *Criminal and administrative penalties.* (1) As established in 6 U.S.C. 673(f), whoever, being an officer or employee of the United States or of any department or agency thereof, knowingly publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law, any information protected from disclosure by the CII Act coming to the officer or employee in the course of his or her employment or official duties or by reason of any examination or investigation made by, or return, report, or record made to or filed with, such department or agency or officer or employee thereof, shall be fined under title 18 of the United States Code, imprisoned not more than one year, or both, and shall be removed from office or employment.

(2) In addition to the penalties set forth in paragraph (d)(1) of this section, if the PCII Program Manager determines that an entity or person who has received PCII has violated the provisions of this part or used PCII for an inappropriate purpose, the PCII Program Manager may disqualify that entity or person from future receipt of any PCII or future receipt of any sensitive homeland security information under 6 U.S.C. 482, provided, however, that any such decision by the PCII Program Manager may be appealed to the Director.

Alejandro Mayorkas,

Secretary, Department of Homeland Security.

[FR Doc. 2022–27171 Filed 12–20–22; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

8 CFR Parts 214 and 274a

[CIS No. 2731–22, DHS Docket No. USCIS–2022–0015]

RIN 1615–AC82

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 655

[DOL Docket No. ETA–2022–0008]

RIN 1205–AC14

Exercise of Time-Limited Authority To Increase the Numerical Limitation for FY 2023 for the H–2B Temporary Nonagricultural Worker Program and Portability Flexibility for H–2B Workers Seeking To Change Employers; Correction

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS), and Employment and Training Administration and Wage and Hour Division, U.S. Department of Labor (DOL).

ACTION: Temporary rule; correction and correcting amendment.

SUMMARY: On December 15, 2022, the Department of Homeland Security and Department of Labor jointly published a temporary rule titled ''Exercise of Time-Limited Authority to Increase the Numerical Limitation for FY 2023 for the H–2B Temporary Nonagricultural Worker Program and Portability Flexibility for H–2B Workers Seeking to Change Employers.'' The temporary rule contains errors that this document corrects.

DATES: Effective on December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Charles L. Nimick, Chief, Business and Foreign Workers Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 5900 Capital Gateway Drive, Camp Springs, MD 20746; telephone 240–721–3000 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: In the temporary rule, FR Doc. 2022–27236, beginning on page 76816 in the issue of Thursday, December 15, 2022, make the following corrections:

1. On page 76816, in the first column, the DOL docket is corrected to read ''[DOL Docket No. ETA 2022–0008]''.

2. On page 76829, in the third column, in footnote 93, the citation to ''(h)(6)(xii)(A)(*1*)(*b*)'' is corrected to read ''(h)(6)(xiii)(A)(*1*)(*ii*)''.

3. On page 76830, in the second column, in footnote 94, the citation to ''(h)(6)(xii)(A)(*1*)(*c*)'' is corrected to read ''(h)(6)(xiii)(A)(*1*)(*iii*)''.

4. On page 76831, in the second column, in footnote 100, the citation to ''(h)(6)(xii)(A)(*2*)'' is corrected to read ''(h)(6)(xiii)(A)(*2*)''.

5. On page 76840, in the third column, in footnote 142, the citation to ''*Notification of Temporary Travel Restrictions Applicable to Land Ports of Entry and Ferries Service Between the United States and Mexico,* 87 FR 24048 (Apr. 22, 2022)'' is corrected to read ''*Notification of Temporary Travel Restrictions Applicable to Land Ports of Entry and Ferries Service Between the United States and Canada,* 87 FR 24048 (Apr. 22, 2022)''.

List of Subjects in 8 CFR Part 214

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

Accordingly, 8 CFR part 214 is corrected by making the following correcting amendments:

DEPARTMENT OF HOMELAND SECURITY

PART 214—NONIMMIGRANT CLASSES

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

Authority: 6 U.S.C. 202, 236; 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1186a, 1187, 1221, 1281, 1282, 1301–1305, 1357, and 1372; sec. 643, Pub. L. 104–208, 110 Stat. 3009–708; Pub. L. 106–386, 114 Stat. 1477–1480; section 141 of the Compacts of Free Association with the Federated States of Micronesia and the Republic of the Marshall Islands, and with the Government of Palau, 48 U.S.C. 1901 note and 1931 note, respectively; 48 U.S.C. 1806; 8 CFR part 2; Pub. L. 115–218, 132 Stat. 1547 (48 U.S.C. 1806).

§ 214.2 [Amended]

■ 2. In § 214.2:

■ a. In paragraph (h)(6)(xiii)(C)(*1*), remove the citation ''(h)(6)(xiii)(A)(*1*)(*a*)'' and add ''(h)(6)(xiii)(A)(*1*)(*i*)'' in its place.

■ b. In paragraph (h)(6)(xiii)(C)(*2*), remove the citation ''(h)(6)(xii)(A)(*1*)(*ii*)'' and add ''(h)(6)(xiii)(A)(*1*)(*ii*)'' in its place.

Christina E. McDonald,

Federal Register Liaison, U.S. Department of Homeland Security.

Laura Dawkins,

Federal Register Liaison, U.S. Department of Labor.

[FR Doc. 2022–27804 Filed 12–20–22; 8:45 am]

BILLING CODE 9111–97–P

FEDERAL ELECTION COMMISSION

11 CFR Part 104

Reports by Political Committees and Other Persons (52 U.S.C. 30104)

CFR Correction

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

In Title 11 of the Code of Federal Regulations, revised as of January 1, 2022, in part 104, make the following amendments:

■ 1. In § 104.3:

■ a. Revise paragraphs (a)(3)(vii)(B) and (C) and remove paragraph (D).

■ b. Revise paragraph (b)(3)(vii)(B).

■ c. Redesignate paragraph (b)(3)(vii)(C) as paragraph (b)(3)(vii)(D) and revise newly redesignated paragraph (b)(3)(vii)(D).

■ d. Add new paragraph (b)(3)(vii)(C).

The revisions and additions read as follows:

§ 104.3 Contents of Reports (52 U.S.C. 30104(b), 30114).

* * * * *

(a) * * *

(3) * * *

(vii) * * *

(B) Loans made, guaranteed, or endorsed by a candidate to his or her authorized committee including loans derived from a bank loan to the candidate or from an advance on a candidate's brokerage account, credit card, home equity line of credit, or other lines of credit described in 11 CFR 100.83 and 100.143; and

(C) Total loans;

* * * * *

(b) * * *

(3) * * *

(vii) * * *

(B) For each independent expenditure reported, the committee must also provide a statement which indicates whether such independent expenditure is in support of, or in opposition to a particular candidate, as well as the

name of the candidate and the office sought by such candidate (including State and Congressional district, when applicable), and a certification, under penalty of perjury, as to whether such independent expenditure is made in cooperation, consultation or concert with, or at the request or suggestion of, any candidate or authorized committee or agent of such committee; and

(C) For an independent expenditure that is made in support of or opposition to a presidential primary candidate and is publicly distributed or otherwise publicly disseminated in six or more states but does not refer to any particular state, the political committee must report the independent expenditure as a single expenditure—*i.e.,* without allocating it among states—and must indicate the state with the next upcoming presidential primary among those states where the independent expenditure is distributed, as specified in § 104.4(f)(2). The political committee must use memo text to indicate the states in which the communication is distributed.

(D) The information required by paragraphs (b)(3)(vii)(A) through (C) of this section shall be reported on Schedule E as part of a report covering the reporting period in which the aggregate disbursements for any independent expenditure to any person exceed $200 per calendar year. Schedule E shall also include the total of all such expenditures of $200 or less made during the reporting period.

* * * * *

[FR Doc. 2022–27819 Filed 12–20–22; 8:45 am]

BILLING CODE 0099–10–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1003

[Docket No. CFPB–2019–0021]

RIN 3170–AA76

Home Mortgage Disclosure (Regulation C); Judicial Vacatur of Coverage Threshold for Closed-End Mortgage Loans

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Technical amendment.

SUMMARY: In April 2020, the Consumer Financial Protection Bureau (Bureau or CFPB) issued a final rule (2020 HMDA Rule) to amend Regulation C to increase the threshold for reporting data about closed-end mortgage loans. The 2020 HMDA Rule increased the closed-end mortgage loan reporting threshold from 25 loans to 100 loans in each of the two preceding calendar years, effective July 1, 2020. On September 23, 2022, the United States District Court for the District of Columbia vacated the 2020 HMDA Rule as to the increased loan-volume reporting threshold for closed-end mortgage loans. As a result of the September 23, 2022 order, the threshold for reporting data about closed-end mortgage loans is 25, the threshold established by the 2015 HMDA Rule. Accordingly, this technical amendment updates the *Code of Federal Regulations* to reflect the closed-end mortgage loan reporting threshold of 25 mortgage loans in each of the two preceding calendar years.

DATES: This technical amendment is effective December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Jaclyn Maier or Alexandra Reimelt, Senior Counsels, Office of Regulations, at 202–435–7700 or *https://reginquiries.consumerfinance.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Home Mortgage Disclosure Act (HMDA) requires certain banks, savings associations, credit unions, and for-profit nondepository institutions to collect, report, and disclose data about originations and purchases of mortgage loans, as well as mortgage loan applications that do not result in originations (for example, applications that are denied or withdrawn).[1] The Bureau's Regulation C, 12 CFR part 1003, implements HMDA, 12 U.S.C. 2801 through 2810.

In October 2015, the Bureau issued a final rule (2015 HMDA Rule) that, among other things, established institutional and transactional loan-volume coverage thresholds in Regulation C that determine whether financial institutions are required to report certain HMDA data on closed-end mortgage loans or open-end lines of credit.[2] These thresholds apply uniformly to covered depository and nondepository institutions; they took effect for depository institutions on January 1, 2017, and for nondepository institutions on January 1, 2018. The loan-volume thresholds in the 2015 HMDA Rule required an institution that originated at least 25 closed-end mortgage loans or at least 100 open-end lines of credit in each of the two preceding calendar years to report HMDA data, provided that the institution meets all other criteria for institutional coverage.

In April 2020, the Bureau issued a final rule (2020 HMDA Rule) to amend Regulation C to increase the thresholds for reporting data about both closed-end mortgage loans and open-end lines of credit.[3] In particular, the 2020 HMDA Rule set the closed-end mortgage loan reporting threshold at 100 in each of the two preceding calendar years, effective July 1, 2020, and the open-end line of credit reporting threshold at 200 in each of the two preceding calendar years, effective January 1, 2022.

On July 30, 2020, five nonprofit organizations and the City of Toledo, Ohio, initiated a lawsuit challenging the 2020 HMDA Rule.[4] On September 23, 2022, the United States District Court for the District of Columbia concluded that the 2020 HMDA Rule's increased reporting threshold for closed-end mortgage loans was arbitrary and capricious. The Court issued an order vacating and remanding the loan-volume reporting threshold for closed-end mortgage loans under the 2020 HMDA Rule. Accordingly, the threshold for reporting data about closed-end mortgage loans is 25 in each of the two preceding calendar years, which is the threshold set by the 2015 HMDA Rule. This technical amendment reflects the vacatur in the *Code of Federal Regulations* by replacing the closed-end reporting threshold numbers in §§ 1003.2(g)(1)(v)(A) and (2)(ii)(A), and 1003.3(c)(11), and comments 2(g)–5 and 3(c)(11)–2 with those in effect on June 30, 2020; and replacing in their entirety, comments 2(g)–1 and 3(c)(11)–1 with the versions in effect on June 30, 2020.

[1] HMDA requires financial institutions to collect, record, and report data. The Bureau generally refers herein to the obligation to report data instead of listing all of these obligations in each instance.

[2] Home Mortgage Disclosure (Regulation C), 80 FR 66128 (Oct. 28, 2015). The reporting thresholds for closed-end mortgage loans and open-end lines of credit operate independently. Thus, an institution that meets the threshold for closed-end mortgage loans but not the threshold for open-end lines of credit is a covered institution and required to report HMDA data about its closed-end loans, provided it meets the other criteria for institutional coverage. Conversely, an institution that meets the threshold for open-end lines of credit but not the threshold for closed-end loans is a covered institution and required to report HMDA data about its open-end lines of credit, provided it meets the other criteria for institutional coverage.

[3] Home Mortgage Disclosure (Regulation C), 85 FR 28364 (May 12, 2020), *vacated in part by Nat'l Cmty. Reinvestment Coal., et al.* v. *Consumer Fin. Prot. Bureau,* No. 20–cv–2074, 2022 WL 4447293 (D.D.C. Sept. 23, 2022).

[4] The five nonprofit organizations are the National Community Reinvestment Coalition, Montana Fair Housing, the Texas Low Income Housing Information Service, Empire Justice Center, and the Association for Neighborhood & Housing Development.

II. Regulatory Requirements

This action is not a rule under the Administrative Procedure Act (APA), because the Bureau is not interpreting, implementing, or prescribing law or policy.[5] Instead, the Bureau is updating the published *Code of Federal Regulations* so that it accurately reflects the court's vacatur of part of the underlying 2020 HMDA Rule. In the alternative, if this action were a rule, the Bureau finds that notice and comment would be unnecessary under the APA, because there is no basis for disagreement that the court's ruling vacates the relevant portion of the 2020 HMDA Rule.[6]

List of Subjects in 12 CFR Part 1003

Banks, Banking, Credit unions, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations.

Authority and Issuance

For the reasons set forth in the preamble, the CFPB amends Regulation C, 12 CFR part 1003, as set forth below:

PART 1003—HOME MORTGAGE DISCLOSURE (REGULATION C)

■ 1. The authority citation for part 1003 continues to read as follows:

Authority: 12 U.S.C. 2803, 2804, 2805, 5512, 5581.

■ 2. Section 1003.2 is amended by revising paragraphs (g)(1)(v)(A) and (g)(2)(ii)(A) to read as follows:

§ 1003.2 Definitions.

* * * * *

(g) * * *

(1) * * *

(v) * * *

(A) In each of the two preceding calendar years, originated at least 25 closed-end mortgage loans that are not excluded from this part pursuant to § 1003.3(c)(1) through (10) or (c)(13); or

* * * * *

(2) * * *

(ii) * * *

(A) In each of the two preceding calendar years, originated at least 25 closed-end mortgage loans that are not excluded from this part pursuant to § 1003.3(c)(1) through (10) or (c)(13); or

* * * * *

■ 3. Section 1003.3 is amended by revising paragraph (c)(11) to read as follows:

§ 1003.3 Exempt institutions and excluded and partially exempt transactions.

* * * * *

(c) * * *

(11) A closed-end mortgage loan, if the financial institution originated fewer than 25 closed-end mortgage loans in either of the two preceding calendar years; a financial institution may collect, record, report, and disclose information, as described in §§ 1003.4 and 1003.5, for such an excluded closed-end mortgage loan as though it were a covered loan, provided that the financial institution complies with such requirements for all applications for closed-end mortgage loans that it receives, closed-end mortgage loans that it originates, and closed-end mortgage loans that it purchases that otherwise would have been covered loans during the calendar year during which final action is taken on the excluded closed-end mortgage loan;

* * * * *

■ 4. Supplement I to part 1003 is amended as follows:

■ a. Under *Section 1003.2—Definitions,* revise *2(g) Financial Institution.*

■ b. Under *Section 1003.3—Exempt Institutions and Excluded and Partially Exempt Transactions,* under *3(c) Excluded Transactions,* revise *Paragraph 3(c)(11).*

The revisions read as follows:

Supplement I to Part 1003—Official Interpretations

* * * * *

Section 1003.2—Definitions

* * * * *

2(g) Financial Institution

1. *Preceding calendar year and preceding December 31.* The definition of financial institution refers both to the preceding calendar year and the preceding December 31. These terms refer to the calendar year and the December 31 preceding the current calendar year. For example, in 2019, the preceding calendar year is 2018 and the preceding December 31 is December 31, 2018. Accordingly, in 2019, Financial Institution A satisfies the asset-size threshold described in § 1003.2(g)(1)(i) if its assets exceeded the threshold specified in comment 2(g)–2 on December 31, 2018. Likewise, in 2020, Financial Institution A does not meet the loan-volume test described in § 1003.2(g)(1)(v)(A) if it originated fewer than 25 closed-end mortgage loans during either 2018 or 2019.

2. *Adjustment of exemption threshold for banks, savings associations, and credit unions.* For data collection in 2022, the asset-size exemption threshold is $50 million. Banks, savings associations, and credit unions with assets at or below $50 million as of December 31, 2021, are exempt from collecting data for 2022.

3. *Merger or acquisition—coverage of surviving or newly formed institution.* After a merger or acquisition, the surviving or newly formed institution is a financial institution under § 1003.2(g) if it, considering the combined assets, location, and lending activity of the surviving or newly formed institution and the merged or acquired institutions or acquired branches, satisfies the criteria included in § 1003.2(g). For example, A and B merge. The surviving or newly formed institution meets the loan threshold described in § 1003.2(g)(1)(v)(B) if the surviving or newly formed institution, A, and B originated a combined total of at least 200 open-end lines of credit in each of the two preceding calendar years. Likewise, the surviving or newly formed institution meets the asset-size threshold in § 1003.2(g)(1)(i) if its assets and the combined assets of A and B on December 31 of the preceding calendar year exceeded the threshold described in § 1003.2(g)(1)(i). Comment 2(g)–4 discusses a financial institution's responsibilities during the calendar year of a merger.

4. *Merger or acquisition—coverage for calendar year of merger or acquisition.* The scenarios described below illustrate a financial institution's responsibilities for the calendar year of a merger or acquisition. For purposes of these illustrations, a ''covered institution'' means a financial institution, as defined in § 1003.2(g), that is not exempt from reporting under § 1003.3(a), and ''an institution that is not covered'' means either an institution that is not a financial institution, as defined in § 1003.2(g), or an institution that is exempt from reporting under § 1003.3(a).

i. Two institutions that are not covered merge. The surviving or newly formed institution meets all of the requirements necessary to be a covered institution. No data collection is required for the calendar year of the merger (even though the merger creates an institution that meets all of the requirements necessary to be a covered institution). When a branch office of an institution that is not covered is acquired by another institution that is not covered, and the acquisition results in a covered institution, no data collection is required for the calendar year of the acquisition.

ii. A covered institution and an institution that is not covered merge. The covered institution is the surviving institution, or a new covered institution is formed. For the calendar year of the merger, data collection is required for covered loans and applications handled in the offices of the merged institution that was previously covered and is optional for covered loans and applications handled in offices of the merged institution that was previously not covered. When a covered institution acquires a branch office of an institution that is not covered, data collection is optional for covered loans and applications handled by the acquired branch office for the calendar year of the acquisition.

iii. A covered institution and an institution that is not covered merge. The institution that is not covered is the surviving institution, or a new institution that is not covered is formed. For the calendar year of the merger, data collection is required for covered loans and applications handled in offices of the previously covered institution that took place prior to the merger. After the merger date, data collection is optional for

[5] 5 U.S.C. 551(4).

[6] 5 U.S.C. 553(b)(B).

covered loans and applications handled in the offices of the institution that was previously covered. When an institution remains not covered after acquiring a branch office of a covered institution, data collection is required for transactions of the acquired branch office that take place prior to the acquisition. Data collection by the acquired branch office is optional for transactions taking place in the remainder of the calendar year after the acquisition.

iv. Two covered institutions merge. The surviving or newly formed institution is a covered institution. Data collection is required for the entire calendar year of the merger. The surviving or newly formed institution files either a consolidated submission or separate submissions for that calendar year. When a covered institution acquires a branch office of a covered institution, data collection is required for the entire calendar year of the merger. Data for the acquired branch office may be submitted by either institution.

5. *Originations.* Whether an institution is a financial institution depends in part on whether the institution originated at least 25 closed-end mortgage loans in each of the two preceding calendar years or at least 200 open-end lines of credit in each of the two preceding calendar years. Comments 4(a)–2 through –4 discuss whether activities with respect to a particular closed-end mortgage loan or open-end line of credit constitute an origination for purposes of § 1003.2(g).

6. *Branches of foreign banks—treated as banks.* A Federal branch or a State-licensed or insured branch of a foreign bank that meets the definition of a ''bank'' under section 3(a)(1) of the Federal Deposit Insurance Act (12 U.S.C. 1813(a)) is a bank for the purposes of § 1003.2(g).

7. *Branches and offices of foreign banks and other entities—treated as nondepository financial institutions.* A Federal agency, State-licensed agency, State-licensed uninsured branch of a foreign bank, commercial lending company owned or controlled by a foreign bank, or entity operating under section 25 or 25A of the Federal Reserve Act, 12 U.S.C. 601 and 611 (Edge Act and agreement corporations) may not meet the definition of ''bank'' under the Federal Deposit Insurance Act and may thereby fail to satisfy the definition of a depository financial institution under § 1003.2(g)(1). An entity is nonetheless a financial institution if it meets the definition of nondepository financial institution under § 1003.2(g)(2).

* * * * *

Section 1003.3—Exempt Institutions and Excluded and Partially Exempt Transactions

* * * * *

3(c) Excluded Transactions

* * * * *

Paragraph 3(c)(11)

1. *General.* Section 1003.3(c)(11) provides that a closed-end mortgage loan is an excluded transaction if a financial institution originated fewer than 25 closed-end mortgage loans in either of the two preceding calendar years. For example, assume that a bank is a financial institution in 2018 under § 1003.2(g) because it originated 600 open-end lines of credit in 2016, 650 open-end lines of credit in 2017, and met all of the other requirements under § 1003.2(g)(1). Also assume that the bank originated 10 and 20 closed-end mortgage loans in 2016 and 2017, respectively. The open-end lines of credit that the bank originated or purchased, or for which it received applications, during 2018 are covered loans and must be reported, unless they otherwise are excluded transactions under § 1003.3(c). However, the closed-end mortgage loans that the bank originated or purchased, or for which it received applications, during 2018 are excluded transactions under § 1003.3(c)(11) and need not be reported. See comments 4(a)–2 through –4 for guidance about the activities that constitute an origination.

2. *Optional reporting.* A financial institution may report applications for, originations of, or purchases of closed-end mortgage loans that are excluded transactions because the financial institution originated fewer than 25 closed-end mortgage loans in either of the two preceding calendar years. However, a financial institution that chooses to report such excluded applications for, originations of, or purchases of closed-end mortgage loans must report all such applications for closed-end mortgage loans that it receives, closed-end mortgage loans that it originates, and closed-end mortgage loans that it purchases that otherwise would be covered loans for a given calendar year. Note that applications which remain pending at the end of a calendar year are not reported, as described in comment 4(a)(8)(i)–14.

Rohit Chopra,

Director, Consumer Financial Protection Bureau.

[FR Doc. 2022–27204 Filed 12–20–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 200

[Release No. 33–11139; 34–96508; IA–6203; IC–34774]

Technical Amendments to Commission Rules

AGENCY: Securities and Exchange Commission.

ACTION: Final rule; technical amendments.

SUMMARY: To conform with current **Federal Register** requirements of structuring statutory authority citations within the Code of Federal Regulations (''CFR''), the Securities and Exchange Commission (''Commission'') is adopting technical amendments to its regulations regarding organization; conduct and ethics; and information and requests. The technical amendments move the citations of statutory authority for the regulations from the subpart level to the part level and amend related citations to remove duplicative statutory citations at the subpart level.

DATES: *Effective:* December 21, 2022.

FOR FURTHER INFORMATION CONTACT: J. Matthew DeLesDernier, Deputy Secretary, Office of the Secretary, (202) 551–5400, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SUPPLEMENTARY INFORMATION: To conform with current **Federal Register** requirements for structuring statutory authority citations within the CFR, the Commission is making technical changes to Commission rules to provide enhanced clarity regarding citations of statutory authority for part 200 of 17 CFR (''part 200'') and its subparts.[1] Specifically, the Commission is moving the citations of statutory authority contained in subparts of 17 CFR part 200 to appear directly under 17 CFR part 200. Currently, the citations of statutory authority for part 200 are provided at the subpart level. The technical amendments move these citations of statutory authority from the subpart level to the part level. In connection with these changes, the Commission is amending the citations to statutory authority for the subparts of part 200 to: (1) remove duplication in the citations of statutory authority resulting from this change; and (2) update citation formats to match current **Federal Register** standards.

I. Administrative Law Matters

The Commission finds, in accordance with the Administrative Procedure Act (''APA''), that these amendments relate solely to agency organization, procedure, or practice.[2] Accordingly, the APA's provisions regarding notice of rulemaking and opportunity for public comment are not applicable. These changes are therefore effective on December 21, 2022. In accordance with the APA, we find that there is good cause to establish an effective date less than 30 days after publication of these amendments.[3] These amendments do not substantially affect the rights or obligations of non-agency parties and pertain to clarifying the authority of internal Commission operations. For the same reasons, the provisions of the Small Business Regulatory Enforcement Fairness Act are not applicable.[4]

[1] *See* 17 CFR 200.1 through 200.800.

[2] 5 U.S.C. 553(b)(3)(A).

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

[4] *See* 5 U.S.C. 804(3)(C) (the term ''rule'' does not include ''any rule of agency organization, procedure, or practice that does not substantially

Additionally, the provisions of the Regulatory Flexibility Act,[5] which apply only when notice and comment are required by the APA or other law, are not applicable.[6] These amendments do not contain any collection of information requirements as defined by the Paperwork Reduction Act of 1995.[7] Further, because these amendments impose no new burdens on private parties, the Commission does not believe that the amendments will have any impact on competition for purposes of section 23(a)(2) of the Exchange Act.[8]

II. Statutory Authority

We are adopting these technical amendments under the authority set forth in section 19(a) of the Securities Act of 1933 [15 U.S.C. 77s], section 319 of the Trust Indenture Act of 1939 [15 U.S.C. 77sss], section 23(a) of the Securities Exchange Act of 1934 [15 U.S.C. 78w(a)], section 38(a) of the Investment Company Act of 1940 [15 U.S.C. 80a–37(a)], and section 211(a) of the Investment Advisers Act of 1940 [15 U.S.C. 80b–11(a)].

List of Subjects in 17 CFR Part 200

Administrative practice and procedure, Authority delegations (Government agencies).

Text of Amendments

For reasons set forth in the preamble, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

■ 1. Add an authority citation for part 200 to read as follows:

Authority: 5 U.S.C. 552, 552a, 552b, and 557; 11 U.S.C. 901 and 1109(a); 15 U.S.C. 77c, 77e, 77f, 77g, 77h, 77j, 77o, 77q, 77s, 77u, 77z–3, 77ggg(a), 77hhh, 77sss, 77uuu, 78b, 78c(b), 78d, 78d–1, 78d–2, 78e, 78f, 78g, 78h, 78i, 78k, 78k–1, 78*l,* 78m, 78n, 78o, 78o–4, 78q, 78q–1, 78w, 78t–1, 78u, 78w, 78*ll*(d), 78mm, 78eee, 80a–8, 80a–20, 80a–24, 80a–29, 80a–37, 80a–41, 80a–44(a), 80a–44(b), 80b–3, 80b–4, 80b–5, 80b–9, 80b–10(a), 80b–11, 7202, and 7211 *et seq.;* 29 U.S.C. 794; 44 U.S.C. 3506 and 3507; Reorganization Plan No. 10 of 1950 (15 U.S.C. 78d nt); sec. 8G, Pub. L. 95–452, 92 Stat. 1101 (5 U.S.C. App.); sec. 913, Pub. L. 111–203, 124 Stat. 1376, 1827; sec. 3(a), Pub. L. 114–185, 130 Stat. 538; E.O. 11222, 30 FR 6469, 3 CFR, 1964–1965 Comp., p. 36; E.O. 12356, 47 FR 14874, 3 CFR, 1982 Comp., p. 166; E.O. 12600, 52 FR 23781, 3 CFR, 1987 Comp., p. 235; Information Security Oversight Office Directive No. 1, 47 FR 27836; and 5 CFR 735.104 and 5 CFR parts 2634 and 2635, unless otherwise noted.

Subpart A—Organization and Program Management

■ 2. Remove the authority citation for part 200, subpart A.

Subpart B—Disposition of Commission Business

■ 3. Remove the authority citation for part 200, subpart B.

Subpart C—Canons of Ethics

■ 4. Remove the authority citation for part 200, subpart C.

Subpart D—Information and Requests

■ 5. Remove the authority citation for part 200, subpart D.

Subpart F—Code of Behavior Governing Ex Parte Communications Between Persons Outside the Commission and Decisional Employees

■ 6. Remove the authority citation for part 200, subpart F.

Subpart G—Plan of Organization and Operation Effective During Emergency Conditions

■ 7. Remove the authority citation for part 200, subpart G.

Subpart H—Regulations Pertaining to the Privacy of Individuals and Systems of Records Maintained by the Commission

■ 8. Remove the authority citation for part 200, subpart H.

Subpart I—Regulations Pertaining to Public Observation of Commission Meetings

■ 9. Remove the authority citation for part 200, subpart I.

Subpart J—Classification and Declassification of National Security Information and Material

■ 10. Remove the authority citation for part 200, subpart J.

Subpart K—Regulations Pertaining to the Protection of the Environment

■ 11. Remove the authority citation for part 200, subpart K.

Subpart L—Enforcement of Nondiscrimination on the Basis of Handicap in Programs or Activities Conducted by the Securities and Exchange Commission

■ 12. Remove the authority citation for part 200, subpart L.

Subpart M—Regulation Concerning Conduct of Members and Employees and Former Members and Employees of the Commission

■ 13. Remove the authority citation for part 200, subpart M.

Subpart N—Commission Information Collection Requirements Under the Paperwork Reduction Act: OMB Control Numbers

■ 14. Remove the authority citation for part 200, subpart N.

By the Commission.

Dated: December 15, 2022.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–27636 Filed 12–20–22; 8:45 am]

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affect the rights or obligations of non-agency parties'').

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

[6] *See* 5 U.S.C. 601(2).

[7] *See* 5 CFR 1320.3.

[8] 15 U.S.C. 78w(a)(2).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 170 and 570

[Docket No. FDA–2017–D–0085]

Best Practices for Convening a GRAS Panel; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''Best Practices for Convening a GRAS Panel.'' This guidance document is intended for any person who is responsible for a conclusion that a substance may be used in food on the basis of the generally recognized as safe (GRAS) provision of the Federal Food, Drug, and Cosmetic Act (FD&C Act) when that person convenes a panel of experts (''GRAS panel'') to independently evaluate whether the available scientific data, information, and methods establish that the substance is safe under the conditions of its intended use in human food or animal food. This guidance provides our current thinking on best practices to identify GRAS panel

members who have appropriate and balanced expertise; to take steps to reduce the risk that bias (or the appearance of bias) will affect the credibility of the GRAS panel's output (often called a ''GRAS panel report''), including the assessment of potential GRAS panel members for conflict of interest and the appearance of conflict of interest; and to limit the data and information provided to a GRAS panel to public information (*e.g.,* by not providing the GRAS panel with information such as trade secret information).

DATES: The announcement of the guidance is published in the **Federal Register** on December 21, 2022.

ADDRESSES: You may submit either electronic or written comments on FDA guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–0085 for ''Best Practices for Convening a GRAS Panel.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–200), 5001 Campus Dr., College Park, MD 20740, or to the Office of Surveillance and Compliance (HFV–200), Center for Veterinary Medicine, 12225 Wilkins Ave., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: *Regarding substances that would be used in human food:* Paulette M. Gaynor, Office of Food Additive Safety (HFS–255), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1192. *Regarding substances that would be used in animal food:* Geoffrey K. Wong, Office of Surveillance and Compliance (HFV–225), Center for Veterinary Medicine, Food and Drug Administration, 12225 Wilkins Ave., Rockville, MD 20855, 240–402–5838. *Regarding other questions about this document:* Alexandra Jurewitz, Office of Regulations and Policy (HFS–024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

Section 201(s) of the FD&C Act (21 U.S.C. 321(s)) defines a ''food additive'' as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use. Under this definition, a substance that is GRAS under the conditions of its intended use is not a ''food additive'' and is therefore not subject to mandatory premarket review by FDA under section 409 of the FD&C Act (21 U.S.C. 348). In this document, we refer to a person who is responsible for a conclusion that a substance may be used in human food or animal food on the basis of the GRAS provision of the FD&C Act, without premarket review by FDA under section 409 of the FD&C Act, as the ''proponent'' of that substance.

We have established regulations implementing the GRAS provision of section 201(s) of the FD&C Act in part 170 (21 CFR part 170) for human food

and in part 570 (21 CFR part 570) for animal food. Those regulations include a voluntary procedure (''GRAS notification procedure'') through which a proponent may notify us of a conclusion that a substance is GRAS under the conditions of its intended use in human food (part 170, subpart E) or animal food (part 570, subpart E).

In some cases, the process whereby the proponent evaluates whether the available data and information support a conclusion that a substance is GRAS under the conditions of its intended use includes considering the opinion of a ''GRAS panel'' of qualified experts who independently evaluate whether the available scientific data, information, and methods establish that a substance is safe under the conditions of its intended use in human food or animal food. Depending on the outcome of the GRAS panel's analysis, the proponent could either reach a conclusion regarding the safety of the substance under the conditions of its intended use or be advised of one or more issues (such as gaps in the data and information or alternative interpretations of the available data and information) that warrant investigation before a conclusion can be drawn about whether the substance is safe under the conditions of its intended use. When the outcome of the GRAS panel's analysis supports the proponent's conclusion that a substance is safe under the conditions of its intended use, in essence the proponent then relies on the members of the GRAS panel to act as a proxy for the larger scientific community knowledgeable about the safety of substances directly or indirectly added to food and, in so doing, relies on the outcome of the GRAS panel's analysis to support the proponent's conclusion that the safety of the intended use is ''generally recognized'' by qualified experts. Whether a GRAS panel is a sufficient proxy for the larger scientific community depends on a number of factors, such as the subject matter expertise of the members of the GRAS panel and whether the members of the GRAS panel would be considered representative of experts qualified by scientific training and experience to evaluate the safety of the substance under the conditions of its intended use.

A GRAS panel is one mechanism that proponents have used to demonstrate that the safety of a substance under the conditions of its intended use is generally recognized by qualified experts. However, the use of a GRAS panel is not the only mechanism for doing so, and the use of a GRAS panel does not necessarily mean that the GRAS criteria have been met (81 FR 54960 at 54974 through 54975, August 17, 2016).

We are announcing the availability of a guidance for industry entitled ''Best Practices for Convening a GRAS Panel.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. 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.

In the **Federal Register** of November 16, 2017 (82 FR 53433), we made available a draft guidance for industry entitled ''Best Practices for Convening a GRAS Panel'' (''draft guidance''), which was intended for any proponent who convenes a GRAS panel and provided our current thinking on best practices to identify GRAS panel members who have appropriate and balanced expertise; to take steps to reduce the risk that bias (or the appearance of bias) will affect the credibility of a GRAS panel report, including the assessment of potential GRAS panel members for conflict of interest and the appearance of conflict of interest; and to limit the data and information provided to a GRAS panel to public information (*e.g.,* by not providing the GRAS panel with information such as trade secret information). We gave interested parties until May 15, 2018, to submit comments for us to consider before beginning work on the final version of the guidance.

We received 13 comments on the draft guidance. Most comments supported the draft guidance and offered ideas on how to improve the guidance. One comment discussed FDA's analysis of the proposed collection of information, and another comment involved issues not related to the draft guidance. We have modified the final guidance where appropriate. Changes to the guidance include:

- Emphasizing that, in many cases, a GRAS panel is not necessary, in response to comments suggesting the GRAS notification process may become too burdensome;
- Providing additional background information regarding the value of a GRAS panel in providing evidence to support the ''general acceptance'' aspect of the criteria for eligibility for GRAS status through scientific procedures;
- Clarifying the GRAS panel policy discussions around evaluating and managing conflicts of interest and appearance issues, as well as honoraria;
- Removing one reference, as it has been withdrawn since publication of the draft guidance; and
- Removing a mistaken reference to a section V.J.

The guidance announced in this notice finalizes the draft guidance dated November 2017.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in this guidance have been approved under OMB control number 0910–0911.

This guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR parts 170 and 570 have been approved under OMB control number 0910–0342.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA websites listed in the previous sentence to find the most current version of the guidance.

Dated: December 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27714 Filed 12–20–22; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2018–0746; FRL–6494.1–02–OAR]

RIN 2060–AV54

Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action; reconsideration of the final rule.

SUMMARY: On August 12, 2020, the U.S. Environmental Protection Agency (EPA) published the final risk and technology review (RTR) for the Miscellaneous Organic Chemical Manufacturing NESHAP (2020 MON final rule) pursuant to Clean Air Act (CAA).

Subsequently, the EPA received and granted petitions for reconsideration on two issues, specifically, on the use of the EPA's IRIS value for ethylene oxide in assessing cancer risk for the source category, and the use of the Texas Commission on Environmental Quality's (TCEQ's) risk value for ethylene oxide as an alternative risk value to the EPA's IRIS value for purposes of evaluating risk as part of the CAA residual risk review. On February 4, 2022, the EPA proposed the Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants (NESHAP): Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review to address these two issues and request public comment. This action finalizes the EPA's decision to use the IRIS value for ethylene oxide in the risk assessment for the 2020 MON final rule and our decision to reject the use of the TCEQ's risk value for ethylene oxide as an alternative risk value to the EPA's IRIS value. As such, in this final action, EPA is making no changes to the risk assessment or related regulatory text for the miscellaneous organic chemical manufacturing source category.

DATES: This final action is effective on December 21, 2022.

ADDRESSES: The U.S. Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA–HQ–OAR–2018–0746. All documents in the docket are listed on the *https://www.regulations.gov/* website. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information 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 either electronically through *https://www.regulations.gov/,* or in hard copy at the EPA Docket Center, WJC West Building, Room Number 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time (EST), Monday through Friday. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Ms. Susan Paret, Sector Policies and Programs Division (E–120 C), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5516; and email address: *paret.susan@epa.gov.* For specific information regarding these reconsideration decisions, contact Amy Vasu, Health and Environmental Impacts Division (C539–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0107; and email address: *vasu.amy@epa.gov.* For information about the applicability of the NESHAP to a particular entity, contact John Cox, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–1395; and email address: *cox.john@epa.gov.*

SUPPLEMENTARY INFORMATION: *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
CRA Congressional Review Act
EtO ethylene oxide
HAP hazardous air pollutants(s)
IRIS Integrated Risk Information System
MACT maximum achievable control technology
MCPU miscellaneous organic chemical manufacturing process unit
MIR maximum individual risk
MON Miscellaneous Organic Chemical Manufacturing NESHAP
NESHAP national emission standards for hazardous air pollutants
NIOSH National Institute for Occupational Safety and Health
NTTAA National Technology Transfer and Advancement Act
PRA Paperwork Reduction Act
RFA Regulatory Flexibility Act
RTR risk and technology review
SAB Science Advisory Board
SSM startup, shutdown, and malfunction
UMRA Unfunded Mandates Reform Act
URE unit risk estimate

Background information. On February 4, 2022, the EPA proposed the Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants (NESHAP): Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review (87 FR 6466). In this action, we are finalizing decisions on the two issues for which we granted reconsideration. We summarize specific comment topics received on our proposed action and our responses central to our rationale for the decisions in this action. A summary of all public comments on the proposal and the EPA's responses to those comments is available in *Summary of Public Comments and Responses for the Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review,* Docket ID No. EPA–HQ–OAR–2018–0746.

Organization of this document. The information in this preamble is organized as follows:

I. General Information

A. What is the source of authority for this reconsideration action?

The source of 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—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS FINAL ACTION

NESHAP and source category	NAICS [1] code
40 CFR part 63, subpart FFFF, Miscellaneous Organic Chemical Manufacturing.	3251, 3252, 3253, 3254, 3255, 3256, and 3259, with several exceptions.

[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 the final action for the source category 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 this NESHAP, please contact the appropriate 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 final action will also be available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at: *https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version and key technical documents at this same website.

Copies of all oral and written comments received on the proposed rulemaking (Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants (NESHAP): Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review (87 FR 6466; February 4, 2022) are available at the EPA Docket Center Public Reading Room. Comments are also available electronically through *https://www.regulations.gov/* by searching Docket ID No. EPA–HQ–OAR–2018–0746. Additional information is available on the RTR website at *https://www.epa.gov/stationary-sources-air-pollution/risk-and-technology-review-national-emissions-standards-hazardous.* This information includes an overview of the RTR program and links to project websites for the RTR Source categories.

D. Judicial Review and Administrative Reconsideration

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit by February 21, 2023. Under CAA section 307(b)(2), the requirements established by this final action may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

II. Background Information

The EPA promulgated the Miscellaneous Organic Chemical Manufacturing NESHAP (MON) on November 10, 2003 (68 FR 63852), and further amended the MON on July 1, 2005 (70 FR 38562), and July 14, 2006 (71 FR 40316). The standards are codified at 40 CFR part 63, subpart FFFF. The MON regulates HAP emissions from miscellaneous organic chemical manufacturing process units (MCPUs) located at major sources. An MCPU includes equipment necessary to operate a miscellaneous organic chemical manufacturing process, as defined in 40 CFR 63.2550(i), and must meet the following criteria: (1) it manufactures any material or family of materials described in 40 CFR 63.2435(b)(1); (2) it processes, uses, or generates any of the organic HAP described in 40 CFR 63.2435(b)(2); and, (3) except for certain process vents that are part of a chemical manufacturing process unit, as identified in 40 CFR 63.100(j)(4), the MCPU is not an affected source or part of an affected source under another subpart of 40 CFR part 63. An MCPU also includes any assigned storage tanks and transfer racks; equipment in open systems that is used to convey or store water having the same concentration and flow characteristics as wastewater; and components such as pumps, compressors, agitators, pressure relief devices (PRDs), sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used to manufacture any material or family of materials described in 40 CFR 63.2435(b)(1). Sources of HAP emissions regulated by the MON include the following: process vents, storage tanks, transfer racks, equipment leaks, wastewater streams, and heat exchange systems.

The EPA conducted an RTR for the MON, pursuant to CAA sections 112(d)(6) and (f)(2), publishing proposed amendments on December 17, 2019 (84 FR 69182). As of November 6, 2018, the Source category covered by this MACT standard included 201 facilities, herein referred to as ''MON facilities.'' This facility population count was developed using methods described in section II.C of the RTR proposal preamble (84 FR 69182, 69186–87). A complete list of known MON facilities is available in Appendix 1 of the document, *Residual Risk*

Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2019 Risk and Technology Review Proposed Rule, which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0011). After soliciting and considering public comments, the EPA took final action in 2020 (85 FR 49084; August 12, 2020). The 2020 MON final rule included revisions to the NESHAP pursuant to the technology review for equipment leaks and heat exchange systems, and revisions pursuant to the risk review to specifically address ethylene oxide emissions from storage tanks, process vents, and equipment leaks. In addition, the 2020 MON final rule corrected and clarified regulatory provisions related to emissions during periods of startup, shutdown, and malfunction (SSM), including removing general exemptions for periods of SSM, adding work practice standards for periods of SSM where appropriate, and clarifying regulatory provisions for certain vent control bypasses. The final action also added monitoring and operational requirements for flares that control ethylene oxide emissions and flares used to control emissions from processes that produce olefins and polyolefins, added provisions for electronic reporting of performance test results and other reports, and included other technical corrections to improve consistency and clarity.

In the 2020 MON final rule's risk assessment,[1] the Agency calculated cancer risks associated with emissions of ethylene oxide using the EPA's IRIS value for that pollutant,[2] [3] and the risk review included a determination that the risks for this source category under the current Maximum Achievable Control Technology (MACT) provisions were unacceptable due to ethylene oxide emissions. When risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level. As such, the EPA promulgated final amendments to the MON pursuant to CAA section 112(f)(2) that require control of ethylene oxide emissions for process vents, storage tanks, and equipment in ethylene oxide service. The 2020 MON final rule reduced risks to an acceptable level that also provides an ample margin of safety to protect public health.

The EPA received comments from TCEQ during the public comment period that included their draft cancer dose-response assessment for ethylene oxide. The final rule preamble stated that ''the EPA remains open to new and updated scientific information'' and new dose-response values, such as the dose-response value then being developed by the TCEQ (85 FR at 49098). However, by the close of the public comment period for the proposed rulemaking, on March 19, 2020, the TCEQ dose-response value had not yet been finalized and could not be considered in the final action.

Following promulgation of the 2020 MON final rule, the EPA received five separate petitions for reconsideration from four unique petitioners. The EPA received two petitions from the American Chemistry Council (ACC) (one petition dated October 2020, one dated December 2020), one from the TCEQ (dated October 2020), one from Squire Patton Boggs (US) LLP (submitted on behalf of Huntsman Petrochemical, LLC) (dated October 2020), and one from Earthjustice (submitted on behalf of RISE St. James, Louisiana Bucket Brigade, Louisiana Environmental Action Network, Texas Environmental Justice Advocacy Services (t.e.j.a.s.), Air Alliance Houston, Ohio Valley Environmental Coalition, Blue Ridge Environmental Defense League, Inc., Environmental Justice Health Alliance for Chemical Policy Reform, Sierra Club, Environmental Integrity Project, and Union of Concerned Scientists) (dated October 2020). Copies of the petitions are available in the docket for this rulemaking (see Docket ID Nos. EPA–HQ–OAR–2018–0746–0259, EPA–HQ–OAR–2018–0746–0260, EPA–HQ–OAR–2018–0746–0261, EPA–HQ–OAR–2018–0746–0262, and EPA–HQ–OAR–2018–0746–0263).

Three petitioners (ACC, TCEQ, and Huntsman Petrochemical, LLC) requested that EPA reconsider the rule to reassess the risk assessment for the 2020 MON final rule using the TCEQ's alternative risk value for ethylene oxide instead of the EPA's IRIS value for ethylene oxide. These three petitioners further argued that the EPA's IRIS value for ethylene oxide is flawed, citing their disagreement with the EPA Office of Research and Development's model selection and inclusion of breast cancer data in the IRIS assessment. In their petitions, ACC and Earthjustice also raised other issues unrelated to the use of the IRIS value or the TCEQ value for assessing risk from ethylene oxide emissions.

On June 22, 2021, the EPA sent letters to all of the petitioners informing them that: (1) the EPA was granting reconsideration requests on two specific issues (described in the next paragraph), (2) the EPA intended to issue a **Federal Register** document initiating a document 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 may choose to initiate reconsideration of additional issues in the future. Copies of the letters to petitioners are available in the docket for this rulemaking (see Docket ID Nos. EPA–HQ–OAR–2018–0746–0249, EPA–HQ–OAR–2018–0746–0250, EPA–HQ–OAR–2018–0746–0251, and EPA–HQ–OAR–2018–0746–0252).

On February 4, 2022 (87 FR 6466), pursuant to CAA section 307(d)(7)(B), the EPA proposed to take comment on the issues for which reconsideration was granted in the June 22, 2021 letters. In the proposal, the EPA solicited public comment on the following aspects of the 2020 MON final rule: (1) the use of the EPA's IRIS value for ethylene oxide in assessing cancer risk for the Source category, and (2) the use of the TCEQ risk value for ethylene oxide as an alternative risk value to the EPA's IRIS value for purposes of evaluating risk under CAA section 112(f)(2). Reconsideration was granted on these two topics on the following bases: the TCEQ risk value for ethylene oxide was finalized after the comment period for the proposed MON rulemaking closed, and the 2020 MON final rule preamble stated that the EPA remains open to new and updated scientific information, such as the TCEQ value; and because the risk posed by ethylene oxide is of central relevance to the EPA's determination that the risks from sources in the Miscellaneous Organic Chemical Manufacturing Source category remaining after imposition of the then-current CAA section 112(d)(2) MACT standards were unacceptable and that more stringent standards are required.

[1] Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review: Final Rule, August 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0189*.

[2] The IRIS value is, specifically, the inhalation unit risk estimate (URE) for ethylene oxide. The URE is the upper bound additional lifetime cancer risk estimated to result from continuous (24 hours/day) lifetime (70 years) exposure to ethylene oxide at a concentration of 1 μg/m^3 in air. Because ethylene oxide is mutagenic (*i.e.,* damages DNA), an age-dependent adjustment factor was applied to the URE to account for childhood exposures. Therefore, the IRIS value used in the risk assessment is the age-adjusted inhalation URE for ethylene oxide, which is 0.005 per μg/m^3.

[3] U.S. EPA. *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75–21–8) In Support of Summary Information on the Integrated Risk Information System (IRIS).* December 2016. EPA/635/R–16/350Fa. Available at: *https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

Note that, for this reconsideration action, the EPA sought comment only on the two issues subject to mandatory reconsideration described in the proposal preamble for this reconsideration (87 FR 6466; February 4, 2022). Because the criteria for mandatory reconsideration under CAA section 307(d)(7)(B) have been satisfied, the Agency is publishing this final reconsideration action in the **Federal Register**.

III. Final Action

In this section of the preamble, the EPA sets forth its final decisions on the two issues for which reconsideration was granted and on which the EPA solicited comment in the proposed document of reconsideration. We also present the Agency's rationale for the decisions.

A. Issue 1: Use of the EPA's IRIS Value for Ethylene Oxide in Assessing Cancer Risk for the Source Category

1. EPA's Final Decision on the Use of the IRIS Value for Ethylene Oxide In Assessing Cancer Risk For The Source Category

After careful consideration of the comments and information submitted through the public comment process for this rulemaking, the Agency has decided that use of the EPA IRIS value for ethylene oxide for the risk assessment performed for the 2020 MON final rule was appropriate. As described in the reconsideration proposal (87 FR 6466, 6471; February 4, 2022), EPA has an established approach supported by the Science Advisory Board for selecting dose-response values for the CAA section 112(f)(2) risk reviews.[4] [5] Application of this approach generally results in an EPA IRIS value being given preference over values from other organizations or agencies. Neither the petitioners nor commenters identified a basis for the EPA to deviate from this documented approach for selecting dose-response values for use in the risk assessment for the 2020 MON final rule. Further, the EPA IRIS assessment of ethylene oxide is scientifically sound, as evidenced by the toxicological assessment itself,[6] as well as the supporting technical documentation. As described in section III.A.2 below and in greater detail in sections 4.1.1 and 4.1.2 of the response to comment document for this rulemaking, the IRIS assessment underwent an extensive peer and public review process that adhered to the guidelines in EPA's *Peer Review Handbook*[7] for peer review of highly influential scientific assessments. The IRIS assessment and supporting documentation provide evidence of full consideration of the array of scientific questions and comments presented to the EPA and addressed by the EPA prior to issuing the final assessment in December 2016. In addition, since the issuance of the final assessment, there is no new scientific information that would alter EPA's derivation of the IRIS value or other aspects of the EPA IRIS assessment for ethylene oxide. The IRIS assessment continues to provide sound scientific conclusions that are consistent with the latest scientific knowledge. For these reasons, which are addressed in section III.A.2 below, and in greater detail in the response to comment document for this rulemaking, the EPA IRIS value for ethylene oxide is the most appropriate risk value to use in assessing cancer risk for the MON Source category.

2. Comments Received on the Use of the EPA's IRIS Value for Ethylene Oxide In Assessing Cancer Risk for the Source Category

The Agency received a range of comments on the proposed rule. While many commenters agreed with the use of EPA's IRIS value for ethylene oxide, several commenters disagreed with EPA's choice to rely on the Agency's IRIS assessment, as opposed to TCEQ's assessment, as the source of the value used to calculate cancer risk from ethylene oxide exposure.

Many of the comments submitted regarding the EPA IRIS assessment of ethylene oxide have been addressed previously by the EPA as part of the extensive peer review and public review process of the draft IRIS assessment of ethylene oxide. For those comments challenging the IRIS assessment, documented in detail in the response to comment document for this rulemaking, we cite to our previous responses. For example, we again received comments claiming that potential background levels of ethylene oxide (ethylene oxide present in ambient air or produced through metabolism in a person's body (*i.e.,* endogenously)) contribute to cancer risk but were not accounted for in the calculation of the cancer risk value. We have addressed these comments previously in the 2020 MON final rule[8] and in the IRIS Assessment for ethylene oxide,[9] in addition to the EPA's December 13, 2021, response[10] to the Request for Correction (RFC)[11] of the IRIS value that was submitted to the EPA by petitioner ACC under the Information Quality Act, Public Law 106–554 (IQA). We cite these responses in the response to comment document for this rulemaking, where we explain:

> It is important to recognize that the IRIS [unit] risk estimate for EtO represents the increased cancer risk due to exposure to ethylene oxide emissions—above any potential existing risks from endogenous or ambient background levels of EtO exposure. The occupational exposures in the NIOSH study represent workplace EtO levels these workers experienced—and are in addition to any endogenous or broad population background exposures to which the workers may also have been exposed.

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[4] U.S. EPA. *Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing,* June 2009. EPA–452/R–09–006. *https://www3.epa.gov/airtoxics/rrisk/rtrpg.html.*

[5] Recommendations of the SAB Risk and Technology Review Methods Panel are provided in their report, which is available at: *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100RODV.txt* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[6] U.S. EPA. *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75–21–8) In Support of Summary Information on the Integrated Risk Information System (IRIS).* December 2016. EPA/635/R–16/350Fa. Available at: *https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[7] U.S. EPA, 2015. Peer Review Handbook, 4th edition. Science and Technology Policy Council. October 2015. EPA/100/B–15/001. *https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf*

[8] Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing. *https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0200.*

[9] U.S. EPA. *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75–21–8) In Support of Summary Information on the Integrated Risk Information System (IRIS).* December 2016. EPA/635/R–16/350Fa. *See* Appendix K, p. K–9. Available at: *https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[10] U.S. EPA. EPA's Response to American Chemistry Council (ACC)'s Request for Correction to the IRIS Value for Ethylene Oxide (EtO) used in the National Air Toxics Assessment (NATA) in 2018. December 13, 2021. Available at: *https://www.epa.gov/quality/epa-information-qualityguidelines-requestscorrection-and-requestsreconsideration#18003* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[11] American Chemistry Council. Request for Correction under the Information Quality Act: 2014 National Air Toxics Assessment (NATA). September 20, 2018. Available at: *https://www.epa.gov/quality/epa-information-qualityguidelines-requests-correction-and-requestsreconsideration#18003* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

In this section, we describe specific comment topics central to our rationale for EPA's decision to continue to use the EPA IRIS value; detailed comment summaries and responses are presented in the response to comment document for this rulemaking.

a. Comments Concerning Selection of Dose-Response Values for CAA Section 112(f)(2) Risk Reviews

EPA received a number of comments in support of and against the use of the EPA IRIS value for ethylene oxide. As described in the reconsideration proposal (87 FR 6466, 6471; February 4, 2022), EPA has a documented approach for selecting dose-response values for the CAA section 112(f)(2) risk reviews. For these risk reviews, the EPA performs health risk assessments for the hazardous air pollutants (HAP) that are emitted from the source category after imposition of MACT standards under CAA section 112(d)(2). Consistent with the purpose of the IRIS database and the advice from the EPA SAB, and as described in the risk assessment documentation for the 2020 MON final rule,[12] the IRIS database is the preferred source of chronic dose-response data.

Based on EPA's careful review, the Agency has determined that neither the petitioners requesting that EPA reconsider the 2020 MON final rule nor commenters on the proposed reconsideration identified a basis for EPA to change our approach generally, nor our approach to the risk assessment specifically in the 2020 MON final rule. Where commenters identified specific topics, such as new analyses or information related to the cancer risk value for ethylene oxide, we address those comments either in the preamble to this final action or in sections 3 and 4 of the response to comment document for this action.

b. Comments About the EPA IRIS Assessment of Ethylene Oxide Being Scientifically Sound and Robust

Some commenters oppose the use of the ethylene oxide IRIS value, for the most part reiterating previously provided comments (*e.g.,* on model selection) and citing information that the Agency has already considered, including in the development of the IRIS assessment or the 2020 MON final rule. Where new comments or information have been provided, we address those in this preamble or in the response to comment document for this rulemaking.

Many commenters supporting the use of the EPA IRIS value reiterated that the IRIS value must be applied because it reflects the latest scientific knowledge and is the result of an extensive review process. The EPA agrees that the EPA IRIS assessment is scientifically sound and robust and represents the best estimate of the increased cancer risk posed by inhalation exposure to ethylene oxide for use in a risk assessment. This is evidenced by the toxicological assessment itself[13] and its supporting technical documentation, as well as the extensive peer and public review process that was an integral part of the development of the final assessment.

Many of the comments received on the peer and public review of the EPA IRIS ethylene oxide assessment have been addressed previously by the EPA. Specifically, as stated in the response to comments received on the 2020 MON final rule,[14] the EPA followed its standard review process in the ethylene oxide IRIS assessment, which included multiple rounds of review and comment by experts and the public. This included internal agency review, interagency review, public external peer review, and public review. The ethylene oxide IRIS assessment underwent two peer and public review processes over a 10-year period. After the second peer and public review, the Agency followed its normal process to finalize the assessment by considering the peer and public review comments received, making final revisions to the assessment in response to those comments, and then issuing the final ethylene oxide IRIS assessment.

Given this process, the EPA stated that it disagreed with comments suggesting that scientific information and comments were not fully addressed during the IRIS assessment development and review process. In responding to these comments, the EPA further noted the Agency's adherence to the guidelines in the EPA's *Peer Review Handbook*[15] for highly influential scientific assessments. The IRIS assessment itself and supporting documentation provide evidence of full consideration of the array of scientific questions and comments presented to the EPA. Responses to new comments received regarding statistical support for the IRIS dose-response model are included in the response to comments document.

As described in the EPA's *Peer Review Handbook,*[16] there are a range of types of peer review. For the ethylene oxide IRIS assessment, the Agency requested review by the EPA SAB. The EPA's SAB is a statutorily established committee with a broad mandate to provide advice and recommendations to the Agency on scientific and technical matters. The SAB considers requests for advice and peer review from across the Agency as part of an annual process, initiated by a request from the Deputy Administrator to the EPA's senior leadership to identify requests for review by the EPA. Highly influential scientific assessments, such as IRIS assessments, or other scientific work products associated with highly visible or controversial environmental issues are most suited to review by the SAB. Much of the SAB's peer review work is done using *ad hoc* panels formed to review specific EPA draft technical products. All SAB panels provide advice through the chartered SAB, which is composed of approximately 50 nationally renowned scientists, engineers and economists who are screened for conflicts of interest. The chartered SAB further reviews reports prepared by project-specific panels, accepts further public comment, and reports final conclusions directly to the EPA Administrator.

In addition, to address concerns raised about opportunities for review of the draft IRIS assessment, it is important to note that the assessment review and revision process took place over a 10-year period, from 2006 to 2016. Stakeholders, including the American Chemistry Council, had an awareness of the Agency's IRIS assessment early in the process, as evidenced by their review of the 2006 and 2013 draft IRIS assessments and the extensive comments that the ACC and other stakeholders provided on those drafts.

After completion of an initial draft of the assessment, the EPA undertook an

[12] Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2020 Risk and Technology Review: Final Rule, August 2020. Available at: *https://www.regulations.gov/document/EPA-HQOAR-2018-0746-0189.*

[13] U.S. EPA. *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75–21–8) In Support of Summary Information on the Integrated Risk Information System (IRIS).* December 2016. EPA/635/R–16/350Fa. Available at: *https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[14] Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing, August 2020. See section 4.1.3, response to Comment 29. Available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0200.*

[15] U.S. EPA, 2015. Peer Review Handbook, 4th edition. Science and Technology Policy Council. October 2015. EPA/100/B–15/001. *https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf.*

[16] *Id.*

extensive, transparent review process. We agree with commenters who stated that the ethylene oxide assessment underwent extensive internal EPA review, as well as external review by other federal agencies. Drafts of the assessment were available for public comment at three different times and were twice submitted for external peer review by the SAB, which is an additional round of external review than is typically received by IRIS assessments. It is correct that at least four drafts of the IRIS ethylene oxide cancer evaluation were reviewed by a wide range of ''EPA scientists, interagency reviewers from other federal agencies and the Executive Office of the President, the public, and independent scientists external to the EPA.'' [17]

Not only did the SAB reviews involve large panels of experts with diverse expertise; they also provided opportunity for public comment and SAB consideration of that comment. EPA's IRIS assessment methods and conclusions directly relied on detailed recommendations presented by the SAB (*e.g.,* SAB, 2015, page 9 presents specific recommendations on preferred dose-response models). The EPA has determined that the IRIS assessment is scientifically sound and robust and represents the best inhalation cancer risk value for ethylene oxide.

c. Comments Suggesting That There Is New Scientific Information That Would Alter Aspects of the EPA IRIS Assessment

Regarding comments questioning EPA's use of the best available and most recent scientific knowledge, EPA has carefully considered the range of information submitted to EPA on the IRIS assessment since its issuance in 2016. This includes, for example, the EPA's response to the ACC's Request for Correction of the use of the IRIS value for ethylene oxide.[18] The Agency's response documents further evidence of consideration of scientific information submitted to the EPA on the assessment of ethylene oxide since the IRIS assessment was issued in 2016. While there have been several new publications since issuance of the final ethylene oxide IRIS assessment in December 2016, those publications most pertinent to developing an inhalation cancer risk value for ethylene oxide have focused on re-analyses of published studies previously considered in the 2016 IRIS assessment and, therefore, yield no new scientific information. EPA is not aware of new epidemiological, toxicological, or basic scientific studies that suggest the current cancer risk value is no longer appropriate or that could fundamentally alter the basis for the current ethylene oxide IRIS assessment. Specifically, there is no new scientific information that would alter aspects of the EPA IRIS assessment or call into question the scientific judgements reflected in that assessment. The IRIS value for ethylene oxide continues to reflect the latest scientific knowledge.

B. Issue 2: Use of the TCEQ Risk Value for Ethylene Oxide in Assessing Cancer Risk for the Source Category

1. EPA's Final Decision on the Use of the TCEQ Risk Value for Ethylene Oxide in Assessing Cancer Risk for the Source Category

After careful consideration of the final TCEQ assessment [19] and comments and information submitted through the public comment process for this rulemaking, the Agency finds that the TCEQ risk value is unsuitable for use as an alternative to the IRIS value for ethylene oxide in assessing cancer risk under CAA section 112(f).

The EPA disagrees with several foundational aspects of the final TCEQ assessment. First, EPA disagrees with TCEQ's decision to exclude breast cancer in women as an endpoint for ethylene oxide dose response assessment. EPA finds that TCEQ's decision to exclude breast cancer in women in their derivation of the ethylene oxide risk value is not scientifically sound; this decision reduces the accuracy of, and confidence in, the TCEQ risk value as an appropriate metric of increased cancer risk from inhalation exposure to ethylene oxide. Second, with regard to TCEQ's dose-response modeling, the EPA finds that: (1) the dose-response model selected by TCEQ is unsupported by the underlying epidemiological data, and (2) TCEQ's analyses to justify their model choice were erroneous and relied on flawed assumptions. For the reasons listed here and described in detail in section III.B.2 below, as well as in the response to comment document for this rulemaking, the TCEQ risk value for ethylene oxide is not appropriate to use in assessing cancer risk for the MON Source category.

2. Comments Received on the Use of the TCEQ Risk Value for Ethylene Oxide in Assessing Cancer Risk for the Source Category

While many commenters were opposed to EPA's use of the TCEQ risk value for ethylene oxide, several commenters were in favor of the use of the TCEQ value. In this section, we describe specific comment topics key to explaining the rationale for EPA's decision to reject the use of the TCEQ risk value for assessing cancer risk for the source category; detailed comment summaries and responses are presented in the response to comment document for this rulemaking.

a. Comments on Inclusion and Exclusion of Breast Cancer as an Endpoint

While many commenters agree with the inclusion of breast cancer as an endpoint in the dose-response assessment of ethylene oxide, as was done in the EPA IRIS assessment, several commenters, including TCEQ and ACC, support exclusion of breast cancer as an endpoint, as was done in the final TCEQ assessment of ethylene oxide.

EPA disagrees with TCEQ and other commenters who support exclusion of breast cancer in women as an endpoint when assessing the cancer risk from exposure to ethylene oxide. In the IRIS assessment of ethylene oxide, the EPA determined that the available epidemiological evidence for a causal relationship between ethylene oxide exposure and breast cancer in women was strong, and there were sufficient data to include breast cancer in the derivation of the IRIS value for ethylene oxide. The SAB supported this determination. Comments on the evidence for breast cancer as an endpoint following ethylene oxide exposure were also addressed during the review process for the IRIS ethylene oxide assessment. For example, in response to a public comment on the IRIS 2013 draft claiming that the evidence for breast cancer is too weak to rely on in setting the URE, the EPA responded: ''Although the epidemiological database for breast

[17] U.S. EPA. *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75–21–8) In Support of Summary Information on the Integrated Risk Information System (IRIS).* December 2016. EPA/635/R–16/350Fa. Available at: *https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[18] U.S. EPA. EPA's Response to American Chemistry Council (ACC)'s Request for Correction to the IRIS Value for Ethylene Oxide (EtO) used in the National Air Toxics Assessment (NATA) in 2018. December 13, 2021. Available at: *https://www.epa.gov/quality/epa-information-qualityguidelines-requests-correction-and-requestsreconsideration#18003* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[19] Ethylene Oxide Carcinogenic Dose-Response Assessment: Development Support Document, May 15, 2020. Texas Commission on Environmental Quality. *https://www.tceq.texas.gov/downloads/toxicology/dsd/final/eto.pdf.*

cancer is more limited (*i.e.,* few studies with sufficient numbers of female breast cancer cases) than that for lymphohematopoietic cancers, the EPA determined that the available evidence is sufficient to consider breast cancer a potential hazard from ethylene oxide exposure . . . The 2007 SAB panel did not object to the derivation of unit risk estimates based on the available breast cancer evidence.'' [20] The IRIS cancer risk value is representative of potential health risks to the general population because it reflects the combined cancer risk of developing lymphoid cancers in all people, and breast cancer in women.

EPA examined what TCEQ describes as new scientific information and found it to primarily consist of publications providing further reviews covering the same epidemiological data on breast cancer that had already been comprehensively reviewed in the EPA's ethylene oxide IRIS assessment. EPA's examination of these review articles finds that the authors of these journal article reviews have mostly dismissed the strongest data on ethylene oxide and breast cancer, and EPA finds these decisions to be unwarranted. Comments against the inclusion of breast cancer cite two meta-analyses addressing ethylene oxide breast cancer studies that were published after the completion of the 2016 IRIS assessment (Marsh et al. (2019). Both reviews included five breast cancer studies, all of which were examined in the IRIS assessment (Coggon, 2004; Mikoczy, 2011; Norman, 1995; Steenland, 2003; and Steenland, 2004). The conclusions of these meta-analyses are flawed for two major reasons: (1) the authors did not consider findings of increased cancer incidence or mortality in highly exposed study subgroups, and (2) the authors excluded published findings using internal comparison groups within the worker populations, which goes against best practice in epidemiology.[21] Consequently, the meta-analyses inappropriately omitted all positive findings from the Steenland et al. (2003 and 2004) and Mikoczy et al. (2011) studies for breast cancer mortality and incidence and treated these studies as providing negative evidence of an effect of ethylene oxide on breast cancer. These flawed re-analyses of data (data that had been previously reviewed in the IRIS assessment and found to provide positive evidence) led the authors to conclude that the weight of evidence does not support breast cancer as an endpoint.

EPA also examined a new study by Jain (2020) using NHANES data to investigate associations between exposure to ethylene oxide in tobacco smoke and self-reported diagnosis of cancers. The author concluded that levels of ethylene oxide in the general population in the U.S. were not found to be associated with cancers, including breast cancer. There are three major issues that call into question the interpretation of the results from this study. First, it appears that Jain misleadingly interpreted a biomarker of exposure as ''[ethylene oxide] levels in the blood''. Importantly, since NHANES did not measure ethylene oxide levels in the blood, this suggests a misunderstanding of the NHANES data consistent with Jain's overinterpretation of the results. Second, Jain failed to note the large number of unaccounted-for variables that may contribute to one's lifetime breast cancer risk, such as lifestyle, a history of breast cancer in relatives, co-exposures, and cumulative exposure to ethylene oxide and other chemicals. NHANES provides cross-sectional data representing a snapshot in time of exposure and health outcome and is not designed to establish temporal causality between chemical exposure and cancer outcomes. For this reason, NHANES data cannot be used to reliably rule out causation between chemical exposure and breast cancer. Third, biomarker measurements that offer a snapshot in time of one's exposure to chemicals are not necessarily representative of continuous, lifetime exposure leading to the development of breast cancer. Taken together, the Jain study results do not support the author's conclusion.

EPA disagrees with commenters that dismiss the breast cancer findings in the National Institute for Occupational Safety and Health (NIOSH) studies of sterilizer workers. Available epidemiologic data provide strong evidence of an elevated breast cancer risk in female workers exposed to ethylene oxide. Results from the NIOSH studies of sterilizer workers (Steenland et al., 2003, and Steenland et al., 2004) demonstrate excess breast cancer risk, substantiated through several different epidemiological analysis approaches. Other smaller studies also indicate an elevated breast cancer risk. No substantial studies challenge this conclusion. The breast cancer findings from the studies of Steenland et al. (2003, 2004) are broadly regarded as the largest and most detailed studies of this endpoint. These studies presented cancer findings for the NIOSH cohort of workers at U.S. sterilization facilities with Steenland et al. (2004) examining cancer mortality rates for breast and other cancers and Steenland et al. (2003) specifically studying incidence (occurrence of disease) of breast cancer. Particularly for breast cancer in women (who are not adequately represented in some industrial cohorts), the NIOSH study is generally regarded as preeminent. These cancer mortality and incidence studies include multiple statistical comparisons that provide evidence of the effect of ethylene oxide exposure increasing breast cancer rates. EPA reaffirms that it is sound and reasonable to include breast cancer as a major endpoint in the IRIS ethylene oxide assessment. Detailed comment summaries and responses on this subject are provided in the response to comment document for this rulemaking.

For these reasons, the EPA finds TCEQ's decision to exclude breast cancer as an endpoint in the derivation of their ethylene oxide risk value to be without adequate scientific basis.

b. Comments on Dose-Response Model Selection

EPA received a range of comments regarding the dose-response model selection for the final TCEQ assessment and for the EPA IRIS assessment. A number of the comments submitted on the reconsideration proposal were on aspects of the dose-response model that EPA had previously addressed either in the peer review of the EPA IRIS ethylene oxide assessment [22] or in the response to comment document for the 2020 MON final rule.[23] New comments regarding TCEQ's assessment focused primarily on support for, and opposition to, the model itself and TCEQ's analyses to support the model selected.

After examining the final TCEQ assessment, as well as analyses and

[20] U.S. EPA. *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75–21–8) In Support of Summary Information on the Integrated Risk Information System (IRIS).* December 2016. EPA/635/R–16/350Fa. Appendix K, p. K–3. Available at: *https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

[21] Internal comparisons are particularly valuable, as they provide a basis for examining compound-related increases in cancer rates without relying on an assumption that cancer rates in the studied workers would be identical to general population average cancer rates in the absence of exposure to the compound.

[22] U.S. EPA. *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75–21–8) In Support of Summary Information on the Integrated Risk Information System (IRIS).* December 2016. EPA/635/R–16/350Fa. Available at: *https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746–0202).

[23] Summary of Public Comments and Responses for the Risk and Technology Review for Miscellaneous Organic Chemical Manufacturing, August 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OAR-2018-0746-0200.*

arguments submitted as part of the public comment process for the MON reconsideration proposed rulemaking, the EPA disagrees with TCEQ's model selection, including TCEQ's claim that the biological evidence supports a model with a single, gradual slope through the full range of both general population and occupational exposures. For their model selection, TCEQ chose a model that is inconsistent with the underlying epidemiological data, particularly for ethylene oxide levels in the range of general population exposure (where the general population would include children and other potentially vulnerable groups), which is of most relevance for the CAA section 112 risk assessments.

The epidemiological data indicate that cancer risk rises more rapidly with increasing exposure in the lower exposure range and more gradually in the higher exposure range. TCEQ selected a model that is unable to fit the shape of the data throughout the exposure range. The slope of TCEQ's model is more representative of higher, occupational exposures. By using a single slope (a line) to project risks, TCEQ's model predicts risks at lower exposure ranges that are inconsistent with the underlying epidemiological dose-response data. EPA rejects TCEQ's model because it is inconsistent with the underlying epidemiological dose-response data and mischaracterizes risk at the lower exposure range (*i.e.,* the range representing potential general population exposures).

It is important to note that, as part of the ethylene oxide IRIS assessment, EPA considered and evaluated 12 dose-response models for lymphoid cancer mortality and 9 dose-response models for breast cancer incidence. The dose-response model selected by TCEQ (a Cox proportional hazards model) is one of the models that was considered by the EPA as part of the IRIS assessment. EPA found that the linear curve selected by TCEQ was highly influenced by the uppermost 5% of the exposure range and did not fit the full range of epidemiological data points, leading to an underestimation of risk for points below the highest exposure levels. After considering all models, EPA found that the two-piece spline model best captured the initial increase in risk at lower doses followed by an attenuation at higher doses. Spline models are generally useful for exposure-response data in which risk increases with exposure at low doses but attenuates at higher exposures, as observed in the ethylene oxide lymphoid cancer data. The plateauing exposure-response relationship has been observed for other occupational carcinogens and may be explained by the depletion of susceptible subpopulations at high exposures, mismeasurement of high exposures, or a healthy worker survivor effect (Stayner et al., 2003). The EPA subsequently rejected the model selected by TCEQ, as well as other similar models, and selected a two-piece linear spline model. In its response to the SAB's recommendations,[24] the EPA noted: ''The EPA has followed the SAB's recommendations for model selection. Model selection for both the breast cancer incidence (see section 4.1.2.3) and lymphoid cancer (see section 4.1.1.2) data prioritizes functional forms that allow more local fits in the low exposure range (*e.g.,* spline models), relies less on AIC,[25] and includes consideration of biological plausibility . . .'' As such, in the ethylene oxide IRIS assessment, the EPA selected a model that best represented potential general population exposures, making it align well with the purpose of the risk assessment in the 2020 MON final rule, which sought to assess general risk exposure to the public. Importantly, EPA found TCEQ's chosen model to be a poor fit of the data in the low exposure range (*i.e.,* the range representing potential general population exposures).[26]

Unlike model selection for the TCEQ assessment of ethylene oxide, for the ethylene oxide IRIS assessment, EPA selected the model that best represented potential general population exposures, as well as higher, occupational exposures. EPA's statistical model selection was based on model fit with the observed results in the NIOSH study and was consistent with peer review advice received from the SAB. In the terminology of cancer risk assessment and EPA's Carcinogen Guidelines, the EPA two-piece linear spline model predicts a linear association between environmentally relevant ethylene oxide exposures and cancer risk.[27] SAB (2015) peer review comments noted consistency in model fit and categorical results.[28]

In addition to disagreeing with the dose-response model selected by TCEQ, EPA also disagrees with TCEQ's analytical approach to justifying its model selection. TCEQ supported their model choice using flawed calculations and inappropriate assumptions. TCEQ takes an approach that they claim allows for statistical testing of model predictions. EPA has examined TCEQ's inferences and calculations and has identified problems with: (1) TCEQ's assumption that national lymphoid cancer *mortality* rates equal rates of cancer mortality for members of the NIOSH cohort in the absence of ethylene oxide exposures; (2) TCEQ's calculation of projected cancer rates; and (3) the statistical confidence intervals TCEQ developed for the ''predicted'' numbers of cancers. These are summarized below and described in greater detail in the response to comment document for this rulemaking.

TCEQ made errors in their calculation of projected cancer rates and in the ''reality check'' calculations they used to justify their model choice. TCEQ's ''reality check'' calculations are not statistically appropriate and do not support TCEQ's claims. Further, TCEQ relied on flawed assumptions. For example, in making a claim that TCEQ's model more accurately predicts cancers attributable to ethylene oxide exposure, TCEQ incorrectly assumes that, in the absence of ethylene oxide exposure, cancer incidence rates in the worker cohort (the basis of the URE calculation in EPA's IRIS assessment) would be the same as national cancer mortality rates for the general population. This is, at best, a rough approximation and is subject to considerable error. Importantly, the development of Cox model ''internal'' risk estimates instead of a national mortality rate-based analysis by Steenland et al. (2004) reflects that comparisons to national mortality rates are not appropriate for this worker cohort. Use of an ''internal'' statistical analysis rather than an

[24] U.S. EPA. *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75–21–8) In Support of Summary Information on the Integrated Risk Information System (IRIS).* December 2016. EPA/635/R–16/350Fa. See Appendix I, p. I–3. Available at: *https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746–0202).

[25] The Akaike information criterion (AIC) is a mathematical model for evaluating how well a model fits the underlying dataset from which it was generated.

[26] U.S. EPA. EPA's Response to American Chemistry Council (ACC)'s Request for Correction to the IRIS Value for Ethylene Oxide (EtO) used in the National Air Toxics Assessment (NATA) in 2018. December 13, 2021. Available at: *https://www.epa.gov/quality/epa-information-qualityguidelines-requests-correction-and-requestsreconsideration#18003* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746–0264).

[27] Ibid.

[28] SAB. (2015). *Science Advisory Board Review of the EPA's Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide: Revised external review draft—August 2014 [EPA Report].* (EPA–SAB–15–012). Washington, DC: U.S. EPA, SAB.Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/BD2B2DB4F84146A585257E9A0070E655/$File/EPA–SAB–15–012+unsigned.pdf* and in the docket for this rulemaking (see Docket ID No. EPA–HQ–OAR–2018–0746).

external (national mortality rate-based) analysis is broadly accepted as best practice in occupational epidemiology and was endorsed by the EPA SAB for the EtO IRIS assessment. The EPA disagrees with TCEQ's approach and these assumptions, as described in detail in the response to comment document for this rulemaking.

For the reasons stated above, the EPA finds that the dose-response model selected by TCEQ is unsupported by the data, and the analyses fail to justify the selection of the model. The TCEQ assessment, petitions, and the comments submitted as part of this rulemaking process do not provide a scientifically supportable basis for relying on the TCEQ risk value to assess the residual risk for sources in the 2020 MON final rule. No new studies or other information have been identified by TCEQ, the petitioners requesting reconsideration, or the commenters that would call into question the conclusions in the IRIS ethylene oxide assessment. The EPA reaffirms its use of the EPA IRIS value for ethylene oxide for the risk assessment performed for the 2020 MON final rule.

IV. Summary of Cost, Environmental, and Economic Impacts and Additional Analyses Conducted

A. What are the affected facilities?

We estimate that, as of November 6, 2018, there were 201 MON facilities, nine of which reported ethylene oxide emissions to the 2014 National Emissions Inventory. However, as the EPA is not finalizing any changes to the regulatory text or regulatory requirements in this action, we do not anticipate that any sources will be affected by this reconsideration. A complete list of known MON facilities is available in Appendix 1 of the document, *Residual Risk Assessment for the Miscellaneous Organic Chemical Manufacturing Source Category in Support of the 2019 Risk and Technology Review Proposed Rule,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2018–0746–0011).

B. What are the air quality impacts?

The EPA does not project any air quality impacts associated with this action because this action does not finalize any changes to the standards or other requirements on affected sources.

C. What are the cost impacts?

The EPA does not project any incremental costs associated with this action because it does not finalize any changes to the standards or other requirements on affected sources.

D. What are the economic impacts?

The EPA does not project any economic impacts because there are no incremental costs associated with this action.

E. What are the benefits?

The EPA does not project any incremental benefits associated with this action because it does not finalize any changes to the standards or other requirements on affected sources.

F. What analysis of environmental justice did we conduct?

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This regulatory action acts to reaffirm decisions made in a previously promulgated regulatory action and does not have any impact on human health or the environment.

G. What analysis of children's environmental health did we conduct?

This action is not subject to Executive Order 13045 because it is not economically significant, as defined in Executive Order 12866, and because this action does not present any changes to the rule that would affect environmental health or safety risks, including those that would present a disproportionate risk to children.

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 Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the EPA concludes that the impact of concern for this rule is any significant adverse economic impact on small entities and that the Agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities if the rule has no net burden on the small entities subject to the rule. As we are not finalizing any changes to the regulatory text or regulatory requirements, we do not anticipate any economic impacts resulting from this action. We have therefore concluded that this action will have no net regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action finalizes no enforceable duty on any state, local or tribal governments or the private sector.

E. 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.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. None of the MON facilities that have been identified as being affected by this action are owned or operated by tribal governments or located within tribal lands within a 10 mile radius. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because this action does not present any changes to the rule that would affect environmental health or safety risks, including those that would present a disproportionate risk to children.

H. 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.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This regulatory action acts to clarify the language in the preamble of a previously promulgated regulatory action and does not have any impact on human health or the environment.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances, Intergovernmental relations.

Michael S. Regan,

Administrator.

[FR Doc. 2022–27522 Filed 12–20–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 107, 171, and 173

[Docket No. PHMSA–2016–0014 (HM–224I)]

RIN 2137–AF20

Hazardous Materials: Enhanced Safety Provisions for Lithium Batteries Transported by Aircraft (FAA Reauthorization Act of 2018)

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule revises the Hazardous Materials Regulations for lithium cells and batteries transported by aircraft and is consistent with the previously published Interim Final Rule, which responded to congressional mandates; prohibited the transport of lithium ion cells and batteries as cargo on passenger aircraft; required lithium ion cells and batteries to be shipped at not more than a 30 percent state of charge aboard cargo-only aircraft when not packed with or contained in equipment; and limited the use of alternative provisions for smaller lithium cell or battery shipments to one package per consignment. In response to comments, this final rule provides editorial amendments and modification of certain provisions including marking requirements, requests for an extension on the compliance date, and exception for lithium cells or batteries used for medical devices with approval by the Associate Administrator.

DATES: This final rule is effective on January 20, 2023.

FOR FURTHER INFORMATION CONTACT: Eugenio Cardez, (202) 366–9542, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

The safe transport of lithium batteries by air has been an ongoing concern due to the unique challenges they pose to safety in the air transportation environment. Unlike most other hazardous materials, lithium batteries have a dual hazard of chemical and electrical. This combination of hazards, when involved in a fire, has the potential to create a scenario that exceeds the fire suppression capability of an aircraft and lead to a catastrophic failure of the aircraft.

The Pipeline and Hazardous Materials Safety Administration (PHMSA) issued an interim final rule (IFR) [1] to amend the hazardous materials regulations (HMR; 49 CFR parts 171–180) to (1) prohibit the transport of lithium ion cells and batteries as cargo on passenger aircraft; (2) require all lithium ion cells and batteries to be shipped at not more than a 30 percent state of charge (SOC) on cargo-only aircraft; and (3) limit the use of alternative provisions for smaller lithium cells or batteries to one package per consignment. The IFR amendments predominately affected air carriers (both passenger and cargo-only) and shippers that offer lithium ion cells and batteries for transport as cargo by aircraft. The IFR amendments neither restricted passengers or crew members from bringing electronic devices containing lithium cells or batteries aboard aircraft nor restricted the air transport of lithium ion cells or batteries when packed with or contained in equipment. The IFR also fulfilled the section 333 mandates in the Federal Aviation Administration (FAA) Reauthorization Act of 2018 and amended the HMR to allow shipments of not more than two replacement lithium cells or batteries specifically used for medical devices as cargo on passenger aircraft—with the approval of the Associate Administrator—to accommodate persons in areas potentially not serviced daily by cargo aircraft. Furthermore, these lithium batteries may be excepted from the SOC requirements when they meet certain provisions.

As discussed in further detail in this final rule (see IV. Section-by-Section Review), PHMSA amends certain sections of the HMR in response to public comments received to the IFR. Overall, the comments to the IFR were supportive of PHMSA's action; however, PHMSA did receive a few comments seeking further clarification or revisions to the IFR which PHMSA also addresses in this final rule. Specifically, PHMSA revises the HMR to better ensure that it reflects the original intent of the IFR, particularly in the alignment with the lithium battery transportation requirements with the International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transportation of Dangerous Goods by Air (Technical Instructions). In addition, PHMSA clarifies the implementation of the exception, with approval of the Associate Administrator, for air transportation of lithium batteries intended for use in medical devices. Finally, PHMSA responds to comments related to the marking requirement for smaller lithium ion cells or batteries

[1] 84 FR 8006 (Mar. 6, 2019).

transported by modes other than aircraft and addresses a safety risk associated with lithium batteries transported in overpacks.

A final regulatory impact analysis (RIA) is included in the docket for this rulemaking and supports the amendments made in this rulemaking. PHMSA examined the benefits and costs of PHMSA action in this rulemaking using the final rule as a baseline as shown in Table 1 below.

TABLE 1—SUMMARY OF INCREMENTAL COSTS AND BENEFITS FOR LITHIUM BATTERY PROVISIONS FROM THE BASELINE

Provision	Benefits	Unquantified costs	10-Year quantified cost (7%)
State of Charge	None	None	N/A.
Consignment Limit	None	None	N/A.
Lithium Battery Prohibition as Cargo on Passenger Aircraft	None	None	N/A.
Marking overpacks with statement of prohibition from transport aboard passenger aircraft or a CAO label * .	None	None	$1,574,680.
Total			10-Year: $1,574,680. Annualized: $224,199.

* PHMSA's baseline assumes compliance with the IFR, including marking requirements. PHMSA did not previously quantify the costs and benefits of the requirement for packages shipped via all modes except air to be marked with a statement of prohibition from transportation on passenger aircraft or a CAO label. Thus, PHMSA quantifies the costs associated with this requirement and attributes them to the IFR and not the final rule (see Appendix I: Methodology for Estimating Lithium Battery Shipments). There are no quantifiable benefits associated with this requirement. PHMSA expects that the requirement will ensure regulatory consistency. Further, the communication is necessary to ensure safe transportation, as it will prevent smaller lithium cells and batteries, including those packed with or contained in equipment greater than 5 kg, from being transported as cargo on passenger aircraft.

PHMSA estimates the present value of costs at about $1.6 million over 10 years and about $0.2 million annualized (at a 7 percent discount rate).

PHMSA expects adoption of these amendments will improve the safety of shipments of lithium batteries, which are expected to increase as the use of lithium batteries in the transportation sector and other economic sectors increases in the years ahead. The final rule also provides regulatory consistency and harmonization with international standards, which reduces delays and interruptions in the global transportation of lithium batteries.

II. Background

PHMSA issued an IFR to amend the HMR) to (1) prohibit the transport of lithium ion cells and batteries as cargo on passenger aircraft; (2) require all lithium ion cells and batteries to be shipped at not more than a 30 percent state of charge (SOC) on cargo-only aircraft; and (3) limit the use of alternative provisions for smaller lithium cells or batteries to one package per consignment. The IFR amendments predominately affected air carriers (both passenger and cargo-only) and shippers that offer lithium ion cells and batteries for transport as cargo by aircraft. The IFR amendments did not affect requirements for passenger and crew personal items containing lithium cells or batteries aboard aircraft, nor restricted the air transport of lithium ion cells or batteries when packed with or contained in equipment. The IFR fulfilled the section 333 requirement in the FAA Reauthorization Act of 2018 to allow shipments of not more than two replacement lithium cells or batteries specifically used for medical devices as cargo on passenger aircraft—with the approval of the Associate Administrator—to accommodate persons in areas potentially not serviced daily by cargo aircraft. Furthermore, these lithium batteries may be excepted from the SOC requirements when they meet certain provisions. See ''Section II. Comment Discussion; Exception for Medical Devices'' for further discussion.

The IFR was necessary to address an immediate safety hazard and meet a statutory requirement to harmonize the HMR with emergency amendments to the 2015–2016 edition of the ICAO Technical Instructions. The serious public safety hazards associated with lithium battery transportation and the statutory deadline in the FAA Reauthorization Act of 2018 necessitated the immediate adoption of these standards in accordance with the APA. 5 U.S.C. 553(b)(3)(B) and 553(d)(3). The potential for a catastrophic loss of an aircraft, especially a passenger aircraft carrying lithium battery cargo, the need for harmonization of the HMR with emergency amendments to the ICAO Technical Instructions, and the statutory deadline in the FAA Reauthorization Act of 2018 [2] provided compelling justification to adopt these changes into the HMR immediately without prior notice and comment.

The IFR, including the APA good cause determination, was supported by the findings of lithium battery research conducted by the FAA's William J. Hughes Technical Center (FAA Technical Center), the National Transportation Safety Board (NTSB), and several other well-respected academic sources on lithium batteries and their hazards with respect to amendments that were adopted. The FAA Technical Center's research found that lithium batteries subject to certain conditions could result in adverse events, such as smoke and fire, that could impair the safe operation of the aircraft. Specifically, they found that in a lithium battery fire, flammable gases could collect, ignite, and ultimately exceed the capabilities of an aircraft's fire suppression system. See ''Section III. Need for the Rule'' of the IFR for further explanation of the testing and research that supports this finding. The ICAO also recognized these dangers and adopted additional measures into the international air transport standards, which went into effect on April 1, 2016. The potential for a catastrophic loss of an aircraft, especially a passenger aircraft carrying lithium battery cargo, the need for harmonization of the HMR with emergency amendments to the ICAO Technical Instructions, and the statutory deadline in the FAA Reauthorization Act of 2018 provided compelling justification to adopt these changes into the HMR immediately without prior notice and comment.

In this final rule, PHMSA responds to public comments received to the IFR and revises the HMR based on those

[2] PHMSA's finding of good cause was based on the impracticability of providing the public with notice-and-comment while attempting to comply with the 90-day statutory rulemaking mandate in the FAA Reauthorization Act of 2018, Public Law 115–254 (October 5, 2018, FAA Reauthorization Act of 2018). PHMSA's compliance with the statutory deadline was negatively impacted by a lapse in funding from December 22, 2018, through January 25, 2019, that affected PHMSA, FAA, and other government agencies.

comments. Specifically, PHMSA revises the HMR to better align the lithium battery transportation requirements with the ICAO Technical Instructions. In addition, PHMSA clarifies the implementation of the exception, with approval of the Associate Administrator, for lithium batteries intended for use in medical devices. PHMSA also responds to comments related to the marking requirement for smaller lithium ion cells or batteries transported by modes other than aircraft.

III. IFR Comment Discussion

In response to the March 6, 2019, IFR, PHMSA received comments from the following organizations and individuals, which are listed in order of docket submission:

- Linda Seubert (PHMSA–2016–0014–0005 and –0006)
- Kevin McAuley (PHMSA–2016–0014–0007)
- The Rechargeable Battery Association (PRBA) (PHMSA–2016–0014–0010 and –0028)
- Anonymous (PHMSA–2016–0014–0012)
- Joel Gregier (PHMSA–2016–0014–0014 and –0015)
- Medical Device Battery Transport Council (MDBTC) (PHMSA–2016–0014–0016) [3]
- Infotrac (PHMSA–2016–0014–0017)
- Sandra Harding (PHMSA–2016–0014–0018)
- Michael Stoddard (PHMSA–2016–0014–0019)
- Anonymous (PHMSA–2016–0014–0020)
- Taylor Cu (PHMSA–2016–0014–0021)
- Justin Davis (PHMSA–2016–0014–0022)
- Logistics Supply Chain Coalition (LSCC) (PHMSA–2016–0014–0023)
- Anonymous (PHMSA–2016–0014–0024)
- United Airlines (PHMSA–2016–0014–0025)
- Council on Safe Transportation of Hazardous Articles, Inc. (COSTHA) (PHMSA–2016–0014–0026)
- Retail Industry Leaders Association (RILA) (PHMSA–2016–0014–0027)
- United Parcel Service (UPS) (PHMSA–2016–0014–0029)
- Air Line Pilots Association, International (ALPA) (PHMSA–2016–0014–0030)
- Alaska Air Carriers Association (AACA) (PHMSA–2016–0014–0031)

Below, PHMSA addresses comments to the IFR, including a brief synopsis and response. Additional comments are discussed in ''Section III. Section-by-Section Review.'' Those comments not addressed herein were considered beyond the scope of the rulemaking.

A. Harmonization With International Standards

The IFR intended to align the HMR with international air transport standards for the transportation of lithium cells and batteries, as mandated in the FAA Reauthorization Act of 2018, specifically to (1) prohibit the transport of lithium ion cells and batteries as cargo on passenger aircraft; (2) require all lithium ion cells and batteries to be shipped at not more than a 30 percent SOC on cargo-only aircraft; and (3) limit the use of alternative provisions for smaller lithium cells or batteries to one package per consignment.

Commenters were generally supportive of this rulemaking. Out of 23 comments received (one duplicate), 15 commenters expressed general support, three (3) expressed opposition based on certain provisions, and the remainder sought amendment of certain provisions to improve clarity or avoid unintended consequences. Specifically, commenters supported the rulemaking's alignment with international standards and acknowledged the potential risk that lithium ion cells and batteries pose in passenger and cargo aircraft transportation.

B. Marking Requirements for Transport Modes Other Than Aircraft

The IFR prohibited the transportation of lithium ion cells and batteries as cargo on passenger aircraft. Prior to publication of the IFR, only lithium metal cells and batteries were prohibited from transportation as cargo on passenger aircraft. For smaller lithium metal cells and batteries, the HMR required that these packages display a statement of prohibition or the cargo aircraft only (CAO) label, regardless of the mode of transportation. Because the IFR expanded the passenger aircraft transportation prohibition to include lithium ion cells and batteries, PHMSA also expanded the smaller lithium metal cell and battery marking or labeling requirement to include smaller lithium ion cells or batteries. PHMSA expected that the expansion of the hazard communication requirement would help to ensure that smaller lithium ion cells and batteries would not be accidentally transported as cargo on passenger aircraft. PHMSA notes that internationally—*i.e.,* under the 2015–2016 ICAO Technical Instructions, and later editions—lithium ion battery packages are required to be labeled with the CAO label. See ICAO Technical Instructions Packing Instruction 965.

PHMSA received several comments that opposed this requirement, particularly when the package of smaller lithium ion cells and batteries is transported by a mode other than aircraft (*e.g.,* highway, rail, and/or vessel), citing additional transport burden and costs. While PHMSA acknowledges the additional burden, if there is no indication on the package that the package is forbidden for transport aboard passenger aircraft, there is a higher likelihood that these packages will be placed on a passenger aircraft. Although packages shipped by highway, rail, and/or vessel may be part of a closed transportation system, a package of smaller lithium ion cells or batteries that is only marked with the lithium battery mark—without an indication that it is forbidden for passenger aircraft—could still find its way into the air transportation stream. For example, recent FAA data shows that there have been approximately 306 reported incidents where lithium cells and batteries forbidden aboard passenger aircraft have been transported aboard passenger aircraft. As discussed in the IFR, based on past incidents and the inherent potential danger of lithium ion battery thermal runaway events, there is a safety reason to reduce the likelihood that lithium ion batteries are placed on passenger aircraft as cargo. Therefore, PHMSA and FAA expect that the marking, which serves as a clear visual indication that the package is forbidden for transport on passenger aircraft, will help prevent air operator workers from inadvertently loading lithium ion battery packages as cargo on passenger aircraft. Because of this safety concern, PHMSA opted to maintain the requirement that packages of smaller lithium ion cells and batteries must be marked with an indication that the package is forbidden for transport aboard passenger aircraft or labeled with the CAO label. However, to communicate fully the burdens associated with this requirement, PHMSA quantified the costs attributable to the IFR in Appendix 11 of the final RIA.

PHMSA also received suggestions for potential exceptions from the forbidden for passenger air mark or CAO label requirement for packages of smaller lithium cells and batteries. For example, COSTHA, PRBA, Alaska Air Carriers Association, RILA and other commenters recommended that PHMSA provide an exception from this mark or label requirement for packages of smaller lithium ion cells and batteries transported only by highway on

[3] Since submitting comments to the IFR, the Medical Device Battery Transport Council has changed their name to the Medical Device Transport Council.

dedicated trucks (*i.e.,* a private fleet) that are not transferred between motor carriers. PHMSA acknowledges that there may be some circumstances where the potential for packages to be placed on passenger aircraft is minimized considerably, however, no exceptions are adopted. As mentioned previously, it is vital to ensure that lithium ion cells and batteries are not placed on a passenger aircraft as cargo in the interest of safe transportation. Additionally, as there are no exceptions from this marking or labeling requirement for smaller lithium metal cells and batteries, the addition of an exception for only lithium ion cells and batteries will create an inconsistency in the application of the HMR and may result in uncertainties when complying with the HMR lithium battery requirements. The availability of the special permit program allows a person to present its case via application for an exemption from the mark or label requirement in accordance with 49 CFR part 107, subpart B. This process of issuing a special permit on a case-by-case basis allows PHMSA to maintain oversight by way of specific, tailored operational and safety controls that will prevent lithium ion batteries from being transported on passenger aircraft. For example, PHMSA has issued two special permits [4] that exempt the § 173.185(c)(1)(iii) marking or labeling requirements, subject to certain operational or safety controls. The special permits were granted to Amazon.com, Inc. and Inmar Supply Chain Solutions, LLC. The operational and safety controls included modal restrictions to highway and rail. The special permits also authorized the transportation of lithium batteries to designated locations only and required markings on overpacks such as ''OVERPACK,'' special permit number, the words ''Packages must remain within this overpack during transport,'' and the words ''LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD AIRCRAFT AND VESSEL.'' These special permit operational and safety controls demonstrated equivalent levels of safety while providing relief from certain HMR requirements while also requiring package marking to ensure lithium battery packagings are not unintentionally placed as cargo on passenger aircraft.

Commenters also noted that PHMSA did not revise the sections of the HMR associated with authorization and use of international standards and regulations (*i.e.,* §§ 171.12 (North American shipments), 171.24 (additional requirements for use of the ICAO Technical instructions), and 171.25 (additional requirements for use of the International Maritime Dangerous Goods (IMDG) Code)) to mirror the changes made in § 173.185. Specifically, commenters noted that §§ 171.12 and 171.24 did not include the restriction of lithium ion cells and batteries from transportation on passenger aircraft and §§ 171.12, 171.24, and 171.25 did not include the additional marking or labeling requirement for smaller lithium ion cells and batteries, as currently specified for smaller lithium metal cells and batteries. Additionally, COSTHA, Infotrac, MDBTC, PRBA, and Ms. Sandra Harding commented that the smaller lithium ion cell and battery requirement did not align with the IMDG Code or Transport Canada's Transportation of Dangerous Goods (TDG) Regulations and requested clarification on how the mark or label requirement for smaller lithium ion cells and batteries applies to international shipments. While PHMSA acknowledges that the marking requirement differs, as previously mentioned, PHMSA expects that the requirement will increase the safe transportation of lithium batteries. Furthermore, Part 5;2.4.1.3 of the ICAO Technical Instructions allows for markings required by other international or national transport regulations in addition to marks required by the ICAO Technical Instructions, provided they are not confused with or conflict with any ICAO prescribed markings.

The absence of the conforming regulatory language for the passenger aircraft restriction and smaller lithium ion cell and battery mark or label requirement was an unintentional omission and PHMSA thanks commenters for bringing it to PHMSA's attention. Therefore, PHMSA adds language to §§ 171.12 and 171.24 to specify that lithium ion cells and batteries are forbidden from transportation as cargo on passenger aircraft. Additionally, PHMSA adds language to §§ 171.12, 171.24, and 171.25 to indicate that smaller lithium ion cells and batteries must be marked with an indication that the package is forbidden for transport aboard passenger aircraft or be labeled with a CAO label. See ''Section IV. Section-by-Section Review; Section 171.12,'' ''Section IV. Section-by-Section Review; Section 171.24,'' and ''Section IV. Section-by-Section Review; Section 171.25'' for a further discussion on these changes.

Commenters also suggested that PHMSA provide an additional text marking option for smaller lithium cells and batteries without specifically indicating the battery chemistry (*i.e.,* ''LITHIUM BATTERIES—FORBIDDEN FOR PASSENGER AIRCRAFT'') as lithium battery chemistry (*i.e.,* ion vs. metal) no longer differentiates whether the package may be offered for transportation as cargo on passenger aircraft. PHMSA agrees that this additional option provides greater flexibility, without a reduction in safety. Specifically, this also allows shippers to use preprinted packaging and avoids the need for separate markings if both smaller lithium ion and metal cells and batteries are shipped in the same package. Therefore, PHMSA adds the additional marking option of a general lithium battery indication to § 173.185(c)(3)(iii) as well as §§ 171.24(d)(1)(ii) and 171.25(b)(3).

Lastly, RILA requested clarification that when the § 173.185(c)(1)(iv) marking is applied to a shipment (*i.e.,* a package) of intermediate-sized lithium cells or batteries, the mark or label in § 173.185(c)(1)(iii) is not also required to be displayed. PHMSA did not intend for the mark or label required by § 173.185(c)(1)(iii) to also apply to packages of lithium batteries marked as specified in § 173.185(c)(1)(iv). Section 173.185(c)(1)(iv) authorizes that when transported only by highway or rail the lithium content limitation in § 173.185(c)(1)(ii) may be increased to 5 g for a lithium metal cell or 25 g for a lithium metal battery and the watt-hour (Wh) rating limitation in § 173.185(c)(1)(i) may be increased to 60 Wh for a lithium ion cell or 300 Wh for a lithium ion battery. This allowance is authorized contingent on the outer package being marked: ''LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD AIRCRAFT AND VESSEL.'' Because this outer package marking provides an indication that the lithium batteries may not be transported by aircraft or vessel, the marking in § 173.185(c)(1)(iii), which indicates that the package is forbidden for passenger aircraft, would be redundant and the CAO label option would be confusing because the authorize increase in lithium content is not allowed for aircraft transportation (both passenger and cargo). To ensure that there is no confusion, PHMSA adds an indication in § 173.185(c)(1)(iv) to specify that a shipment of lithium cells and batteries marked with the forbidden for transport aboard aircraft and vessel statement does not need to display the marking required in § 173.185(c)(1)(iii).

[4] See DOT Special Permits 16413 and 20480.

C. Compliance Date

PHMSA received five comments that PHMSA delay the compliance date [5] for the marking or labeling requirement in § 173.185(c)(1)(iii) for modes other than aircraft, including requests to issue a Statement of Enforcement Discretion. One of these comments was submitted as a direct letter to the Department of Transportation (DOT) by PRBA, MDBTC, Dangerous Goods Advisory Council (DGAC), Power Tool Institute, National Electrical Manufacturers Association, Outdoor Power Equipment Institute, and International Vessel Operators Dangerous Goods Association.[6] PHMSA issued a response to this request on April 4, 2019, in which PHMSA specified that a transition period was not provided and a Statement of Enforcement Discretion would not be issued.[7] PHMSA explained that this marking or labeling requirement is essential to ensure smaller lithium ion cells and batteries are not inadvertently transported as cargo by passenger aircraft consistent with the prohibition of the carriage of lithium metal batteries as cargo on passenger aircraft and thus, no transition period is provided (*i.e.,* no delay in compliance date).

PHMSA also received an anonymous comment that PHMSA provide a transition period for the entire rulemaking. The commenter stated that a transition period would assist with rerouting of shipments where a cargo aircraft option does not exist and allow for proper notification of potential delays to customers. While PHMSA acknowledges that the immediate compliance of the IFR may have placed some burden on scheduling and potential delays, immediate compliance ensured continued safety for air transportation as the risks posed by lithium batteries on an aircraft were promptly minimized.

D. Allowance of CAO Label for Modes Other Than Aircraft

As previously mentioned, § 173.185(c)(1)(iii) provides a variety of methods to identify that a package is forbidden for transportation by passenger aircraft, which includes use of the CAO label. PRBA, COSTHA, RILA and some anonymous commenters noted that the use of the CAO label should not be authorized when the package is not properly prepared for cargo aircraft (*i.e.,* lithium ion batteries shipped above a 30 percent SOC and not contained in or packed with equipment), as the CAO label is an indication that the package is permitted on cargo aircraft. PHMSA disagrees with the commenters' understanding. The intent of the CAO label is only to provide an indication that the package is forbidden for passenger aircraft. It does not indicate that the package is authorized or has been properly prepared for transport on cargo aircraft. Instead, the CAO label represents that the hazard of the contents of the package are too great of a risk for transportation in passenger aircraft. This is articulated by the message on the CAO label, which states ''FORBIDDEN IN PASSENGER AIRCRAFT.'' Therefore, PHMSA maintains that this label can still be used as an appropriate indication that the package of smaller lithium ion cells or batteries is forbidden for transportation aboard passenger aircraft, even if, for example, the batteries do not meet the SOC requirement for transport of lithium ion batteries aboard cargo aircraft.

E. Exception for Medical Devices

In addition to instructing DOT to harmonize lithium battery regulations with the ICAO Technical Instructions, the FAA Reauthorization Act of 2018 instructed DOT to issue limited exceptions to the restrictions on transportation of lithium ion and metal cells and batteries specifically used for a medical device.[8] PHMSA added paragraph (g) to § 173.185 to provide limited exceptions for the air transportation of medical device batteries, with the approval of the Associate Administrator. PRBA, MDBTC, and AACA all submitted comments related to the regulatory text in paragraph (g).

PRBA asserts that PHMSA's regulatory text is inconsistent with the intent of the medical device batteries mandate. Specifically, PRBA does not consider the approval requirement outlined in the IFR to be an exception to the HMR's requirements. MDBTC also asserts that the approval requirement does not constitute an exception, claiming that the legislative intent was ''to allow shipments of medical device batteries aboard passenger aircraft in urgent situations and for PHMSA to define the parameters where this exception can be used.'' AACA expresses support for MDBTC's comments, and further states that the legislative intent of the FAA Reauthorization Act of 2018 ''must include small and large quantities of lithium ion and lithium metal batteries . . . in urgent situations.'' PRBA, MDBTC, and AACA allege that PHMSA's approval process for medical device batteries under § 173.185(g) would fail to accommodate urgent situations where medical device batteries need to be shipped expeditiously, such as for patients that require urgent medical care. MDBTC and AACA also note that the timeline for the approval process—90 to 120 days—is unrealistic to meet real-world situations when batteries are urgently needed.

PHMSA does not agree with the commenters' description of the legislative intent, and notes that there is no legislative history available to support the commenters' assertions. The regulatory text under § 173.185(g) establishes a process to authorize the transport of medical device batteries consistent with the Act's limited exceptions mandate under Section 333(b)(2), and PHMSA remains confident that the approval process can accommodate urgent shipping needs.

Section 333(b)(1) of the FAA Reauthorization Act of 2018 sets forth that DOT shall consider and either grant or deny, not later than 45 days after receipt, an application submitted in compliance with part 107 of title 49, Code of Federal Regulations, for special permits or approvals for air transportation of lithium ion cells or batteries specifically used by medical devices. Section 333(b)(2) directs DOT to ''issue limited exceptions'' to the HMR ''to allow the shipment on a passenger aircraft of not more than two (2) replacement batteries specifically used for a medical device'' if certain conditions are met.

The statutory language does not specify how PHMSA should limit these exceptions, and there is no legislative history available. In the absence of direction from Congress, PHMSA responded to these mandates by authorizing, contingent on the approval of the Associate Administrator, a limited exception of up to two (2) lithium batteries used for medical devices to be transported on passenger aircraft and, as applicable, at an SOC higher than 30 percent, when the intended destination of the batteries is not serviced daily by cargo aircraft. The approval process is subject to an expedited processing period of no longer than 45 days. Under this approval process up to two replacement lithium cells or batteries specifically used for a medical device may be

[5] The IFR became effective March 6, 2019. PHMSA received comments with requests for extending the compliance date between four months (*i.e.,* July 1, 2019) and twenty-one months (*i.e.,* December 31, 2020).

[6] *https://www.regulations.gov/document?D=PHMSA-2016-0014-0010.*

[7] *https://www.regulations.gov/document?D=PHMSA-2016-0014-0032.*

[8] Public Law 115–254, 333, 132 Stat. 3186, 3274.

transported as cargo on a passenger aircraft, when approved by the Associate Administrator and provided the conditions set forth in the Section 333(b)(2) of the FAA Reauthorization Act of 2018 are met. PHMSA also adopted the definition of medical device as used in Section 333(b)(3) of the FAA Reauthorization Act of 2018.

Further, as discussed in the IFR preamble,[9] even though Section 333(b)(1) of the FAA Reauthorization Act of 2018 references lithium ion batteries and not lithium metal batteries, PHMSA understands the language to also apply to lithium metal batteries because Section 333(b)(2) applies to both lithium ion and lithium metal batteries for medical devices. Therefore, all approvals requested pursuant to § 173.185 are subject to the expedited processing period of no longer than 45 days.

PHMSA's regulatory text complies with the FAA Reauthorization Act of 2018 by: (1) adopting the Act's definition of medical device, (2) setting up an expedited approval process to allow the transport of medical devices on an urgent basis, and (3) implementing packaging requirements mandated in the Act to ensure the safe transportation of each medical device battery that is transported at a SOC greater than 30 percent. Limiting the exception via an approval requirement allows PHMSA to maintain oversight of these lithium battery shipments and address the risks they pose in air transportation, with the aim of ensuring the aircraft's cargo and the aircraft's passengers arrive safely at their destination. To date, PHMSA has received only two approval applications neither of which sought exception from the SOC requirements. These requests were denied due to not making the case for how the requested transport would mitigate risks posed by a lithium battery heat, smoke, or fire event on a passenger aircraft. Based on this experience with approval applications, PHMSA maintains its position that approval oversight is needed.

Additionally, AACA and MDBTC assert that PHMSA's approval process needs to be clarified, including whether each shipment of medical device batteries would require approval. PHMSA understands this viewpoint and provides clarity as follows. When an applicant applies for any PHMSA approval—including this type of medical device batteries approval—they may choose to request an approval for a one-time shipment or for recurring shipments, on either a periodic or as needed basis. *See* 49 CFR 107.705(b)(2). Specific to recurring shipments, PHMSA expects that issuing this type of approval will accommodate emergency circumstances because a person who wishes to offer or transport lithium batteries for medical devices will have prior approval before the emergency need occurs.

MDBTC also commented that the expedited approval process should be codified in part 107. PHMSA agrees that the unique procedures for lithium cells and batteries for medical devices in § 173.185(g) should be included in part 107. PHMSA revises §§ 107.709(b) and (f) to reflect the expedited application process found in the FAA Reauthorization Act of 2018. See ''Section IV. Section-by-Section Review; Section 107.709'' for further detail on the specific revisions to these paragraphs.

Additionally, PHMSA requested comment on certain criteria for this provision, including potential impacts these criteria may have on stakeholders. The following details the criteria, along with a discussion of the comments PHMSA received.

• *Definition of ''not more than two replacement lithium cells or batteries.* PHMSA requested comment on whether the limitation that ''not more than two replacement lithium cells or batteries'' applies to the number of cells or batteries per package. MDBTC agreed the intent of Section 333(b)(2) of the 2018 FAA Reauthorization Act provision is two cells or batteries per package (and not per shipment or consignment). As this provision minimizes the number of batteries in each package, which reduces the potential for a thermal runaway event in transportation and thus increases safety, PHMSA maintains § 173.185(g) as written such that not more than two (2) lithium cells or batteries are allowed per package.

• *Determination of destination no longer ''serviced daily by cargo aircraft'':* PHMSA requested comment on what should be considered to determine when a destination is no longer ''serviced daily by a cargo aircraft.'' MDBTC, supported by the AACA, commented that it was not necessary for PHMSA to specify a specific distance to define when a location is no longer serviced daily by cargo aircraft. Furthermore, MDBTC commented that availability of the exception should be based on the need for urgent patient care when other means of transport are unavailable or inappropriate. AACA also stated that the distance should not be a condition of the exception. PHMSA agrees with MDBTC and AACA that ''serviced daily by a cargo aircraft'' should not be tied to a specified distance, as this will provide greater flexibility for handling unique transport circumstances. It is necessary for the person who wishes to transport the lithium cell or battery for medical devices to demonstrate that the location is not serviced daily by cargo aircraft in their application, as this is a condition for the exception that is articulated in § 173.185(g). PHMSA is also making a conforming revision to add § 107.705(b)(6) to specify that this information must be provided in the approval application.

• *Definition of batteries ''required for medically necessary care'':* PHMSA stated that batteries ''required for medically necessary care'' are batteries that are needed for a medical device that is used by the recipient for medical care and requested comment on stakeholder impact. MDBTC commented that the definition of ''required for medically necessary care'' is appropriate. PHMSA received no further comment on this subject. Therefore, PHMSA maintains that batteries required for medically necessary care in § 173.185(g) means the batteries are needed for a medical device that is used by the recipient for medical care.

MDBTC and PRBA both commented that PHMSA should harmonize the HMR with Special Provision A334 found in the Supplement to ICAO Technical Instructions for all lithium batteries. MDBTC further stated that this provision would expand the allowance to ship lithium batteries for emergency needs to remote areas in circumstances outside of medical device transportation. AACA was supportive of MDBTC's comments and further commented that allowances should be made for small quantities of lithium ion cells and batteries to be shipped to remote locations. Special Provision A334 provides guidance to competent authorities on exceptions for lithium cells or batteries to be transported on passenger aircraft when other forms of transport—including cargo aircraft—are impracticable. This special provision identifies specific quantity limits and performance test criteria that can be used to acquire the approval of the State of Origin, the State of the Operator, and the State of Destination. It is unnecessary to adopt this specific language as PHMSA already provides a general approval mechanism for lithium batteries that do not conform to the provisions of the HMR (*see* § 173.185(h)). Finally, as previously mentioned, the FAA Reauthorization Act of 2018 required PHMSA to harmonize the HMR with emergency

[9] 84 FR 8006 at 8019 (Mar. 6, 2019).

amendments to the 2015–2016 edition of the ICAO TI. Special Provision A334 was not part of these emergency amendments to the 2015–16 edition but rather part of the Supplement to the ICAO TI that provides non-binding guidance to competent authorities (*e.g.,* State of Origin) on approval requirements. Therefore, PHMSA is choosing to use the non-binding guidance offered in Special Provision A334 as part of the approval process already in place in § 173.185(h) and not specifically codify the Special provision A334 non-binding guidance into the HMR.

F. Fire Resistant Containers and Fire Containment Covers Effectiveness

UPS commented that the IFR preamble language ineffectively portrayed the effectiveness of Fire Resistant Containers (FRCs) and Fire Containment Covers (FCCs). Specifically, UPS stated that the FRC tests used preliminary container configurations and containers altered from the specification, and while important steps, the tests were not a final assessment. Furthermore, UPS commented that they have quantifiable data that demonstrates FRC and FCC effectiveness as shipping devices for lithium ion batteries, especially when it is combined with a multi-layered approach to safety measures.

PHMSA appreciates this feedback from UPS and agrees that testing is continuously ongoing, and the current state of results is not intended to be an indication of the final assessment in ensuring the safe transportation of lithium ion batteries by aircraft. PHMSA looks forward to continuing to work with UPS and any other industry partners to better enhance safety through measures such as performance packaging while ensuring continued efficient operations in lithium battery transportation and appreciates any data that can be shared that will help inform decision-making.

G. Miscellaneous Comments

PHMSA received several additional comments on various subjects, which are discussed as follows.

Mr. Kevin McAuley requested clarification on whether the provisions of the IFR prohibited lithium batteries from being transported as cargo on passenger and cargo aircraft or whether the prohibition only applied to lithium ion batteries transported above a 30 percent SOC on cargo aircraft. The IFR and this final rule prohibit lithium ion cells and batteries from being offered *as cargo* on passenger aircraft (emphasis added). Further, regarding carriage on cargo aircraft, consistent with international standards, this rulemaking prohibits lithium ion cells and batteries from being offered as cargo on cargo aircraft above a 30 percent SOC. Finally, when smaller lithium cells and batteries (both ion and metal) are offered as cargo on cargo-only aircraft, they are limited to one package per consignment as provided in § 173.185(c)(4)(iii).

AACA supported an automatic approval system, particularly for Alaska and other states where the population is less than 25 people per square mile, noting that other agencies have provided special exemptions based on that population density. PHMSA is not implementing an automatic approval in response to this comment, which is not mandated under § 333(b) of the FAA Reauthorization Act of 2018. However, while PHMSA has worked to streamline the approval process over the years, such as approval submissions being accepted via an online portal, PHMSA continues to look for new ways to improve this process. PHMSA looks forward to working with AACA and other stakeholders in the future to continue to identify new and improved avenues to expedite the approval process.

AACA also commented on the need for additional allowances for shipments of larger quantities of lithium ion and metal batteries by aircraft, particularly to remote areas. PHMSA understands that there may be additional unique transport circumstances beyond the scope of § 173.185(g). While scenarios outside of § 173.185(g) are not identified, PHMSA can facilitate shipments of lithium batteries through the issuance of an approval under § 173.185(h) or a special permit and urges those persons offering these large shipments to apply.

An anonymous commenter requested that PHMSA add new paragraph § 173.185(a)(4), which would contain the SOC limitation (specifically, the commenter suggested: ''For [transport] by air only, lithium ion cells or batteries, [except] when they are contained in equipment, shall not exceed [SOC] 30%.''). PHMSA added Special Provision A100 to the list of special provisions in § 172.102 and assigned it to the entry for ''UN3480, Lithium ion batteries'' in Column (7) in the § 172.101 Hazardous Materials Table (HMT). This special provision specifies that lithium ion cells and batteries must be offered for transportation at a SOC that does not exceed 30 percent of their rated capacity. Adding the SOC limitation to § 173.185(a) is not necessary and would create confusion because § 173.185(a)(1) details the classification requirements for all lithium cells or batteries, regardless of the United Nations (UN) Identification number, mode of transportation, or if shipped separately or contained in or packed with equipment. Furthermore, placement of the requirement in the HMR as a special provision is consistent with its applicability only to the air mode.

IV. Section-by-Section Review

The following is a section-by-section review of the amendments adopted in this final rule:

Part 107

Section 107.705

Section 107.705 details the requirements for an approval application. PHMSA adds paragraph (b)(6) to specify that an applicant applying for an approval for lithium cells and batteries for medical devices, as authorized in § 173.185(g), must include details on the extent to which the destination(s) of the lithium cells and batteries are not serviced daily by cargo aircraft. See ''Section II.E IFR Comment Discussion; Exception for Medical Devices'' for additional discussion on this revision. In addition, PHMSA revises paragraphs (b)(4) and (5)(ii) editorially to account for the new paragraph.

Section 107.709

This section includes the processing requirements for approvals. Paragraph (b) specifies PHMSA's process for reviewing approval applications, including the time frame for requesting additional information. Paragraph (f) specifies that PHMSA will notify the approval applicant in writing of the decision on the application. PHMSA revises paragraphs (b) and (f) to detail the expedited review process for § 173.185(g) shipments of lithium cells and batteries specifically used for medical devices. PHMSA revises paragraph (b) to specify that there will be an expedited review. PHMSA also revises paragraph (f) to specify that for approvals of lithium cells and batteries for medical devices, as outlined in § 173.185(g), the approvals will be either granted or denied no later than 45 days after receipt of a completed application. See ''Section II.E IFR Comment Discussion; Exception for Medical Devices'' for additional discussion on this revision.

Part 171

Section 171.12

This section details the requirements for the transportation of hazardous

materials throughout North America. Specifically, paragraph (a) provides allowances for the shipment of hazardous materials in accordance with the Transport Canada TDG Regulations. Paragraph (a)(6) details additional requirements when lithium metal cells and batteries are transported in accordance with the TDG regulations. COSTHA and PRBA both commented that PHMSA did not revise § 171.12(a)(6) to reflect the newly adopted provisions that lithium ion cells and batteries were forbidden for transportation aboard passenger aircraft. PHMSA agrees with the commenters as this was an unintentional omission. Therefore, PHMSA amends § 171.12(a)(6) to add an indication that lithium ion cells and batteries (UN3480) are prohibited for transport as cargo aboard passenger aircraft.

Additionally, PHMSA revises paragraph (a)(6) to add a reference to § 173.185(c)(1)(vi). As discussed in ''Section III. Section-by-Section Review; Section 173.185,'' PHMSA revises § 173.185(c)(1)(vi) to add a requirement that when a package is marked or labeled in accordance with §§ 173.185(c)(1)(iii) or (iv) and is placed in an overpack, the selected marking or label must either be clearly visible through the overpack, or the marking or label must also be affixed on the outside of the overpack. This requirement addresses a hazard communication safety gap and ensures that the overpack includes the same hazard information as displayed on the package. Therefore, to ensure this requirement also applies to shipments transported in accordance with the TDG regulations, PHMSA adds a cross reference to § 173.185(c)(1)(vi).

Section 171.24

This section provides additional requirements for the use of the ICAO Technical Instructions. COSTHA, MDBTC, and PRBA noted that PHMSA did not revise § 171.24(d)(1)(ii) to reflect the IFR provisions, specifically the prohibition of lithium ion cells and batteries from being transported aboard passenger aircraft and the requirement in § 173.185(c)(1)(iii) to mark the outside of a package containing smaller lithium ion cells and batteries (*i.e.,* Packaging Instruction 965, Section II) with a mark or label that indicates the package is forbidden for transport aboard passenger aircraft. This was an unintentional omission. PHMSA agrees with the commenters and makes the conforming amendment in § 171.24(d)(1)(ii) to reflect the prohibition and hazard communication requirement.

PHMSA also received comments that PHMSA add an alternative forbidden for passenger aircraft marking in § 173.185(c)(1)(iii) (*i.e.,* ''LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT''). Since PHMSA allows this alternative in § 173.185(c)(1)(iii), for consistency, PHMSA adds this marking alternative in § 171.24(d)(1)(ii) to allow packages containing smaller lithium cells and batteries of both chemistries to be appropriately marked. See ''Section II.B IFR Comment Discussion; Marking Requirements for Transport Modes Other than Aircraft'' for further discussion.

Lastly, PHMSA revises paragraph (d)(1)(ii) to specify that when a package that is marked or labeled with an indication that the package is forbidden for transport aboard passenger aircraft and is placed in an overpack, the selected mark or label must either be clearly visible through the overpack, or the marking or label must be affixed on the outside of the overpack. As discussed in ''Section III. Section-by-Section Review; Section 173.185,'' PHMSA revises § 173.185(c)(1)(vi) to add this requirement to address a hazard communication safety gap and ensure that the overpack also communicates that it is forbidden for transport on passenger aircraft. Therefore, to ensure this requirement also applies to shipments transported in accordance with the ICAO Technical Instructions, PHMSA adds the same requirement to § 171.24.

Section 171.25

This section provides additional requirements for use of the IMDG Code. COSTHA, MDBTC, PRBA, Infotrac, and Ms. Sandra Harding commented that PHMSA did not revise § 171.25(b)(3) to reflect the IFR provisions in § 173.185(c)(1)(iii) to require a mark or label that indicates a package of smaller lithium ion cells or batteries transported in accordance with Special Provision 188 is forbidden for transportation on passenger aircraft. This was an unintentional omission. PHMSA agrees with the commenters and is making the conforming amendment in § 171.25(b)(3) to reflect the prohibition and hazard communication requirement.

PHMSA also received comments that requested PHMSA add an alternative forbidden for passenger aircraft marking in § 173.185(c)(1)(iii) (*i.e.,* ''LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT''). Since PHMSA allows this alternative in § 173.185(c)(1)(iii), for consistency, PHMSA adds this marking alternative in § 171.25(b)(3) to allow packages containing smaller lithium cells and batteries of both chemistries to be appropriately marked. See ''Section II.B IFR Comment Discussion; Marking Requirements for Transport Modes Other than Aircraft'' for further discussion.

Lastly, PHMSA revises paragraph (b)(3) to specify that when a package that is marked or labeled with an indication that the package is forbidden for transport aboard passenger aircraft and is placed in an overpack, the selected mark or label must either be clearly visible through the overpack, or the marking or label must be affixed on the outside of the overpack. As discussed in ''Section III. Section-by-Section Review; Section 173.185,'' PHMSA revises § 173.185(c)(1)(vi) to add this requirement to address a hazard communication safety gap and ensure that the overpack also communicates that it is forbidden for transport on passenger aircraft. Therefore, to ensure this requirement also applies to shipments transported in accordance with the IMDG Code, PHMSA adds the same requirement to § 171.25.

Part 172

Section 172.101

This section outlines the HMT and instructions for its use. PHMSA received no comments to the amendments. The IFR amendments met the requirements of Section 333 of the FAA Reauthorization Act of 2018, harmonize with international standards, and ensure the safe transportation of lithium batteries. Accordingly, no changes are being made to § 172.101.

Section 172.102

This section lists special provisions applicable to specific hazardous materials, as listed in Column (7) of the § 172.101 HMT. PHMSA received no comments to the amendments. The IFR amendments met the requirements of Section 333 of the FAA Reauthorization Act of 2018, harmonize with international standards, and ensure the safe transportation of lithium batteries.

PHMSA added a new special provision A100, assigning it to ''UN3480, Lithium ion batteries, *including lithium ion polymer batteries,* 9.'' This new special provision, consistent with the ICAO Technical Instructions, requires that when lithium ion cells and batteries are offered for transportation by cargo aircraft, they may not be shipped at a SOC that exceeds 30 percent of their rated capacity. Lithium ion cells and batteries

may be offered for transportation at a SOC greater than 30 percent only with the approval of the Associate Administrator. This special provision does not apply to those lithium ion cells and batteries packed with or contained in equipment.

PHMSA received an anonymous comment that requested PHMSA add the SOC limitation (currently specified in special provision A100) in a new paragraph § 173.185(a)(4). It is unclear whether the commenter requested the removal of special provision A100 or the addition of a statement of the SOC limitation in § 173.185(a)(4). As discussed in ''Section II.G IFR Comment Discussion; Miscellaneous Comments,'' PHMSA disagrees with the commenter that it would provide further clarification to a shipper. Furthermore, special provision A100 aligns with ICAO Technical Instructions and ensures the safe transportation of lithium ion batteries on cargo aircraft (see ''Section V.B. State of Charge Requirement'' of the IFR for a more detailed discussion of the positive impacts to transportation at a reduced state of charge). As such, PHMSA maintains special provision A100 as written.

Part 173

Section 173.185

This section prescribes the packaging requirements for the transportation of lithium batteries. PHMSA adopted a new definition for ''medical device'' in the introductory paragraph, as defined in the FAA Reauthorization Act of 2018. As previously detailed, PHMSA adopted the definition of a medical device from section 333(b)(3) of the FAA Reauthorization Act of 2018 to mean ''an instrument, apparatus, implement, machine, contrivance, implant, or in vitro reagent, including any component, part, or accessory thereof, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, of a person.'' PHMSA did not receive any comments related to this definition. PHMSA maintains that this definition provides regulatory clarity in the applicability of § 173.185(g), which aids in increased regulatory compliance and thus, safety. In addition, PHMSA maintains the definition as defined in the FAA Reauthorization Act of 2018, and no changes are being made to the ''medical device'' definition.

Section 173.185(a) details classification criteria for lithium cells and batteries, including the requirements for testing lithium batteries and documenting those test requirements. As previously discussed, an anonymous commenter suggested that PHMSA add a new paragraph (a)(4) to detail SOC limitation requirements. PHMSA disagrees that this new paragraph would add clarity, as the SOC limitation only applies to lithium ion cells and batteries transported by cargo aircraft (*i.e.,* UN3480 assigned to special provision A100) and paragraph (a) applies to the transportation of all lithium cells and batteries, including those packed with and contained in equipment, by all modes. Therefore, no new paragraph is added to specify the lithium ion cell and battery SOC limitation. See ''Section III. IFR Comment Discussion; Miscellaneous Amendments'' for a further additional discussion on this comment.

Paragraph (c) specifies exceptions for smaller lithium cells and batteries. Paragraph (c)(1)(iii) details requirements for marking of packages with an indication that they are forbidden for transport aboard passenger aircraft or labeling of packages with the CAO label. Prior to the IFR, this paragraph only applied to smaller lithium metal cells and batteries, except when lithium metal cells or batteries are packed with or contained in equipment in quantities not exceeding 5 kg net weight. To align with the provision restricting lithium ion cells and batteries from being transported on passenger aircraft, PHMSA revised § 173.185(c)(1)(iii) to include smaller lithium ion cells and batteries in the requirement. PHMSA received several comments that requested PHMSA revise the hazard communication requirement to apply only to shipments of smaller lithium ion cells and batteries intended for transportation via aircraft, all or in part. Alternatively, commenters requested that PHMSA provide for a delayed compliance date (*i.e.,* a transition period) for shipments of smaller lithium ion cells and batteries offered by modes other than aircraft as well as exercise enforcement discretion. Although PHMSA acknowledges this requirement is burdensome on persons who offer smaller lithium ion cells and batteries by modes other than aircraft, PHMSA determined that this hazard communication requirement across all modes ensures that smaller lithium ion cells and batteries are not accidently or unintentionally offered for transportation as cargo on passenger aircraft. As previously mentioned in the IFR, the potential for an uncontrolled fire involving a relatively small quantity of lithium batteries to lead to a catastrophic failure of the airframe, the inability of the package or the aircraft fire suppression system to control such a fire presents an unacceptable safety risk. This ultimately increases safe transportation as it reduces the potential for incidents involving lithium ion cells and batteries to occur aboard passenger aircraft. See ''Section III.B IFR Comment Discussion; Marking Requirements for Transport Modes Other than Aircraft'' and ''Section III.C IFR Comment Discussion; Compliance Date'' for a more detailed discussion on both issues.

PHMSA also received comments from PRBA, Infotrac, MDBTC, COSTHA, RILA, and an anonymous commenter asking that PHMSA add an alternative text marking in § 173.185(c)(1)(iii). This alternative (*i.e.,* ''LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT'') does not specify lithium battery chemistry. Because both lithium ion and lithium metal cells and batteries are now forbidden from transportation as cargo on passenger aircraft, it is not necessary to distinguish the battery chemistry as part of the marking requirement. This also provides greater flexibility with marking options for packages containing batteries of both chemistries without reducing safety. PHMSA agrees with the commenters and amends § 173.185(c)(1)(iii) to include the alternative marking.

Paragraph (c)(1)(iv) authorizes increased size limits for the paragraph (c) exceptions when the package is offered for highway or rail only and the outer package is marked with ''LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD AIRCRAFT AND VESSEL.'' As previously discussed, RILA commented about the potential confusion in whether the § 173.185(c)(1)(iii) mark was also required when a package bears this § 173.185(c)(1)(iv) mark. As the paragraph (c)(1)(iv) mark is more conservative than the paragraph (c)(1)(iii) mark or label, PHMSA adds language in § 173.185(c)(1)(iv) to clarify that the § 173.185(c)(1)(iii) mark is not required. See ''Section II. Comment Discussion; Marking Requirements for Modes other than Aircraft'' for additional discussion on this change.

In final rule HM–215O,[10] PHMSA added a new paragraph (c)(3)(iii) to specify overpack requirements for a package displaying a lithium battery mark. Specifically, when those packages are placed in an overpack and the lithium battery mark is not visible, the mark must be reproduced on the overpack and be marked with the word ''OVERPACK'' at least 12 mm (0.47

[10] 85 FR 27810 (May 11, 2020).

inches) high. In development of this final rule, PHMSA noted that the HM–215O overpack requirement did not include all hazard communication that could potentially be displayed on a package of smaller lithium cells or batteries. Specifically, this requirement does not include requiring the hazard communication in paragraphs (c)(1)(iii) and (iv) (*i.e.,* the CAO label, the paragraph (c)(1)(iii) mark, and the paragraph (c)(1)(iv) mark) to be visible or reproduced on an overpack. As previously discussed, there is a safety need to require the paragraph (c)(1)(iii) hazard communication on all packages of smaller lithium cells and batteries, even if they are not being offered for transportation by air. This need also applies to the paragraph (c)(1)(iv) mark. The requirement to reproduce the hazard communication on the overpack is consistent with the general overpack requirements in § 173.25 specify that when a package is placed in an overpack, the proper shipping name, identification number, and labels on the package must be displayed on the overpack, unless they are otherwise visible. The overpack requirement ensures that the hazard communication that needs to be displayed on packages is not lost when consolidated or further packed in an overpack. Although not originally included, PHMSA determines that when a package bears the paragraph (c)(1)(iii) and (iv) required mark or label, and the package is placed in an overpack, those marks and labels should be visible or must be reproduced on the outside of the overpack. This is consistent with the requirements to reproduce the required markings and CAO label in § 173.185(c)(4)(ii). To address this safety gap, PHMSA redesignates current paragraph (c)(1)(vi) to paragraph (c)(1)(vii) and adds a new paragraph (c)(1)(vi) to specify the overpack requirements. PHMSA expects that this new requirement will reduce the potential for packages of smaller lithium cells or batteries that have been overpacked to be placed on a passenger aircraft and thereby increasing safety of transportation.

Section 173.185(c)(4)(i) details the quantity limitations for smaller lithium cells and batteries offered by air transportation. PHMSA received comments from COSTHA and an anonymous commenter that § 173.185(c)(4)(i) could be misinterpreted to also require that the limitations in the paragraph apply to lithium batteries packed with or contained in equipment. The commenters suggested PHMSA add ''except when packaged with or contained in equipment'' to the text of § 173.185(c)(4)(i). PHMSA agrees with the commenters that this provides greater clarity and harmonizes with the ICAO Technical Instructions. Therefore, PHMSA amends § 173.185(c)(4)(i) to reflect that these conditions and limitations do not apply to batteries packed with or contained in equipment.

An anonymous commenter also recommended that PHMSA add a sentence to the end of paragraph (c)(4)(i) to indicate which paragraphs lithium cells and batteries packed with or contained in equipment are subject to. PHMSA disagrees with this suggestion and expects that such addition would cause additional confusion as paragraph (c)(4)(i) does not apply to smaller lithium cells and batteries packed with or contained in equipment.

Section 173.185(c)(4)(ii) details requirements for transportation of smaller lithium cells and batteries in overpacks. The IFR amended § 173.185(c)(4)(ii) to indicate that only one package of smaller lithium cells and batteries may be placed in an overpack, consistent with ICAO Technical Instructions. PRBA, COSTHA, and MDBTC commented that the reference to only paragraph (c)(4) makes § 173.185(c)(4)(ii) inconsistent with the ICAO Technical Instructions, as lithium cells and batteries packed with or contained in equipment are not limited to one package per overpack. The commenters suggested PHMSA amend the section to instead reference paragraph (c)(4)(i) to distinguish that the requirement only applies to smaller lithium cells and batteries. PHMSA agrees, this was an error. Therefore, PHMSA revises the reference to indicate the requirement only applies to those packages prepared in accordance with § 173.185(c)(4)(i). Furthermore, an anonymous commenter suggested PHMSA delete the requirement completely from the paragraph. The commenter did not specify the reason for removing this requirement. As this provision increases the safe transportation of lithium batteries by air and meets the intent of this rulemaking to align the HMR with ICAO Technical Instructions, PHMSA will not remove the requirement in paragraph (c)(4)(i).

PHMSA expanded the overpack marking requirement in § 173.185(c)(4)(ii) to require that when a package displays the paragraph (c)(1)(iii) required mark or label and is placed in an overpack, the mark or label must be reproduced if not visible through the overpack. However, as previously discussed, in § 173.185(c)(1)(vi), PHMSA adds a requirement that when a package displays the paragraph (c)(1)(iii) required mark or label (as well as the paragraph (c)(1)(iv) mark) and is placed in an overpack, the mark or label must be visible or reproduced on overpack. This applies to all modes of transportation and not just air. Additionally, in the HM–215O final rule, PHMSA added § 173.185(c)(3)(iii) to require that for all modes of transportation, when a package displays the lithium battery mark and is placed in an overpack, the mark must be visible or reproduced on the overpack along with the word ''OVERPACK.'' As both of these requirements apply to all modes of transportation, including air, the second and third sentence of paragraph (c)(4)(ii) are now duplicative. Therefore, PHMSA removes the duplicative requirement in the second and third sentence of paragraph (c)(4)(ii) to eliminate any potential regulatory confusion and increase regulatory compliance.

PHMSA added § 173.185(c)(4)(iii) to specify that a shipper is not permitted to offer more than one package of smaller lithium cells and batteries in any single consignment by aircraft. PHMSA maintains that this requirement aligns the HMR with the ICAO Technical Instructions and increases safety. However, PRBA, COSTHA, MDBTC, and an anonymous commenter noted that the amendments may have unintentionally subjected smaller lithium cells and batteries contained in or packed with equipment to this requirement. PHMSA did not intend the limitation to apply to smaller lithium cells and batteries contained in or packed with equipment, and therefore amends § 173.185(c)(4)(iii) to state that the limitation of one package in any single consignment is only for those packages prepared in accordance with the provisions of paragraph (c)(4)(i).

PHMSA added paragraph (c)(4)(v) to indicate that packages and overpacks of smaller lithium cells and batteries must be offered separately from cargo not subject to the HMR and must not be loaded into a unit load device before being offered to the operator. This paragraph harmonizes with ICAO Technical Instructions and increases safety. PHMSA received comments from PRBA, COSTHA, MDBTC, and an anonymous commenter to revise the reference from ''prepared in accordance with paragraph (c)(4)'' to ''prepared in accordance with paragraph (c)(4)(i)'' to ensure that this requirement does not apply to smaller lithium cells and batteries packed with or contained in equipment. PHMSA agrees and did not intend to require that smaller lithium cells and batteries packed with or

contained in equipment be subject to this requirement. Therefore, PHMSA revises the reference to read as paragraph (c)(4)(i).

To account for redesignated paragraph (c)(1)(iv) and new paragraph (c)(1)(v), PHMSA redesignated paragraph (c)(4)(iv) to paragraph (c)(4)(vi). This paragraph details quantity limitations for smaller lithium cells and batteries packed with or contained in equipment. MDBTC commented that PHMSA should revise this paragraph to specify ''spare sets'' instead of ''spares'' to harmonize more accurately with the ICAO Technical Instructions. PHMSA agrees and this revision was already made in the HM–215O final rule. Therefore, no revisions to this paragraph are needed.

To account for new paragraph (c)(4)(v) and redesignated paragraph (c)(4)(vi), PHMSA redesignated paragraph (c)(4)(v) as paragraph (c)(4)(vii). PHMSA received no comments to this paragraph and there are no revisions to this paragraph.

Following publication of the IFR, PHMSA added paragraph (c)(4)(viii) in the HM–215O final rule to specify that for air transport, smaller lithium cells and batteries may not be placed in the same package as other hazardous materials. Furthermore, packages that contain smaller lithium cells and batteries must not be placed into an overpack with packages that contain materials of Class 1 (explosives) other than Division 1.4S, Division 2.1 (flammable gases), Class 3 (flammable liquids), Division 4.1 (flammable solids) or Division 5.1 (oxidizers). Upon review, PHMSA identified that paragraph (c)(4)(viii) inadvertently referenced packages prepared in accordance with paragraph (c)(4) and not paragraph (c)(4)(i). PHMSA intended that this requirement apply only to packagings of smaller lithium cells and batteries shipped by air, and not those packed with or contained in equipment. Therefore, in § 173.185(c)(4)(viii), PHMSA revises the reference of paragraph (c)(4) to paragraph (c)(4)(i) as a correcting and editorial amendment.

PHMSA added paragraph (c)(5), using text from former paragraph (c)(4)(vi). This paragraph provides minimal exceptions when the number or quantity (mass) limits in the paragraph (c)(4)(i) table, the overpack limit described in paragraph (c)(4)(ii), or the consignment limit in paragraph (c)(4)(iii) is exceeded, but the lithium cells and batteries are still below the size limitations in paragraph (c)(3). PHMSA received an anonymous comment requesting that PHMSA remove the applicability of paragraph (c)(5) to packages that exceed the overpack limit described in paragraph (c)(4)(ii). The commenter did not provide further details to their request for this revision.

If removed, PHMSA would no longer authorize an alternative to limited exceptions when the limitation of one package of lithium cells or batteries per overpack is exceeded. In addition, this would make the regulatory provision inconsistent with the ICAO Technical Instructions, which would decrease consistency and thus, decrease compliance. Therefore, PHMSA does not remove this exception.

Lastly, PHMSA added a new paragraph (g) in the IFR to meet the mandate in the FAA Reauthorization Act of 2018. This new paragraph authorizes, with the approval of the Associate Administrator, an exception for up to two lithium batteries used for medical devices to be transported on passenger aircraft and, as applicable, at a SOC greater than 30 percent, when the intended destination of the batteries is not serviced daily by cargo aircraft. PHMSA received comments from PRBA, MDBTC, and AACA on this new paragraph. As discussed in ''Section II.E Comment Discussion; Exception for Medical Devices,'' no revisions to this paragraph are made.

V. Regulatory Analysis and Notices

A. Statutory/Legal Authority

This final rule is published under the authority of the Federal Hazardous Materials Transportation Act (HMTA; 49 U.S.C. 5101–5127). Section 5103(b) of the HMTA authorizes the Secretary of Transportation to ''prescribe regulations for the safe transportation, including security, of hazardous material in intrastate, interstate, and foreign commerce.'' The Secretary has delegated the authority granted in the HMTA to the PHMSA Administrator at 49 CFR 1.97(b). Lithium cells and batteries are designated as hazardous materials under 49 U.S.C. 5103(a).[11] This final rule revises regulations for the safe transport of lithium cells and batteries by air and the protection of aircraft operators and the flying public.

B. Executive Order 12866 and DOT Regulatory Policies and Procedures

Executive Order 12866 (''Regulatory Planning and Review'')[12] recommends that agencies assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Agencies should consider quantifiable measures and qualitative measure of costs and benefits that are difficult to quantify. Further, Executive Order 12866 recommends that agencies maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach. Similarly DOT Order 2100.6A (''Rulemaking and Guidance Procedures'') requires that regulations issued by PHMSA and other DOT Operating Administrations should consider an assessment of the potential benefits, costs, and other important impacts of the regulatoryaction and should quantify (to the extent practicable) the benefits, costs, and any significant distributional impacts, including any environmental impacts.

Executive Order 12866 and DOT Order 2100.6A require that PHMSA submit ''significant regulatory actions'' to the Office of Management and Budget (OMB) for review. This rulemaking is not considered a significant regulatory action under section 3(f)(1) under Executive Order 12866 and, therefore, was not formally reviewed by OMB. Furthermore, the final rule is not considered an economically significant regulatory action under Section 3(f)(1). The final rule is not estimated to have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities. Lastly, this rulemaking is also not considered a significant rule under DOT Order 2100.6A.

In promulgating this final rule, PHMSA maintains the safety provisions adopted in the IFR, while revising further the lithium battery transport regulations to ensure prohibited lithium battery packages are not transported as cargo on passenger aircraft and ensure better understanding of the requirements to achieve compliance with these provisions. In the absence of this rulemaking, potential benefits may not be gained, including increased air transportation safety and transportation efficiency. These benefits are described qualitatively in the final RIA, which is posted in the rulemaking docket. The costs of this final rule, which are estimated relative to a baseline of IFR regulatory compliance, are qualitatively and quantitatively described in the final RIA. These main costs are attributed to the cost of reproducing the §§ 173.185(c)(i)(iii) or (iv) mark or label

[11] Hazardous materials table entries added for lithium batteries in a December 21, 1990 final rule [55 FR 52402].

[12] 58 FR 51735 (Oct. 4, 1993).

on the outside of an overpack, when a package bearing such mark or label is placed in an overpack and the appropriate mark or label is not visible. Based on the analysis described in this final RIA, at the mean, PHMSA estimates the present value costs of the final rule are estimated at $0.2 million annualized (at a 7 percent discount rate).

C. Executive Order 13132

PHMSA analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism'') [13] and its implementing Presidential Memorandum (''Preemption'').[14] Executive Order 13132 requires agencies to assure meaningful and timely input by state and local officials in development of regulatory policies that may 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.''

This rulemaking may preempt state, local, and Native American Tribe requirements, but does not amend any regulation that has substantial direct effects on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government.

The Federal hazmat law contains an express preemption provision at 49 U.S.C. 5125(b) that preempts state, local, and tribal requirements on certain covered subjects, unless the non-federal requirements are ''substantively the same'' as the federal requirements, including the following:

(1) the designation, description, and classification of hazardous material;

(2) the packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(3) the preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(4) the written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) the design, manufacture, fabrication, inspection, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

This rule addresses subject items (2) and (5) above, which are covered subjects, and therefore, non-federal requirements that fail to meet the ''substantively the same'' standard are vulnerable to preemption under the Federal hazmat law. Moreover, PHMSA will continue to make preemption determinations applicable to specific non-federal requirements on a case-by-case basis, using the obstacle, dual compliance, and covered subjects tests provided in Federal hazmat law.

Therefore, the consultation and funding requirements of Executive Order 13132 do not apply. Consistent with 49 U.S.C. 5125, this final rule will preempt any State, local, or tribal requirements concerning the subjects identified in 49 U.S.C. 5125(b)(1) unless the non-Federal requirements are ''substantively the same'' as the Federal requirements. In addition, this final rule does not have sufficient federalism impacts to warrant the preparation of a federalism assessment.

D. Executive Order 13175

PHMSA analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments'') [15] and DOT Order 5301.1 (''Department of Transportation Policies, Programs, and Procedures Affecting American Indians, Alaska Natives, and Tribes''). Executive Order 13175 and DOT Order 5301.1 require DOT Operating Administrations to assure meaningful and timely input from Native American Tribal government representatives in the development of rules that significantly or uniquely affect tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship and distribution of power between the federal government and Native American Tribes. Because this rulemaking does not significantly or uniquely affect the communities of Tribal governments and does not impose substantial direct compliance costs, the funding and consultation requirements of Executive Order 13175 and DOT Order 5301.1 do not apply.

E. Regulatory Flexibility Act and Executive Order 13272

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires agencies to consider whether a rulemaking would have a ''significant economic impact on a substantial number of small entities'' to include small business, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations under 50,000. The Regulatory Flexibility Act directs agencies to establish exceptions and differing compliance standards for small businesses, where possible to do so and still meet the objectives of applicable regulatory statutes. Executive Order 13272 (''Proper Consideration of Small Entities in Agency Rulemaking'') [16] requires agencies to establish procedures and policies to promote compliance with the Regulatory Flexibility Act and to ''thoroughly review draft rules to assess and take appropriate account of the potential impact'' of the rulemakings on small businesses, governmental jurisdictions, and small organizations. The DOT posts its implementing guidance on a dedicated web page.[17]

This rulemaking has been developed in accordance with Executive Order 13272 and with DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure that potential impacts of rules on small entities are properly considered. This rulemaking addresses safety risks that lithium batteries present in transportation, primarily the risk to passenger aircraft, and facilitates the transportation of hazardous materials in international commerce by providing consistency with international standards. It applies to offerors and carriers of lithium batteries, some of whom are small entities. This includes lithium cell and battery manufacturers, wholesalers, and retailers. As discussed at length in the final RIA posted in the rulemaking docket, the amendments in this final rule impose minimal costs to shippers of lithium cells and batteries when offering a package of lithium cells and batteries in an overpack. However, these costs address a necessary safety gap to ensure the safety of air transportation of lithium cells and batteries. As detailed in the final RIA, PHMSA expects that these amendments will not have a significant economic impact on a substantial number of small entities. For further detail, please review the final regulatory flexibility analysis in the final RIA posted in the rulemaking docket.

F. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), no person is required to respond to any

[13] 64 FR 43255 (Aug. 4, 1999).

[14] 74 FR 24693 (May 22, 2009).

[15] 65 FR 67249 (Nov. 6, 2000).

[16] 67 FR 53461 (Aug. 16, 2002).

[17] DOT, ''Rulemaking Requirements Related to Small Entities,'' *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities* (last accessed June 17, 2021).

information collection unless is has been approved by OMB and displays a valid OMB control number. Pursuant to 44 U.S.C. 3506(c)(2)(B) and 5 CFR 1320.8(d), PHMSA must provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests.

PHMSA has analyzed this final rule in accordance with the Paperwork Reduction Act. PHMSA currently has approved information collections under OMB Control Numbers 2137–0034, ''Hazardous Materials Shipping Papers and Emergency Response Information'' and 2137–0557, ''Approvals for Hazardous Materials.'' In response to the IFR, PHMSA did not receive any comments related to these information collections. However, for the benefit of the reader of this final rule, the IFR discussion of the estimated paperwork burden follows.

For OMB control number 2137–0034, PHMSA estimated a revision in paperwork and recordkeeping burden as a result of smaller lithium batteries being transported as fully regulated shipments. PHMSA estimated this change in shipment because of the required consignment limitation. When shipped without certain provisions in § 173.185(c), the shipments are subject to shipping papers and Notification to the Pilot in Command (NOPIC) requirements in § 175.33. PHMSA estimated that there will be an additional 28,242 shipments annually that will require a shipping paper. PHMSA also estimated that each shipping paper takes one minute and 30 seconds to complete (28,242 shipments × 90 seconds), resulting in approximately 741 additional burden hours. PHMSA did not estimate any increase in out-of-pocket costs. The NOPIC is estimated to take one (1) minute per shipment (28,242 shipments × 1 minute), which resulted in an increase of approximately 471 burden hours. PHMSA did not estimate any increase in out-of-pocket costs. In total for this information collection, PHMSA estimated an approximate increase of 56,484 annual number of responses (28,242 shipping paper responses + 28,242 NOPIC responses) and approximate increase of 1,212 burden hours (741 shipping paper burden hours + 471 NOPIC burden hours).

For OMB control number 2137–0557, PHMSA estimated that the changes will lead to an additional 468 approval requests. This increase in approval requests resulted from the requirement that lithium ion cells and batteries, when transported by cargo aircraft, may only be shipped at greater than a 30 percent SOC under an approval by the Associate Administrator. As detailed in the IFR, PHMSA estimated that it takes approximately 40 hours to complete the paperwork portion of an approval request, resulting in 18,720 additional burden hours (468 approval requests x 40 hours per request). PHMSA did not estimate any increase in out-of-pocket costs.

A summary of the information collection changes from the rulemaking can be found below:

OMB Control Number 2137–0034

Annual Increase in Number of Respondents: 0.

Annual Increase in Annual Number of Responses: 56,484.

Annual Increase in Annual Burden Hours: 1,212.

Annual Increase in Annual Burden Costs: $0.

OMB Control Number 2137–0557

Annual Increase in Number of Respondents: 468.

Annual Increase in Annual Number of Responses: 468.

Annual Increase in Annual Burden Hours: 18,720.

Annual Increase in Annual Burden Costs: $0.

G. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (URMA; 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of federal regulatory actions on state, local, and tribal governments, and the private sector. For any NPRM or final rule that includes a federal mandate that may result in the expenditure by state, local, and tribal governments, or by the private sector of $100 million or more in 1996 dollars in any given year, the agency must prepare, amongst other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under the UMRA. As explained above, it is not expected to result in costs of $100 million or more in 1996 dollars on either state, local, or tribal governments, in the aggregate, or to the private sector in any one year, and is the least burdensome alternative that achieves the objective of the rulemaking.

H. Environmental Assessment

The National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*), requires that federal agencies analyze actions to determine whether the action would have a significant impact on the human environment. The Council on Environmental Quality implementing regulations (40 CFR parts 1500–1508) require federal agencies to conduct an environmental review considering (1) the need for the action, (2) alternatives to the action, (3) probable environmental impacts of the action and alternatives, and (4) the agencies and persons consulted during the consideration process. DOT Order 5610.1C (''Procedures for Considering Environmental Impacts'') establishes departmental procedures for evaluation of environmental impacts under NEPA and its implementing regulations.

1. Need for the Action

This final rule is being promulgated in response to comments to the IFR. The final rule maintains IFR provisions including the: (1) prohibition of the transport of lithium ion cells and batteries as cargo on passenger aircraft; (2) requirement for all lithium ion cells and batteries to be shipped at not more than a 30 percent SOC on cargo-only aircraft; and (3) restriction for smaller lithium cell and battery shipments to one package per consignment or overpack. These provisions addressed safety concerns from lithium battery transportation risks and mandates from the FAA Reauthorization Act of 2018, including adding an exception, with approval from the Associate Administrator, for certain medical device lithium batteries.

This final rule provides amendments on certain IFR provisions including marking requirements. In addition, the final rule addresses a safety need by requiring that when a package of smaller lithium cells and batteries that requires a §§ 173.185(c)(1)(iii) or (iv) mark or label is placed in an overpack, the appropriate mark or label must be visible or reproduced on the overpack.

As explained in greater length in this preamble, final RIA, and in the IFR preamble, this rulemaking addresses safety concerns from lithium batteries when transported by air. PHMSA expects that the continuation of the provisions adopted in the IFR and the revisions in this final rule increase the high safety standard currently achieved under the HMR. PHMSA has evaluated each of the amendments on its own merit, as well as the aggregate impact on transportation safety from adoption of those amendments. This EA focuses on the regulatory changes specific to this final rule. The EA for the IFR is available in the rulemaking docket.[18]

[18] PHMSA–2016–0014

2. Alternatives Considered

PHMSA considered the following alternatives:

Selected Alternative:

The Selected Alternative is the current rulemaking as it appears in this final rule. This final rule revises the IFR regulatory text to ensure the requirements more appropriately harmonize with those amendments in the ICAO Technical Instructions. In addition, PHMSA adds a requirement, to respond to an omission in the IFR, that when a package bears a §§ 173.185(c)(1)(iii) or (iv) mark or label and is placed in an overpack, the appropriate mark or label must be visible or reproduced on the overpack. The amendments included in this alternative are more fully discussed in the preamble and regulatory text section of this rulemaking. The Selected Alternative also clarifies certain marking provisions from the IFR. Also, the Selected Alternative provides more specificity about the approval process to allow certain lithium batteries for medical equipment on aircrafts.

No Action Alternative:

If PHMSA were to select the No Action Alternative, PHMSA would not make any amendments to the IFR, and current regulations remain in place. No provisions would be amended or added. The HMR would not be fully consistent with the ICAO Technical Instructions. The HMR would not be updated to provide important details for the approval process related to the transportation of lithium batteries in medical equipment.

3. Environmental Impacts

Selected Alternative:

PHMSA anticipates that overall, the changes under the Selected Alternative increase the high safety standards currently achieved in the HMR. PHMSA expects that proper harmonization of the HMR with the ICAO Technical Instructions for lithium battery transportation will result in greater protection of human health and the environment by further decreasing the likelihood that an unauthorized package containing lithium batteries could be shipped via cargo or passenger aircraft, which could potentially cause a dangerous incident in air travel. In addition, this harmonization is expected to capture economic and logistic efficiencies gained from avoiding shipping delays and reshipments associated with having to comply with divergent U.S. and international regulatory requirements for transportation of lithium batteries by aircraft. These delays and reshipments can have incremental environmental impacts. In addition, PHMSA expects that ensuring visibility of the markings and labels reduces the risk of harm to human safety and environmental resources from an incident caused by lithium batteries on an aircraft.

PHMSA expects that the Selected Alternative could realize modest reductions in greenhouse gas (GHG) emissions because the differences in the current HMR and the ICAO Technical Instructions for the transportation of lithium batteries absent the changes made in this final rule could potentially result in delays or interruptions. PHMSA anticipates that the No Action Alternative could result in modestly higher GHG emissions from some combination of (1) transfer of delayed hazardous materials to and from interim storage, (2) return of improperly shipped materials to their point of origin, or (3) reshipment of returned materials. The Selected Alternative reduces the inconsistences from the divergence of the HMR and the ICAO Technical Instructions for lithium battery transportation by air and thus, avoids potential transportation inefficiencies. However, PHMSA is unable to quantify any GHG emissions benefits because of the difficulty in estimating or identifying the quantity or characteristics of such interim storage or returns/reshipments. The only potential environmental impact associated with the Selected Alternative would result from the production of additional markings or labels that must be affixed to the any overpack when the original marking or label is not visible through the overpack. The impact would be extremely minimal.

Lastly, the Selected Alternative would avoid any adverse impacts for minority populations, low-income populations, or other underserved and other disadvantaged communities resulting from the potential shipping delays because of the divergence between the HMR and the ICAO Technical Instructions for lithium battery shipments.

No Action Alternative:

Under the No Action Alternative, current regulations would remain in place, and PHMSA would not make additional amendments to the HMR related to the air transportation of batteries to fully achieve the purpose of the IFR. Not adopting the amendments that clarify and address a potential hazard communication gap in this final rule under the No Action Alternative would allow an unintentional gap in marking requirements to persist, which could make it more like that a prohibited package could be offered for transportation on a passenger aircraft.

Additionally, efficiencies gained through proper harmonization in updates to transport standards would not be realized. Foregone efficiencies in the No Action Alternative include freeing up limited resources to concentrate on air transport hazard communication issues of potentially greater environmental impact.

4. Agencies Consulted

PHMSA has coordinated with the FAA, the Federal Motor Carrier Safety Administration, the Federal Railroad Administration, and the U.S. Coast Guard in the development of this rulemaking. The final rule has also been made available to other federal agencies within the interagency review process consistent with Executive Order 12866.

5. Finding of No Significant Impact

The adoption of the Selected Alternative's regulatory amendments enhances the safe and secure transportation of lithium batteries by aircraft, thereby reducing the risks of an accidental or intentional release of hazardous materials that could result in a catastrophic incident on an aircraft, potential loss of life and subsequent environmental damage. Furthermore, PHMSA expects that the Selected Alternative will avoid adverse safety, environmental justice, and GHG emissions impacts of the No Action Alternative. Therefore, PHMSA finds that the final rule amendments would have no significant environmental impacts on the human environment.

I. Executive Order 12898

Executive Orders 12898 (''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations''),[19] 13985 (''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government''),[20] 13990 (''Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis''),[21] 14008 (''Tackling the Climate Crisis at Home and Abroad''),[22] and DOT Order 5610.2C (''Department of Transportation Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'') require DOT agencies to achieve environmental justice as part of their mission by identifying and addressing, as appropriate, disproportionately high

[19] 59 FR 7629 (Feb. 11, 1994).

[20] 86 FR 7009 (Jan. 20, 2021).

[21] 86 FR 7037 (Jan. 20, 2021).

[22] 86 FR 7619 (Feb. 1, 2021).

and adverse human health or environmental effects, including interrelated social and economic effects of their programs, policies, and activities on minority populations, low-income populations, and other underserved and disadvantaged communities.

PHMSA has evaluated this final rule under the above Executive Orders and DOT Order 5610.2C and expects it would not cause disproportionately high and adverse human health and environmental effects on minority, low-income, underserved, and other disadvantaged populations and communities. The rulemaking is facially neutral and national in scope; it is neither directed toward a particular population, region, or community, nor is it expected to adversely impact any particular population, region, or community. And insofar as PHMSA expects the rulemaking would not adversely affect the safe transportation of hazardous materials generally, PHMSA does not expect the amendments would entail disproportionately high adverse risks for minority populations, low-income populations, or other underserved and other disadvantaged communities.

The final rule could reduce risks to minority populations, low-income populations, or other underserved and other disadvantaged communities. Insofar as the HMR amendments could avoid the release of hazardous materials, the final rule could reduce risks to populations and communities—including any minority, low-income, underserved, and other disadvantaged populations and communities—in the vicinity of interim storage sites and transportation arteries and hubs. Additionally, as explained in the above discussion of NEPA, PHMSA expects that the final rule amendments will yield modest GHG emissions reductions, thereby reducing the risks posed by anthropogenic climate change to minority, low-income, underserved, and other disadvantaged populations, and communities.

J. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.* DOT's complete Privacy Act Statement can be reviewed in the **Federal Register** published on April 11, 2000,[23] or on DOT's website at *http://www.dot.gov/privacy.*

K. Executive Order 13609 and International Trade Analysis

Executive Order 13609 (''Promoting International Regulatory Cooperation'') [24] requires that agencies must consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to the Trade Agreements Act, the establishment of standards is not considered an unnecessary obstacle to foreign commerce of the United States, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA participates in the establishment of international standards in order to protect the safety of the American public, and we have assessed the effects of the rulemaking to ensure that it does not cause unnecessary obstacles to foreign trade. In this case, the final rule further harmonizes U.S. lithium battery provisions with the ICAO Technical Instructions so as to reduce regulatory burdens and minimize delays arising from having to comply with divergent regulatory requirements. Accordingly, this rulemaking is consistent with Executive Order 13609 and PHMSA's obligations under the Trade Agreement Act, as amended.

[23] 65 FR 19475 (Apr. 11, 2000).

[24] 77 FR 26413 (May 1, 2012).

L. Executive Order 13211

Executive Order 13211 (''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'') [25] requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' Executive Order 13211 defines a ''significant energy action'' as any action by an agency (normally published in the **Federal Register**) that promulgates, or is expected to lead to the promulgation of, a final rule or regulation that (1)(i) is a significant regulatory action under Executive Order 12866 or any successor order and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy (including a shortfall in supply, price increases, and increased use of foreign supplies); or (2) is designated by the Administrator of the Office of Information and Regulatory Affairs (OIRA) as a significant energy action.

This final rule is a non-significant action under Executive Order 12866, and PHMSA expects it to have an annual effect on the economy of less than $100 million. Further, this action is not likely to have a significant adverse effect on the supply, distribution, or use of energy in the United States. The Administrator of OIRA has not designated the final rule as a significant energy action. For additional discussion of the anticipated economic impact of this rulemaking, please review the final RIA posted in the rulemaking docket.

List of Subjects

49 CFR Part 107

Administrative practice and procedure, Hazardous materials transportation, Packaging and containers, Penalties, Reporting and recordkeeping requirements.

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements, Uranium.

In consideration of the foregoing, PHMSA amends 49 CFR chapter I as follows:

[25] 66 FR 28355 (May 22, 2001).

PART 107—HAZARDOUS MATERIALS PROGRAM PROCEDURES

■ 1. The authority citation for part 107 is amended to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 Section 4; Pub. L. 104–121 Sections 212–213; Pub. L. 104–134 Section 31001; Pub. L. 114–74 Section 701 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97; 33 U.S.C. 1321.

■ 2. In § 107.705, revise paragraphs (b)(4) and (b)(5)(ii) and add paragraph (b)(6) to read as follows:

§ 107.705 Registrations, reports, and applications for approval.

* * * * *

(b) * * *

(4) Any additional information specified in the section containing the approval;

(5) * * *

(ii) Substantiation, with applicable analyses or evaluations, if appropriate, demonstrating that the proposed activity will achieve a level of safety that is at least equal to that required by the regulation; and

(6) For lithium cells and batteries used for a medical device and transported in accordance with § 173.185(g) of this chapter, details on the extent to which the destination(s) of the lithium cell or battery is not serviced daily by cargo aircraft.

* * * * *

■ 3. In § 107.709, revise paragraphs (b) and (f) to read as follows:

§ 107.709 Processing of an application for approval, including an application for renewal or modification.

* * * * *

(b) The Associate Administrator will review an application for an approval, modification of an approval, or renewal of an approval in conformance with the standard operating procedures specified in appendix A of this part (''Standard Operating Procedures for Special Permits and Approvals''). The Associate Administrator will conduct an expedited review process for shipments of lithium cells and batteries specifically used for medical devices, as outlined in § 173.185(g) of this chapter. At any time during the processing of an application, the Associate Administrator may request additional information from the applicant. If the applicant does not respond to a written request for additional information within 30 days of the date the request was received, the Associate Administrator may deem the application incomplete and deny it. The Associate Administrator may grant a 30-day extension to respond to the written request for additional information if the applicant makes such a request in writing.

* * * * *

(f) The Associate Administrator notifies the applicant in writing of the decision on the application. A denial contains a brief statement of reasons. For shipments of lithium cells and batteries specifically used for medical devices, as outlined in § 173.185(g) of this chapter, an approval shall be considered and either granted or denied not later than 45 days after receipt of a completed application.

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

■ 4. The authority citation for part 171 is revised to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 section 4; Pub. L. 104–134, section 31001; Pub. L. 114–74 section 701 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97.

■ 5. In § 171.12, revise paragraph (a)(6) to read as follows:

§ 171.12 North American Shipments.

(a) * * *

(6) *Lithium cells and batteries.* Lithium metal cells and batteries (UN3090) and lithium ion cells and batteries (UN3480) are forbidden for transport as cargo aboard passenger-carrying aircraft. The outside of each package or overpack that contains lithium cells or batteries meeting the conditions for exception in § 173.185(c) of this subchapter and transported in accordance with the Transport Canada TDG Regulations must be marked or labeled in accordance with § 173.185(c)(1)(iii), (iv), and (vi), as appropriate.

* * * * *

■ 6. In § 171.24, revise paragraph (d)(1)(ii) to read as follows:

§ 171.24 Additional requirements for the use of the ICAO Technical Instructions.

* * * * *

(d) * * *

(1) * * *

(ii) *Lithium cells and batteries.* Lithium metal cells and batteries (UN3090) and lithium ion cells and batteries (UN3480) are forbidden for transport as cargo aboard passenger-carrying aircraft. The outside of each package that contains lithium metal cells or batteries transported in accordance with Packing Instruction 968, Section II or lithium ion cells or batteries transported in accordance with Packing Instruction 965, Section II must be appropriately marked: ''PRIMARY LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT'', ''LITHIUM METAL BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT'', ''LITHIUM ION BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT'', or ''LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT'', or labeled with a CARGO AIRCRAFT ONLY label as specified in § 172.448 of this subchapter. When placed in an overpack, the selected mark or label must either be clearly visible through the overpack, or the marking or label must be affixed on the outside of the overpack.

* * * * *

■ 7. In § 171.25, revise paragraph (b)(3) to read as follows:

§ 171.25 Additional requirements for the use of the IMDG Code.

* * * * *

(b) * * *

(3) The outside of each package containing lithium metal cells or batteries (UN3090) or lithium ion cells or batteries (UN3480) transported in accordance with special provision 188 of the IMDG Code must be appropriately marked ''PRIMARY LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT'', ''LITHIUM METAL BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT'', ''LITHIUM ION BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT'', or ''LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT'', or labeled with a CARGO AIRCRAFT ONLY label as specified in § 172.448 of this subchapter. The provisions of this paragraph also apply to packages of lithium cells or batteries packed with, or contained in, equipment that exceed 5 kg (11 pounds) net weight. When placed in an overpack, the selected marking or label must either be clearly visible through the overpack, or the marking or label must also be affixed on the outside of the overpack.

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

■ 8. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

■ 9. In § 173.185:

■ a. Revise paragraphs (c)(1)(iii) and (iv);

■ b. Redesignate paragraph (c)(1)(vi) as paragraph (c)(1)(vii);
■ c. Add new paragraph (c)(1)(vi); and
■ d. Revise paragraphs (c)(4)(i) introductory text and (c)(4)(ii), (iii), (v), and (viii).

The revisions and addition read as follows:

§ 173.185 Lithium cells and batteries.

* * * * *

(c) * * *

(1) * * *

(iii) Except when lithium cells or batteries are packed with or contained in equipment in quantities not exceeding 5 kg net weight, the outer package that contains lithium cells or batteries must be appropriately marked: ''PRIMARY LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT'', ''LITHIUM METAL BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT'', ''LITHIUM ION BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT'', or ''LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT'', or labeled with a ''CARGO AIRCRAFT ONLY'' label as specified in § 172.448 of this subchapter.

(iv) For transportation by highway or rail only, the lithium content of the cell and battery may be increased to 5 g for a lithium metal cell or 25 g for a lithium metal battery and 60 Wh for a lithium ion cell or 300 Wh for a lithium ion battery, provided the outer package is marked: ''LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD AIRCRAFT AND VESSEL.'' A package marked in accordance with this paragraph does not need to display the marking required in paragraph (c)(1)(iii) of this section.

* * * * *

(vi) When a package marked or labeled in accordance with paragraph (c)(1)(iii) or (iv) of this section is placed in an overpack, the selected marking or label must either be clearly visible through the overpack, or the marking or label must also be affixed on the outside of the overpack.

* * * * *

(4) * * *

(i) For transportation by aircraft, lithium cells and batteries may not exceed the limits in the following Table 1 to paragraph (c)(4)(i). The limits on the maximum number of batteries and maximum net quantity of batteries in the following table may not be combined in the same package. The limits in the following table do not apply to lithium cells and batteries packed with, or contained in, equipment.

* * * * *

(ii) Not more than one package prepared in accordance with paragraph (c)(4)(i) of this section may be placed into an overpack.

(iii) A shipper is not permitted to offer for transport more than one package prepared in accordance with the provisions of paragraph (c)(4)(i) of this section in any single consignment.

* * * * *

(v) Packages and overpacks of lithium batteries prepared in accordance with paragraph (c)(4)(i) of this section must be offered to the operator separately from cargo which is not subject to the requirements of this subchapter and must not be loaded into a unit load device before being offered to the operator.

* * * * *

(viii) Lithium cells and batteries must not be packed in the same outer packaging with other hazardous materials. Packages prepared in accordance with paragraph (c)(4)(i) of this section must not be placed into an overpack with packages containing hazardous materials and articles of Class 1 (explosives) other than Division 1.4S, Division 2.1 (flammable gases), Class 3 (flammable liquids), Division 4.1 (flammable solids), or Division 5.1 (oxidizers).

* * * * *

Issued in Washington, DC, on December 14, 2022, under authority delegated in 49 CFR part 1.97.

Tristan H. Brown,

Deputy Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2022–27563 Filed 12–20–22; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 221215–0272; RTID 0648–XC422]

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; 2023 Specifications

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

ACTION: Final rule.

SUMMARY: NMFS issues final specifications for the 2023 Atlantic bluefish fishery, as recommended by the Mid-Atlantic Fishery Management Council and the Atlantic States Marine Fisheries Commission. This action is necessary to establish allowable harvest levels for the stock to prevent overfishing and promote rebuilding, while enabling optimum yield, using the best scientific information available.

DATES: Effective on January 1, 2023.

ADDRESSES: The Mid-Atlantic Fishery Management Council prepared a Supplemental Information Report (SIR) for these specifications that describes the action, and any changes from the original environmental assessment (EA) and analyses for 2023 specifications action. Copies of the SIR, original EA, and other supporting documents for this action, are available upon request from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 North State Street, Dover, DE 19901. These documents are also accessible via the internet at *https://www.mafmc.org/supporting-documents.*

FOR FURTHER INFORMATION CONTACT: Cynthia Ferrio, Fishery Policy Analyst, (978) 281–9180.

SUPPLEMENTARY INFORMATION:

Background

The Mid-Atlantic Fishery Management Council and the Atlantic States Marine Fisheries Commission jointly manage the Atlantic Bluefish Fishery Management Plan (FMP). The FMP requires the specification of annual regulatory limits including: An acceptable biological catch (ABC); commercial and recreational annual catch limits (ACL); commercial and recreational annual catch targets (ACT); a commercial quota; a recreational harvest limit (RHL); and other management measures, for up to 3 years at a time. This action implements adjusted bluefish specifications for the 2023 fishing year, based on the most recent data and Council and Commission recommendations.

Catch limits for the 2023 bluefish fishery were previously projected in a multi-year specifications action (87 FR 5739, February 2, 2022), based on a 2021 assessment update and Amendment 7 to the Bluefish FMP (86 FR 66977, November 24, 2021). Those 2023 specifications would increase the commercial quota 21 percent and the RHL 59 percent from 2022 limits. No changes were necessary to the majority of those projected specifications; however, there was a recreational catch overage of 5.59 million lb (2,536 mt) in

2021 that is required to be paid back pound-for-pound through accountability measures (AM) in 2023, and updated data indicated that the initial projection of recreational discards was too low. To account for this new information, the 2023 RHL has been adjusted from the projected 22.14 million lb (10,044 mt) to 14.11 million lb (6,400 mt), which is an increase of 1.6 percent from 2022, rather than 59 percent. No changes were recommended to recreational management measures because the adjusted RHL is only slightly higher than the 2022 RHL, and there was no compelling reason to change existing measures.

The proposed rule for this action published in the **Federal Register** on November 15, 2022 (87 FR 68434), and comments were accepted through November 30, 2022. NMFS received five comments from the public, and no changes were made to the final rule because of those comments (see Comments and Responses for additional detail). Additional background information regarding the development of these specifications was provided in the proposed rule and is not repeated here.

Final Specifications

This action implements the Council and Commission's recommended 2023 bluefish catch specifications, as outlined in the proposed rule (Table 1). These final specifications increase the coastwide commercial quota by 21 percent, as previously projected, and the RHL by 1.6 percent, rather than 59 percent as originally projected.

TABLE 1—FINAL ADJUSTED 2023 BLUEFISH SPECIFICATIONS *

	Million lb	Metric tons
Overfishing Limit	45.17	20,490
ABC	30.62	13,890
Commercial ACL = Commercial ACT	4.29	1,945
Recreational ACL = Recreational ACT	26.34	11,945
Recreational AM	5.59	2,536
Recreational Discards	6.64	3,012
Commercial Quota	4.29	1,945
RHL	14.11	6,400

* Specifications are derived from the ABC in metric tons (mt). When values are converted to millions of pounds the numbers may slightly shift due to rounding. The conversion factor used is 1 mt = 2,204.6226 lb.

The final coastwide commercial quota is allocated among the coastal states from Maine to Florida based on percent shares specified in the FMP, and the phased-in changes to these share allocations specified in Amendment 7 to the FMP (86 FR 66977, November 24, 2021). The 2023 state bluefish quota allocations (Table 2) are unchanged from what was previously projected, as there are no adjustments to the commercial sector. In addition, no states exceeded their allocated quota in 2021 or 2022; therefore, no AMs for the commercial fishery are required for the 2023 fishing year.

TABLE 2—2023 BLUEFISH STATE COMMERCIAL QUOTA ALLOCATIONS

State	Percent share	Quota (lb)	Quota (kg)
Maine	0.51	21,807	9,892
New Hampshire	0.36	15,331	6,954
Massachusetts	7.69	329,578	149,494
Rhode Island	7.61	326,165	147,946
Connecticut	1.22	52,094	23,629
New York	13.06	560,031	254,026
New Jersey	14.54	623,295	282,722
Delaware	1.48	63,572	28,836
Maryland	2.69	115,409	52,349
Virginia	10.16	435,625	197,596
North Carolina	32.05	1,374,077	623,271
South Carolina	0.05	2,344	1,063
Georgia	0.04	1,544	700
Florida	8.55	366,585	166,280
Total	100.01	4,287,109	1,944,600

As previously mentioned, this action makes no changes to recreational management measures, including the recreational daily bag limit of three fish per person for private anglers and five fish per person for for-hire (charter/party) vessels.

Comments and Responses

The public comment period for the proposed rule ended on November 15, 2022, and NMFS received five comments from the public. No changes were made to final rule as a result of these comments.

Comment 1: Three comments expressed similar opposition to the current recreational bag limits for bluefish; specifically that private anglers are held to a limit of three fish per person, while party/charter boats are allowed five fish per person.

Response: This action does not change or affect the bluefish recreational management measures, including bag limits. That said, the issue of recreational bag limits was discussed at length following the overfished

determination of the stock in 2019, and in the development of specifications for fishing years 2020 and 2021. There is a possibility that these limits will be revisited for the 2024 fishing year following the next assessment, but no changes are considered in this specifications action for 2023.

Comment 2: Another commenter noted that any additional restriction of the recreational bluefish fishery is unnecessary and would cause economic burden.

Response: NMFS understands the concern expressed for the recreational sector; however, this action does not add any restrictions to the bluefish fishery. Even though the RHL is increasing less than previously projected, it is still increasing 1.6 percent from 2022.

Comment 3: The final commenter simply voiced support for the action and encouraged implementation as soon as possible.

Response: NMFS agrees and is implementing this rule in a timely manner.

Changes From the Proposed Rule

There are no substantive changes from the proposed rule.

Classification

Pursuant to section 304(b)(3) of the Magnuson Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the NMFS Assistant Administrator, Greater Atlantic Region, has determined that these final specifications are necessary for the conservation and management of the Atlantic bluefish fishery, and that they are consistent with the Atlantic Bluefish FMP, the Magnuson-Stevens Act, and other applicable law.

The Assistant Administrator for Fisheries, NOAA, finds good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effective date for this rule to ensure that the final specifications are in place as close as practicable to the start of the bluefish fishing year on January 1, 2023. This action establishes the final specifications (*i.e.,* catch limits) for the 2023 bluefish fishery. A delay in effectiveness well beyond the start of this fishing year would be contrary to the public interest as it could create confusion in the bluefish industry, and compromise the effectiveness of the increased quota allocations both to fishery sectors, and commercially among the states. State agencies also use commercially-allocated quotas to set annual state management measures, so the longer these specifications are delayed, the longer it will take for some states to implement their respective regulations. Additionally, because catch limits are increasing, a further delay into the new fishing year could also cause potential economic harm to the fishery through lost opportunity to fish under the higher limits.

Furthermore, regulated parties do not require any additional time to come into compliance with this rule, and thus, a 30-day delay before the final rule becomes effective does not provide any benefit. Unlike actions that require an adjustment period, bluefish fishery participants will not have to purchase new equipment or otherwise expend time or money to comply with these management measures. Rather, complying with this final rule simply means adhering to the new catch limits set for the 2023 fishing year. Fishery stakeholders have also been involved in the development of this action and are anticipating this rule. For these reasons, NMFS finds that a 30-day delay in effectiveness would be contrary to the public interest, and therefore, waives the requirement consistent with 5 U.S.C. 553(d)(3).

This final rule is not subject to review under Executive Order 12866 because the action contains no implementing regulations.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification, and the initial certification remains unchanged. As a result, a final regulatory flexibility analysis is not required and none was prepared.

This final rule does not duplicate, conflict, or overlap with any existing Federal rules.

This action contains no information collection requirements under the Paperwork Reduction Act of 1995.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 15, 2022.

Andrew James Strelcheck,

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

[FR Doc. 2022–27661 Filed 12–20–22; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 87, No. 244
Wednesday, December 21, 2022

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.

FEDERAL LABOR RELATIONS AUTHORITY

5 CFR Part 2429

[Docket Number: 0–MC–33]

Miscellaneous and General Requirements

AGENCY: Federal Labor Relations Authority.

ACTION: Proposed rule and proposed rescission of general statement of policy or guidance and request for comments.

SUMMARY: The Federal Labor Relations Authority (FLRA or Authority) seeks public comments on a proposed revision to its regulations and a proposed rescission of its general statement of policy or guidance (policy statement) in *Office of Personnel Management* (*OPM*), 71 FLRA 571 (2020) (Member Abbott concurring; then-Member DuBester dissenting). The proposed revision and rescission concern the intervals at which Federal employees may revoke their voluntary, written assignments of payroll deductions for the payment of regular and periodic dues allotted to their exclusive representative. Specifically, in addition to rescinding *OPM,* the Authority proposes either revising its regulation entitled ''Revocation of Assignments'' to provide that dues revocations may be processed only at one-year intervals, or, alternatively, rescinding that regulation in its entirety. The Authority seeks comments on these proposals.

DATES: To be considered, comments must be received on or before January 20, 2023.

ADDRESSES: You may send comments, which must include the caption ''Miscellaneous and General Requirements,'' by one of the following methods:

- *Email: FedRegComments@flra.gov.* Include ''FLRA Docket No. 0–MC–33'' in the subject line of the message.
- Mail: Brandon Bradley, Chief, Case Intake and Publication, Federal Labor Relations Authority, Docket Room, Suite 200, 1400 K Street NW, Washington, DC 20424–0001.

Instructions: Do not mail written comments if they have been submitted via email. Interested persons who mail written comments must submit an original and 4 copies of each written comment, with any enclosures, on 8½ × 11 inch paper. Do not deliver comments by hand.

FOR FURTHER INFORMATION CONTACT: Brandon Bradley, Chief, Case Intake and Publication at *bbradley@flra.gov* or at: (771) 444–5809.

SUPPLEMENTARY INFORMATION: In Case Number 0–MC–33, the National Treasury Employees Union (NTEU) has filed a petition, under § 2429.28 of the Authority's regulations, 5 CFR 2429.28, to amend § 2429.19 of those regulations, 5 CFR 2429.19. For the following reasons, the Authority hereby grants NTEU's petition and proposes to: (1) rescind the policy statement that the Authority issued in *OPM,* 71 FLRA 571; and (2) amend 5 CFR 2429.19 to clarify that, once an employee has given an agency a voluntary, written assignment authorizing payroll deduction of regular and periodic dues for the employee's exclusive representative (voluntary dues assignment), the employee may thereafter revoke that assignment only at yearly intervals, or, in the alternative, rescind § 2429.19 in its entirety.

Section 7115(a) of the Statute provides, in pertinent part, that voluntary dues assignments ''may not be revoked for a period of 1 year.'' 5 U.S.C. 7115(a). In its earliest years, in *U.S. Army, U.S. Army Materiel Development and Readiness Command, Warren, Michigan* (*Army*), 7 FLRA 194 (1981), *recons. denied,* 8 FLRA 806 (1982), the Authority unanimously concluded that Section 7115(a) allows employees to revoke voluntary dues assignments only at one-year intervals. *See id.* at 199. The Authority based this conclusion on a detailed assessment of Section 7115(a)'s wording and legislative history, along with the Statute's overall purposes. *See id.* at 196–99.

The Authority applied this interpretation of Section 7115(a) for nearly four decades. *See United Power Trades Org.,* 62 FLRA 493, 495 (2008); *AFGE, AFL–CIO,* 51 FLRA 1427, 1433 n.5 (1996); *NAGE, SEIU, AFL–CIO,* 40 FLRA 657, 688–89 (1991); *AFGE, AFL–CIO, Dep't of Educ. Council of AFGE Locs.,* 34 FLRA 1078, 1080–82 (1990); *AFGE, AFL–CIO, Loc. 1931,* 32 FLRA 1023, 1029 (1988); *Dep't of the Navy, Portsmouth Naval Shipyard, Portsmouth, N.H.,* 19 FLRA 586, 589 (1985); *Veterans Admin., Lakeside Med. Ctr., Chi., Ill.,* 12 FLRA 244, 246 (1983); *Dep't of HHS, SSA, Off. of Program Serv. Ctrs. & Ne. Program Serv. Ctr.,* 11 FLRA 618, 620 (1983); *Dep't of HHS, SSA, Bureau of Field Operations (N.Y.C., N.Y.),* 11 FLRA 600, 602–03, *recons. denied,* 12 FLRA 754 (1983).

Then, in 2020, a majority of the Authority's Members issued the policy statement in *OPM,* 71 FLRA 571. The majority rejected the FLRA's prior, longstanding interpretation of Section 7115(a) and, instead, found that the ''most reasonable way to interpret'' Section 7115(a) was to find that it addressed revocations of voluntary dues assignments only during the first year of an assignment—and that, after the first year, employees should be permitted to revoke their voluntary dues assignments at any time. *Id.* at 572–73. In so finding, the majority stated, among other things, that, ''[e]xcept for the limiting conditions in [Section] 7115(b), which [Section] 7115(a) explicitly acknowledges, nothing in the text of [Section] 7115(a) expressly addresses the revocation of dues assignments after the first year.'' *Id.* at 572. At the same time, however, the majority declined to consider the legislative history that the Authority had discussed at length in *Army,* on the ground that Section 7115(a)'s pertinent wording ''is not ambiguous.'' *Id.* at 573 n.23.

Then-Member DuBester dissented. *See id.* at 576–79.

Subsequently, on March 19, 2020, the majority, with then-Member DuBester again dissenting, published a notice of proposed rulemaking in the **Federal Register**. 85 FR 15742 (March 19, 2020). On July 9, 2020, the majority—again, with then-Member DuBester dissenting—issued a final rule, with an effective date of August 10, 2020. 85 FR 41169 (July 9, 2020). That final rule, set forth at 5 CFR 2429.19, states that an employee may initiate the revocation of a dues assignment pursuant to 5 U.S.C. 7115(a) at any time after the expiration of an initial one-year period following the dues assignment.

On April 1, 2022, NTEU filed the above-mentioned petition for rulemaking (rulemaking petition),

arguing that the Authority should amend § 2429.19 to provide for dues revocations only at one-year intervals. Rulemaking Pet. at 9. NTEU asserts that Section 7115(a) of the Statute requires the Authority to return to the rule that *Army* established. *Id.* at 3. NTEU contends that, although Section 7115(a)'s wording does not address dues revocations after the initial one-year period, its legislative history establishes that Congress intended to allow such revocations only at one-year intervals. *Id.* (citing *Army,* 7 FLRA at 198–99). According to NTEU: before the Statute was enacted, dues revocations could occur only at six-month intervals, *id.* at 4 (citing Labor-Management Relations in the Federal Service, E.O. No. 11,491, § 21, 34 FR 17605, 17614 (Oct. 31, 1969)); and, by passing the Statute, ''Congress unquestionably intended to strengthen the position of federal unions,'' *id.* (citing *Bureau of Alcohol, Tobacco & Firearms* v. *FLRA,* 464 U.S. 89, 107 (1983)). Contrary to that intent, NTEU claims, current § 2429.19 provides federal-sector unions ''with less stability and fewer collective-bargaining rights'' than they had before the Statute's enactment. *Id.* In particular, NTEU claims that, under current § 2429.19, unions no longer have the right to regular dues-revocation intervals—and cannot even *bargain* over such intervals. *Id.* at 4–5. NTEU claims that the Authority has not explained the ''basic contradiction'' between current § 2429.19 and Congress's intent. *Id.* at 4.

In addition, NTEU argues that, for three reasons, its proposed regulatory revision would be ''good, reasonable policy.'' *Id.* at 5.

First, NTEU argues that doing so would restore financial security and predictability for unions. *Id.* NTEU asserts that, for those NTEU bargaining units that are not yet subject to current § 2429.19, NTEU can: plan its fiscal-year budget because it can know, with a reasonable degree of certainty, how much dues revenue will be available; process revocations all at once, which is more efficient than processing them one by throughout the year; and, consequently, concentrate more of its resources on collective bargaining and improving employees' working lives. *Id.* at 6. According to NTEU, agencies also would likely benefit from the efficiency of processing revocations once per year. *Id.*

Second, NTEU contends that revising current § 2429.19 to provide for dues revocation only at one-year intervals would restore unions' bargaining posture. *Id.* at 6. According to NTEU, since 1981, it has relied on *Army* when drafting and negotiating dues-withholding provisions. *Id.* However, when current § 2429.19 took effect, ''suddenly those time-tested provisions became nonnegotiable.'' *Id.* Because federal-sector unions ''have little to bargain over in the first place,'' NTEU contends that current § 2429.19 ''diminish[es]'' unions' role in collective bargaining. *Id.* (citing *NTEU* v. *Chertoff,* 452 F.3d 839, 853–54 (D.C. Cir. 2006)).

Third, NTEU argues that revising § 2429.19 would honor employee choice. *Id.* NTEU contends that allowing revocations only at one-year intervals would not infringe on employees' rights, under Section 7102 of the Statute, to refrain from joining or assisting a union. *Id.* (citing 85 FR 41171). NTEU notes that joining a union and paying dues by payroll deduction always has been an employee's choice, and that the Federal Government's payroll-deduction form, Standard Form (SF) 1187, expressly states that ''completing this form is voluntary'' and tells employees when and how they may cancel their deductions. *Id.* According to NTEU, courts have held that: dues assignments are voluntary, binding contracts, *id.* at 7–8 (citing *Belgau* v. *Inslee,* 975 F.3d 940, 950–51 (9th Cir. 2020), *cert. denied,* 141 S. Ct. 2795 (2021); *IAM Dist. 10 & Loc. Lodge 873* v. *Allen,* 904 F.3d 490, 506 (7th Cir. 2018) (*IAM*), *cert. denied,* 139 S. Ct. 1599 (2019); *NLRB* v. *U.S. Postal Serv.,* 827 F.2d 548, 554 (9th Cir. 1987)); and requiring employees to honor those assignments until the next annual revocation period does not force them to join or assist a union, *id.* at 8 (citing *Belgau,* 975 F.3d at 950; *IAM,* 904 F.3d at 506 (quoting *SeaPak* v. *Indus., Tech., & Prof'l Emps., Div. of Nat'l Mar. Union, AFL–CIO* v. *W.R. & Grace Co.,* 300 F. Supp. 1197, 1201 (S.D. Ga. 1969), *aff'd,* 423 F.2d 1229 (5th Cir. 1970), *aff'd,* 400 U.S. 985 (1971)). Further, NTEU asserts that temporarily irrevocable payment authorizations are common and enforceable in other contexts. *Id.* (citing *IAM,* 904 F.3d at 506 (health-insurance-premium payroll deductions); *Fisk* v. *Inslee,* 759 Fed. Appx. 632, 634 (D. Or. 2019) (consumer contracts)).

Finally, NTEU argues that there has been ''little reliance'' on current § 2429.19 because (1) it has taken effect only for bargaining units whose collective-bargaining agreements were not in force on the rule's effective date of August 10, 2020, and (2) the U.S. Office of Personnel Management has not yet revised SF 1187, so even for units where current § 2429.19 applies, employees may not even be aware of it. *Id.* at 9. Consequently, NTEU claims, returning to the ''[forty]-year status quo under *Army*'' would be a ''virtually seamless transition.'' *Id.*

In the Authority's view, NTEU's rulemaking petition raises several legal and policy reasons for rescinding the policy statement in *OPM,* which led to the promulgation of current § 2429.19, and for rescinding or amending § 2429.19 to return the Authority to its prior interpretation of Section 7115(a) of the Statute. Accordingly, the Authority proposes to: (1) rescind the policy statement in *OPM;* and (2) revise current § 2429.19 to provide that dues revocations may be processed only at one-year intervals, or, in the alternative, rescind § 2429.19 in its entirety.

Thus, as noted above, the Authority hereby solicits comments on these proposals, including, but not limited to, comments addressing:

- Whether the proposals are consistent with the Statute (including Sections 7102 and 7115(a)) and administrative and judicial precedent (including *Council 214,* 835 F.2d 1458);
- The extent to which agencies have implemented current § 2429.19, and any positive and negative effects of such implementation;
- What rules should govern if the Authority rescinds, rather than amends, § 2429.19;
- Whether there are other alternatives that the Authority should consider, such as amending § 2429.19 to allow for an annual, one-month window period for revoking dues.

Regulatory Flexibility Act Certification

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Chairman of the FLRA has determined that this proposed rule, as amended, will not have a significant impact on a substantial number of small entities, because this proposed rule applies only to Federal agencies, Federal employees, and labor organizations representing those employees.

Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs

This proposed rule is not subject to the requirements of Executive Order (E.O.) 13771 (82 FR 9339, Feb. 3, 2017) because it is related to agency organization, management, or personnel, and it is not a ''significant regulatory action,'' as defined in Section 3(f) of E.O. 12866 (58 FR 51735, Sept. 30, 1993)

Executive Order 13132, Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the

National Government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 13132 (64 FR 43255, Aug. 4, 1999), this proposed rule does not have sufficient federalism implications to warrant preparation of a federalism assessment.

Executive Order 12988, Civil Justice Reform

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

Unfunded Mandates Reform Act of 1995

This proposed rule change will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This action is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This proposed rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Paperwork Reduction Act of 1995

The amended regulations contain no additional information collection or record-keeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*

List of Subjects in 5 CFR Part 2429

Administrative practice and procedure, Government employees, Labor management relations.

For the reasons stated in the preamble, the FLRA proposes to amend 5 CFR part 2429 as follows:

PART 2429—MISCELLANEOUS AND GENERAL REQUIREMENTS

■ 1. The authority citation for part 2429 continues to read as follows:

Authority: 5 U.S.C. 7134; § 2429.18 also issued under 28 U.S.C. 2112(a).

Option 1

■ 2a. Revise § 2429.19 to read as follows:

§ 2429.19 Revocation of assignments.

Authorized dues assignments under 5 U.S.C. 7115(b) may be revoked only at intervals of one year.

Option 2

§ 2429.19 [Removed]

■ 2b. Remove § 2429.19.

Approved: December 14, 2022.

Rebecca Osborne,

Federal Register Liaison, Federal Labor Relations Authority.

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

Member Kiko, Dissenting:

It is unsurprising that the Petitioner would seek to reinstate a rule making it more onerous for employees to revoke dues-withdrawal authorization. What is surprising, though, is that the majority indulges the Petitioner by commencing this premature, unnecessary notice-and-comment rulemaking. When the Authority very recently solicited public comment on this regulation, we heard from employees who were frustrated with narrow form-submission windows occurring on indecipherable anniversary dates. In 2020, the Authority enacted a regulation that is consistent with the Federal Service Labor-Management Relations Statute (the Statute) and assures employees the fullest freedom in the exercise of their rights. Regrettably, the majority's proposed rulemaking would discard a valuable reform without affording it even a reasonable trial period. In addition to finding this enterprise premature and ill-advised, I write separately to express several other disagreements with the majority's formulation of the Notice.

Initially, I note that the petition for rulemaking did not request the rescission of *OPM,* 71 FLRA 571 (2020), so it is puzzling how the majority could propose rescinding that decision as the result of granting the petition. Further, I do not believe that an Authority decision can be rescinded through a process that is designed to make rules. If there is legal authority to support this unprecedented approach, then it is missing from the Notice. Notably, when the Authority promulgated the current version of 5 CFR 2429.19, it did not purport to ''rescind'' *U.S. Army, U.S. Army Materiel Development and Readiness Command, Warren, Michigan,* 7 FLRA 194 (1981), which set forth the Authority's previous interpretation of § 7115(a) of the Statute.

Disappointingly, the Notice fails to address the convenient flip-flopping of the Petitioner's position on the Authority's regulatory powers. Just a few years ago, the Petitioner asserted that the Authority lacked the power to issue a rule on this topic, but now the Petitioner insists that the Authority must exercise its rulemaking power in this area. *Compare* NTEU, Comment Letter on Proposed Rule Concerning Miscellaneous and General Requirements (Apr. 9, 2020) at 7 (stating that the Authority would ''exceed its regulatory power'' by issuing a rule to govern when employees may revoke a dues assignment), *with* Pet. at 1 (stating that the Petitioner's proposed rule ''would make sound use of the Authority's rulemaking power'').

Some of the Petitioner's other claims are equally confusing. For example, the Petitioner claims that very few agencies and unions have implemented § 2429.19 because their existing collective-bargaining agreements predate the regulation's promulgation. Pet. at 9. Yet the Petitioner also claims that the regulation is seriously harming unions. *Id.* at 4–7. These two claims are contradictory: If very few unions have been complying with the regulation, then the Petitioner must be exaggerating the scope of the regulation's alleged harm in order to support the petition. Consequently, the Petitioner ought to explain its contradictory claims on the Authority's regulatory powers and the alleged harms from the regulation.

Appropriately, the Notice solicits comments about whether the Petitioner's proposed rule is consistent with the U.S. Court of Appeals for the D.C. Circuit's decision that § 7115(a) of the Statute is designed *primarily for the benefit of employees, not unions. AFGE, Council 214, AFL–CIO* v. *FLRA,* 835 F.2d 1458, 1460–61 (D.C. Cir. 1987). The Petitioner clearly views § 7115(a) as a congressional gift to unions, but judicial precedent says otherwise. *Compare* Pet. at 3 (stating that ''the purpose of [§]7115(a) was to create more financial stability and predictability for unions than before'' the Statute was enacted), *with AFGE, Council 214,* 835 F.2d at 1460 (stating that § 7115(a) ''was designed for the primary benefit and convenience of the employee''). The Petitioner offers three reasons why its proposed rule would be good policy, but none concerns a benefit to employees. According to the Petitioner, the proposed rule would ''provide unions with financial security and predictability,'' Pet. at 5, ''restore unions' status at the bargaining table,'' *id.* at 6, and ''[h]onor[]'' employees' choices by (ironically) restricting

employees' choices, *id.* at 7. As such, the proposed rule's subjugation of employees' individual interests to federal unions' institutional interests appears to conflict with § 7115(a)'s animating purpose.

Moreover, if the majority must issue this premature Notice, then I am gratified that the Notice invites comments on whether there should be a one-month, government-wide revocation period for terminating authorizations of dues withholding. This idea comes from one of the more interesting arguments in the petition. Specifically, the Petitioner asserts that ''the most apt analogy'' to the system of dues-withholding revocation that the Petitioner desires is ''health insurance premium payroll deductions.'' Pet. at 8. In that regard, the Petitioner notes that once federal employees select their health insurance, they generally must wait a year to change or cancel that insurance ''during a one-month window period called open season.'' *Id.* In keeping with the Notice, I urge commenters to offer their views on whether to amend § 2429.19 so that employees have at least one full month each year—occurring at the same time for all federal employees—to decide whether to terminate dues withholding.

There are good reasons to explore a framework for dues-withholding revocation that resembles the federal open season for health insurance. Under the previous system of dues-withholding revocation, before § 2429.19 was adopted, most union members could revoke their dues assignments only during short window periods that preceded the anniversary dates of the members' union enrollments. In an attempt to ensure higher and more predictable dues revenues, most federal unions erected obstacles to revocations. Miscellaneous and General Requirements, 85 FR 41,169, 41,171 (July 9, 2020) (discussing barriers to dues-withholding revocations). The Petitioner's proposed rule would reauthorize such obstacles. Far from a highly advertised, month-long decision period like open season, most employees under the previous system had about two weeks to revoke their previously authorized dues withholdings. Moreover, revocation forms could be rejected if employees did not know their anniversary dates, or did not correctly calculate their unique window periods using contract wording that was indecipherable to most readers. Miscellaneous and General Requirements, 85 FR at 41,171 (providing, as an example, that a revocation form ''must be submitted to the Union between the anniversary date of the effective date of the dues withholding and twenty-one (21) calendar days prior to the anniversary date''). Rather than seeking regulatory authorization to make revocations more difficult again, the Petitioner could ensure predictable revenues—and better serve employees—by offering quality benefits and services that convince union members of the value in continuing their dues payments.

Although the Notice necessarily requests comments on the implications of potentially rescinding § 2429.19 entirely, I wish that the majority had included in the Notice at least a glimpse of the potential consequences of this approach, in order to better focus any comments on this question. By mentioning rescission as little more than an afterthought, the Notice hampers commenters' abilities to offer thoughtful perspectives. Therefore, I encourage commenters to offer fulsome assessments of the potential rescission scenario—in particular, how it would affect the Authority's ability to adjudicate future dues-revocation disputes.

Finally, for the sake of accuracy, I wish to emphasize that § 2429.19 had both an ''effective date'' and an ''applicability date.'' Miscellaneous and General Requirements, 85 FR at 41,169. This distinction was critical to the Authority's conclusion that the rule applied only to the revocation of assignments that were authorized on or after August 10, 2020, and not to the revocation of assignments that were authorized before that date. *See* Office of the Federal Register, *Document Drafting Handbook,* Aug. 2018 Ed. (Rev. 1.4, dated Jan. 7, 2022) 3–9 to 3–10 (discussing the distinction between effective dates and applicability dates), *https://www.archives.gov/files/federal-register/write/handbook/ddh.pdf.*

I continue to strongly disagree that the Authority should expend valuable resources on this rulemaking. However, if commenters offer the benefit of their insights on the important matters that I have raised here, as well as the matters set forth in the Notice, then I hope that the majority will afford their perspectives the careful consideration that they deserve. I assure potential commenters that I will afford their views such consideration.

[FR Doc. 2022–27495 Filed 12–20–22; 8:45 am]

BILLING CODE 6727–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 328

RIN 3064–AF26

FDIC Official Sign and Advertising Requirements, False Advertising, Misrepresentation of Insured Status, and Misuse of the FDIC's Name or Logo

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Notice of proposed rulemaking and request for comment.

SUMMARY: The Federal Deposit Insurance Corporation (FDIC) is seeking comment on a proposal to modernize the rules governing use of the official FDIC sign and insured depository institutions' (IDIs) advertising statements to reflect how depositors do business with IDIs today, including through digital and mobile channels. The proposed rule also would clarify the FDIC's regulations regarding misrepresentations of deposit insurance coverage by addressing specific scenarios where consumers may be misled as to whether they are doing business with an IDI and whether their funds are protected by deposit insurance. The proposal is intended to enable consumers to better understand when they are doing business with an IDI and when their funds are protected by the FDIC's deposit insurance coverage.

DATES: Comments must be received by the FDIC no later than February 21, 2023.

ADDRESSES: Interested parties are invited to submit written comments, identified by RIN 3064–AF26, by any of the following methods:

- *Agency Website: https://www.fdic.gov/resources/regulations/federal-register-publications/.* Follow the instructions for submitting comments on the agency website.
- *Email: comments@fdic.gov.* Include RIN 3064–AF26 in the subject line of the message.
- *Mail:* James P. Sheesley, Assistant Executive Secretary, Attention: Comments—RIN 3064–AF26, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand delivered to the guard station at the rear of the 550 17th Street NW building (located on F Street NW) on business days between 7 a.m. and 5 p.m.
- *Public Inspection:* Comments received, including any personal information provided, may be posted

without change to *https://www.fdic.gov/resources/regulations/federal-register-publications/.* Commenters should submit only information that the commenter wishes to make available publicly. The FDIC may review, redact, or refrain from posting all or any portion of any comment that it may deem to be inappropriate for publication, such as irrelevant or obscene material. The FDIC may post only a single representative example of identical or substantially identical comments, and in such cases will generally identify the number of identical or substantially identical comments represented by the posted example. All comments that have been redacted, as well as those that have not been posted, that contain comments on the merits of the proposed rule will be retained in the public comment file and will be considered as required under all applicable laws. All comments may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Division of Depositor and Consumer Protection: Luke H. Brown, Associate Director, 202–898–3842, *LuBrown@FDIC.gov;* Meron Wondwosen, Senior Policy Analyst, 202–898–7211, *MeWondwosen@FDIC.gov;* Edward J. Hof, Senior Policy Analyst, 202–898–7213, *EdwHof@FDIC.gov;* Legal Division: James Watts, Counsel, 202–898–6678, *jwatts@FDIC.gov;* Vivek Khare, Counsel, 202–898–6847, *vkhare@fdic.gov.*

SUPPLEMENTARY INFORMATION: The FDIC is proposing to amend part 328 of its regulations, which includes requirements for use of the official FDIC sign and IDIs' advertising statements, as well as misrepresentations of insured status and misuse of the FDIC's name or logo. The proposed rule would generally: (1) modernize and amend the rules governing the display of the official sign in branches, to, for example, apply the rules to non-traditional IDI branches; (2) require the use of the FDIC official sign, a new digital sign, and other signs differentiating deposits and non-deposit products across all banking channels, including automated teller machines (ATMs) and evolving digital channels (which functionally serve as digital teller windows); (3) clarify the FDIC's rules regarding misrepresentations of deposit insurance coverage by addressing specific scenarios where information provided to consumers may be misleading; (4) amend definitions of ''non-deposit product'' to include crypto-assets; and (5) require IDIs to maintain policies and procedures addressing compliance with part 328. As explained below, the proposal is intended to enable consumers to better understand when they are doing business with an IDI and when their funds are protected by the FDIC's deposit insurance coverage.

Policy Objectives

In recent years there have been significant changes in the banking landscape, including continued evolution of bank branches and their role in serving depositors, substantially increased reliance on internet and mobile banking channels to access IDI banking services, and growth in financial technology (fintech) companies that seek to offer new options for accessing banking products and services. While these developments are beneficial, they may make it more difficult for depositors and consumers to understand when they are doing business with an IDI and when their funds are protected by the FDIC's deposit insurance. In addition, the FDIC has observed increased misleading representations about deposit insurance in internet banking channels, which can result in consumer confusion and harm. These types of misleading statements create uncertainty and could dilute and weaken the confidence that underpins banks and our nation's broader financial system.

To keep pace with the ongoing market and technological developments, the proposed amendments to part 328 are intended to promote several policy goals. Specifically, the FDIC hopes to bring the certainty and confidence historically provided by the FDIC sign at traditional IDI branch teller windows to the varied and evolving digital channels through which depositors are increasingly handling their banking needs today. These channels serve as the digital teller windows of the modern banking landscape, and it is critical that they provide clear, consistent, and accurate information about deposit insurance upon which consumers, businesses, and other entities may base their financial decisions.

The proposed rule would establish sign requirements across all banking channels, including evolving digital channels, to align with marketplace developments. The proposed sign requirements are also intended to more clearly distinguish insured deposits from non-deposit products, and to better distinguish IDIs from non-banks in the digital space. The proposed rule would allow consumers, businesses, and other entities to better understand when their funds are protected by the FDIC's deposit insurance. At the same time, the proposed sign requirements are intended to permit flexibility for IDIs and other firms in the marketing of their products and services.

The proposed amendments to the FDIC's rules regarding misrepresentations of deposit insurance coverage are intended to address specific scenarios where information provided to consumers may be misleading with respect to deposit insurance coverage. In particular, the FDIC is concerned that certain business relationships between IDIs and non-banks may be confusing to consumers, and proposes to require clear disclosures that would better inform consumers as to when their funds are protected by FDIC deposit insurance. Further clarity in this area would be beneficial for both consumers and the industry.

Background

The FDIC is an independent agency that maintains stability and public confidence in the nation's financial system by, among other things, insuring the deposits of all IDIs. The FDIC has helped to maintain public confidence in the nation's banking system in times of financial turmoil, including the period from 2008 to 2013, when the United States experienced a severe financial crisis, and more recently during the financial stress associated with the COVID–19 pandemic. The FDIC has proactively sought to protect consumers,[1] promote public confidence in insured deposits, and prevent false and misleading representations about the manner and extent of FDIC deposit insurance. Today, there are nearly 5,000 IDIs in the United States.[2]

Statutory Authority and Regulations

Sign and advertising statement requirements for IDIs date back to the Banking Act of 1935, and are now set forth in section 18(a) of the Federal Deposit Insurance Act (FDI Act).[3] Section 18(a) grants the FDIC authority to prescribe regulations with respect to these requirements, which are currently contained in subpart A to 12 CFR part 328.[4]

[1] As used in this document, the term ''consumer'' means any current or potential depositor, including natural persons, organizations, corporate entities, and governmental bodies. *See* 12 CFR 328.101.

[2] FDIC's BankFind Suite, available at: *https://banks.data.fdic.gov/bankfind-suite/bankfind.*

[3] 12 U.S.C. 1828(a)(1). Section 9 of the FDI Act provides the FDIC the authority to prescribe rules and regulations as it may deem necessary to carry out the provisions of this Act or of any other law which it has the responsibility of administering or enforcing. 12 U.S.C. 1819(a) Tenth.

[4] *See* subpart A to 12 CFR part 328 (§§ 328.0 through 328.5–328.99).

The FDIC's official sign and advertising statement regulations require banks to continuously display the FDIC official sign where insured deposits are usually and normally received in the bank's principal place of business and at all of its branches and to use an official advertising statement, such as ''Member FDIC,'' when advertising deposit products and services.[5]

The agency last made major amendments to these regulations in 2006.[6] The current text of the FDIC's sign regulations refer to an IDI's physical premises and Remote Service Facilities, but does not specify other banking channels that have since developed.[7]

In addition, section 18(a)(4) of the FDI Act prohibits any person from misusing the name or logo of the FDIC or from engaging in false advertising or making knowing misrepresentations about deposit insurance.[8] The FDIC has broad statutory authority in this area, and earlier this year, issued specific regulations in subpart B to 12 CFR part 328 regarding false representations related to FDIC insurance and the misuse of the FDIC name and logo.[9] Since the new subpart B regulations took effect, the FDIC has observed additional misconduct by entities misusing the FDIC's name or logo and misrepresenting the extent of FDIC insurance coverage.

Developments in Consumer Access to Banking and Financial Services

In recent years, there have been significant changes in the banking landscape, including the evolution of bank branches and their role in serving consumers, the proliferation of digital channels as a critical and fundamental mechanism to access banking and financial services, and an increasingly broad array of financial products offered through banking channels, including access to non-deposit products. The following overview of these trends is intended to provide context for the proposed rule, which seeks to enable consumers to better understand when they are doing business with an IDI and when their funds are protected by FDIC deposit insurance coverage.

Many bank branches retain a traditional physical branch footprint, serving depositors primarily at teller windows or stations. According to the FDIC's 2021 National Survey of Unbanked and Underbanked Households (Household Survey), roughly 63.4 percent of all banked households used a bank teller to access their accounts at least once in the last 12 months, including 57.8 percent of the youngest banked households between the ages of 15 to 24, and 72.2 percent of the oldest banked households aged 65 or older.[10] However, IDIs have increasingly begun operating branches with different styles and designs. These locations may include electronically-staffed kiosks, interactive ATMs that provide remote assistance with a teller, and teller-less cafés where deposits can be accepted on tablets or through ATMs. The FDIC's existing sign rules, which focus on display of the official sign at teller windows or stations, have not kept pace with these developments.

The existing sign rules also do not reflect evolving digital channels, which have become an increasingly important means of access to banking products and services. While some consumers continue to visit branches, others rely on ATM access and digital channels such as online banking and mobile banking. For these consumers, an IDI's ATM, website, or mobile application effectively serves as a digital teller window. The results of the Household Survey show that the proportion of banked households that used *mobile* banking as their primary method of bank account access increased from 34.0 percent in 2019 to 43.5 percent in 2021.[11] The proportion of banked households that used *online* banking as their primary method of bank account access was similar in 2019 (22.8 percent) and 2021 (22.0 percent).[12] Combined, 65.4 percent of banked households in 2021 used *mobile or online* banking as their primary method of bank account access, up from 56.8 percent in 2019.[13] Given that nearly two-thirds of banked households primarily access banking products through phones, computers, and other devices, the FDIC believes it is critical to update and provide consistent sign requirements for digital channels.

Banking customers are also offered an increasingly wide array of products and services, regardless of whether they are in a branch, using an ATM, or connecting with an IDI through digital channels. In many instances, IDIs offer both deposits and non-deposit products to consumers. For example, IDIs might allow depositors in their branches to consult with an investment adviser and purchase securities or mutual funds. Options to purchase non-deposit products are continuing to evolve, with some IDIs offering ATM or digital banking customers the ability to purchase crypto-assets with their funds. Absent adequate signs or disclosures, simultaneous offering of both insured deposits and non-deposit products may lead consumers (who are aware that the IDI is insured by the FDIC) to mistakenly conclude that all of the products being offered are insured. Some of these uninsured products may be speculative.

Growth in the fintech sector has also served to blur the distinction between IDIs and non-banks in the eyes of many consumers, increasing the potential for confusion regarding deposit insurance coverage. Business arrangements between IDIs and non-banks can take many forms and continue to evolve at a rapid pace. For example, an IDI might enter into an arrangement with the fintech company to offer the IDI's products to the fintech company's customers. In other instances, fintech companies might deposit their customers' funds at an IDI. In such cases, the fintech company might state to its customers that their funds are FDIC-insured, or that they are insured by the FDIC on a ''pass-through'' basis, without an accurate explanation of what this means. The proliferation of relationships and disclosures may confuse consumers as to whether they are dealing with an IDI, whether their funds are insured by the FDIC, and the risks they are protected against.

Industry Outreach—Request for Information

In February 2020 and April 2021, the FDIC published Requests for Information (collectively, the ''RFIs'') in the **Federal Register** to seek public input regarding potential modernization

[5] *See generally,* 12 CFR part 328.

[6] 71 FR 66098 (Nov. 13, 2006).

[7] *See* 12 CFR 328.2. ''Remote Service Facility'' includes any automated teller machine, cash dispensing machine, point-of-sale terminal, or other remote electronic facility where deposits are received. 12 CFR 328.2(a)(1)(ii).

[8] 12 U.S.C. 1828(a)(4). Section 18(a)(4) also provides the FDIC independent authority to investigate and take administrative enforcement actions, including the power to issue cease and desist orders and impose civil money penalties, against any person who misuses the FDIC name or logo or makes misrepresentations about deposit insurance. 12 U.S.C. 1828(a)(4)(C)–(D). Further, under Federal law, it is also criminal offense to misuse the FDIC name or make false representations regarding deposit insurance. *See* 18 U.S.C. 709.

[9] 87 FR 33415 (June 2, 2022); Subpart B to 12 CFR part 328 (§§ 328.100 through 328.109). Subpart B establishes the process by which the FDIC will identify and investigate conduct that may violate section 18(a)(4), the standards under which such conduct will be evaluated, and the procedures which the FDIC will follow when formally and informally enforcing the provisions of section 18(a)(4).

[10] Federal Deposit Insurance Corporation (FDIC), *2021 National Survey of Unbanked and Underbanked Households* (October 2022).

[11] *Id.*

[12] *Id.*

[13] *Id.*

of the official sign and advertising rules to reflect changes in deposit-taking via physical branch, digital, and mobile banking channels.[14] In response to the RFIs, the FDIC received 20 comments from trade associations, IDIs, and others.[15] In addition, FDIC staff met with representatives from IDIs, a technology service provider, and consumer groups. Commenters generally recognized the importance and value of displaying FDIC signs and the advertising statement, and some commenters stressed that depositors place significant trust in FDIC signs.

The majority of comments recognized the need for updating FDIC sign and advertising requirements in response to changes in industry practice and the increasingly significant role played by digital and mobile banking. At the same time, commenters generally favored greater flexibility in terms of the size, design, and location of the official FDIC sign at IDIs' branches. Several commenters proposed requiring a single, conspicuous physical or digital display in the teller area as opposed to smaller signs placed at each window. Some commenters suggested amending the continuous display requirement to allow for rotating digital disclosures.

Commenters also indicated that consumers assume products offered through IDIs are insured and emphasized the importance of enabling consumers to identify uninsured products and understand the role of third parties in offering such products.

Commenters also suggested that the FDIC clarify how sign requirements apply to digital and mobile banking channels. While some requested clarity on the size and location of the FDIC sign on web pages and mobile applications, others urged the FDIC to adopt a flexible policy that better accounts for technological limitations and preservation of user experience. Similarly, several commenters requested clarity on how teller window sign requirements apply to digital banking channels and revisions to the definition of Remote Service Facility to incorporate digital and mobile banking. Some IDIs also indicated that they voluntarily display the FDIC advertising statement on their digital pages.

One commenter noted the increase in uninsured entities offering products and services similar to banks, and indicated the risk of consumer confusion will likely increase. This commenter suggested a clear articulation by the FDIC regarding the obligations that non-banks have with respect to offering these products and services, whether insured or not, can promote consumer understanding and mitigate the risk of consumer confusion.

With respect to advertising requirements, many commenters sought clarification on which products and services require the advertising statement. Some commenters proposed permitting advertisements to host the required statement ''one click away'' in order to permit greater flexibility in advertising format, while others expressed concern that such an arrangement would lead to greater consumer confusion about whether advertised products qualify for deposit insurance.

The FDIC carefully considered comments received in response to the RFIs in formulating this proposal, and remains committed to considering further public input on the modernization of its sign and advertising requirements through this document and comment process. Certain commenters' suggestions are discussed in further detail in the ''Alternatives Considered'' section of this document.[16]

Previous Rulemaking

On May 17, 2022, the FDIC issued a final rule adding a new subpart B to 12 CFR part 328. The final rule describes: (1) the process by which the FDIC will identify and investigate conduct that may violate the prohibitions against misuse and misrepresentation; (2) the standards under which such conduct will be evaluated; and (3) the procedures that the FDIC will follow when formally and informally enforcing these prohibitions.

While this rulemaking was an important step, the FDIC has observed an increase in the number of instances where financial services providers or other entities or individuals have misused the FDIC's name or logo or have made misrepresentations about FDIC insurance. This has caused continuing challenges for consumers in determining whether they are doing business with an IDI and whether their funds are protected by the FDIC's deposit insurance coverage. The FDIC believes that further clarification of subpart B may be helpful to address these challenges, particularly to address specific situations where consumers may be misled as to whether an entity is insured by the FDIC or the nature and extent of deposit insurance coverage.

Description of the Proposed Rule

As explained above, the FDIC is proposing to modernize its sign and advertising requirements to reflect current banking practices, including updating the rules to reflect that deposit-taking via physical branch, digital, and mobile banking channels has evolved since the FDIC last significantly updated its rules in 2006. While various channels are used to access bank products, the FDIC aims to establish sign and advertising requirements that enable IDIs' customers to clearly understand when their funds are protected by the FDIC's deposit insurance coverage. The proposed changes to the sign rules include requirements for physical bank premises, digital channels such as online banking websites and mobile applications, and automated teller machines and similar devices. For simplicity, requirements applicable to each of these channels are set forth in separate sections of the proposed rule.

The proposed rule's sign requirements include three distinct signs relating to deposit insurance. The first is the FDIC's official sign, which is currently displayed at IDIs' principal place of business and branches. Second, the proposed rule would require the display of a digital sign on IDIs' digital deposit-taking channels, such as online banking websites and mobile applications. The digital sign, which would be an abbreviated version of the FDIC's official sign, would promote a clear understanding by consumers of when they are interacting with an IDI rather than a non-bank and when their funds are insured by the FDIC. Third, the proposed rule includes a non-deposit sign requirement that would address the potential for consumer confusion where an IDI offers both insured deposits and non-deposit products through the same channel (*e.g.,* insured deposits and non-deposit products are both offered at a branch). In such instances, the IDI's display of the official FDIC sign could lead consumers to believe that the non-deposit products are insured, absent additional information. Although sold via IDI banking channels, these products: are not insured by the FDIC; are not deposits; and may lose value. This non-deposit sign requirement is intended to be generally consistent with practices described in the longstanding interagency guidance on the retail sale

[14] 85 FR 18528 (Feb. 26, 2020); 86 FR 18528 (Apr. 9, 2021).

[15] Comments to the RFIs can be found on the FDIC's website, *available at https://www.fdic.gov/resources/regulations/federal-register-publications/2020/2020-rfi-fdic-sign-and-advertising-requirements-3064-za14.html and https://www.fdic.gov/resources/regulations/federal-register-publications/2021/2021-rfi-fdic-official-sign-and-advertising-requirements-3064-za14.html.*

[16] *See infra* Section IV.

of non-deposit investment products [17] that many institutions already follow, and thus should be familiar to many consumers.

The FDIC is also proposing limited amendments to its official advertising statement requirements. These updates would provide IDIs with an additional option for a shortened official advertising statement, and include technical corrections to address the statutory increase of the deposit insurance amount that has occurred since the regulation was last amended.

In addition, the FDIC is proposing to amend the provisions of subpart B to provide further clarity on the application of the misrepresentation statute in specific situations where consumers may misunderstand or be misled as to whether an entity is insured by the FDIC or the nature and extent of deposit insurance coverage. The proposed rule is described in further detail below.

Official Sign for IDIs

The proposed rule would retain the existing design of the official sign, which, in addition to prominently bearing the name of the FDIC, includes statements indicating that each depositor is insured up to at least $250,000 and that the FDIC's deposit insurance is backed by the full faith and credit of the U.S. government. Also consistent with current regulations, the proposed rule would define the ''symbol'' of the FDIC as the portion of the official sign that consists of ''FDIC'' and the statements ''Each depositor insured to at least $250,000'' and ''Federal Deposit Insurance Corporation *www.fdic.gov*.''

The proposed rule would retain an IDI's ability to procure physical versions of the official sign from the FDIC for official use at no charge, or to procure similar signage from commercial suppliers at their own expense. Any IDI that promptly submits a written request for an official sign to the FDIC would not be deemed to have violated the rule by failing to display the official sign, unless the IDI fails to display the official sign after receiving it.

Sign Requirements on IDIs' Physical Premises

Section 328.3 of the proposed rule would govern signage within an IDI's premises. Consistent with current regulations, all IDIs would be required to continuously, clearly, and conspicuously display the official sign in their principal place of business and all their U.S. branches.[18] To accommodate evolving styles and footprints of branches, however, the proposed rule would provide separate requirements for traditional footprint branches and non-traditional branches or other places of business, such as café-style branches.

Official Sign in Traditional Branches

IDIs have traditionally received deposits at teller windows or stations, and the proposed rule would continue to provide for display of the official sign at traditional footprint branches in a manner consistent with current regulations. If deposits are usually and normally received at teller windows or stations, IDIs would generally be required to display the official sign at each teller window or station in a size of 7″ by 3″ or larger, with black lettering on a gold background. The FDIC believes, however, that it is appropriate to allow additional flexibility with respect to display of the official sign in instances where the IDI only offers deposit products on the premises. In such cases, the requirement to display the official sign could be satisfied by displaying the official sign in one or more locations visible from the teller windows or stations, in a size large enough to be legible from anywhere in that area. If the IDI also offers non-deposit products on the premises, display of the official sign at each teller window would be required, consistent with current regulations. Under the proposed rule, non-deposit signage would also be required as described below.

Official Sign in Non-Traditional Branches

The proposed rule also would include sign requirements that accommodate the non-traditional footprint branches operated by some IDIs. For example, some IDIs operate café-style branches that include open areas where customers work with bankers. These branches may, or may not, include traditional teller windows or stations. Under the proposed rule, if insured deposits are usually and normally received in areas of the premises other than teller windows or stations, the IDI would be required to display the official sign in one or more locations in a size large enough to be legible anywhere in those areas. The FDIC believes that such signage would ensure that customers are aware that their deposits are protected by deposit insurance. If the IDI also offers non-deposit products on the premises, under the proposed rule, non-deposit signage would also be required as described below.

Non-Deposit Signs on IDIs' Premises

The FDIC is proposing a new requirement for non-deposit signs when both insured deposits and non-deposit products are offered within the IDI's premises. In such instances, an IDI would be required to physically segregate the areas where non-deposit products are offered from areas where insured deposits are usually and normally accepted, and display a sign in the non-deposit areas indicating that non-deposit products: are not insured by the FDIC; are not deposits; and may lose value.[19] This non-deposit sign would be required to be continuously, clearly, and conspicuously displayed; however, the proposed rule does not include specific design or size requirements. To minimize the potential for consumer confusion, the proposed rule would prohibit display of non-deposit signs in close proximity to the official FDIC sign. The proposed rule's non-deposit sign requirements would apply to both traditional footprint branches and non-traditional footprint branches. IDIs that do not offer non-deposit products through traditional or non-traditional branches would not be impacted by this part of the proposal.

Use of Electronic Media or Varied Signs To Satisfy Official Sign and Non-Deposit Sign Requirements on IDIs' Premises

The proposal also provides IDIs the flexibility to utilize electronic media to satisfy sign requirements on an IDI's premises. Electronic signs have become increasingly common in retail environments, and the proposed rule includes a provision expressly permitting the use of electronic media to display required signs. This would apply to both display of the official sign and non-deposit signage, where required. However, where the proposed rule requires ''continuous'' display of signs, this applies equally to signs

[17] *See Interagency Statement on Retail Sales of Nondeposit Investment Products,* FIL–9–94 (Feb. 17, 1994).

[18] The term ''branch'' would be defined by reference to the FDI Act's definition of ''domestic branch,'' 12 U.S.C. 1813(*o*). The FDI Act broadly defines ''domestic branch'' to include any branch bank, branch office, branch agency, additional office, or branch places of business at which deposits are received or checks paid, or money lent. The FDIC believes this definition would generally also include non-traditional footprint branches where customers can receive customer assistance from bank personnel to perform these core banking functions.

[19] As noted above, this requirement is intended to be generally consistent with longstanding interagency guidance on the retail sale of non-deposit investment products that many institutions already follow, and thus should be familiar to many consumers.

utilizing electronic media. Accordingly, a rotating display that includes the required sign periodically would not satisfy the ''continuous'' requirement.

The proposed rule also would retain certain provisions of current regulations that provide IDIs with flexibility in displaying the official sign. IDIs would have the option to display the official sign in locations on the premises other than those required under the rule, except for in areas where non-deposit products are offered. For locations where display of the official sign is required, IDIs could choose to display signs that vary from the official sign in size, color, or material, provided that the sign is no smaller than the official sign, has the same color for the text and graphics, and includes the same content.

New Institutions

Also consistent with current regulations, an IDI would be required to display the official sign at its premises no later than its twenty-first calendar day of operation as an insured institution, unless it promptly requested the official sign from the FDIC but did not receive the official sign before that date.

Sign Requirements for IDIs' Digital Channels

As explained above, consumers are increasingly using IDIs' websites and mobile banking applications to open deposit accounts, deposit and transfer funds, and buy and sell non-deposit products. For many consumers, an IDI's website and applications are the primary method of accessing banking products and, in turn, these platforms functionally serve as a digital teller window. Given these developments, the FDIC believes it is important to require signage with respect to IDIs' digital deposit-taking channels that is consistent with in-branch signage, to the extent feasible. This would promote a clear understanding by consumers of when they are interacting with an IDI and when their funds are protected by the FDIC's deposit insurance coverage.

The proposed rule aims to establish sign requirements applicable to any medium through which deposits are usually and normally received. These changes are intended to enhance consistency of signage between IDIs' digital deposit-taking channels and other traditional channels, providing helpful clarity for consumers.

Digital Deposit-Taking Channels

Section 328.5 of the proposed rule would define ''digital deposit-taking channels'' to mean any electronic communications methods through which an IDI accepts insured deposits. This would include, but not be limited to, IDI websites, web-based applications, and mobile applications that offer consumers access to insured deposits at IDIs. The FDIC intends that the proposed rule would apply to digital channels where insured deposits are received that are analogous to the traditional teller windows or stations that consumers interact with at an IDI's physical premises. The language of the proposed rule is intended to accommodate the ongoing evolution of internet and mobile application infrastructure.

Digital Sign Requirement for Digital Deposit-Taking Channels

Under the proposed rule, an IDI would be required to clearly, continuously, and conspicuously display a digital sign on the IDI's homepage, landing and login pages or screens, and transactional pages or screens involving deposits, to the extent applicable. This digital sign would be intended to visually communicate to consumers that they are doing business with an IDI rather than a non-bank entity. As the homepage and landing page are generally the primary point of interaction between IDIs and consumers, such display would prominently disclose to consumers that the entity is FDIC-insured. The FDIC also believes it is appropriate to require the digital sign on the login page so consumers are informed before signing up for or signing into an online account that such an account is associated with an IDI rather than a non-bank entity. Display of the digital sign also would be required on pages where the customer transacts with insured deposits.

IDIs would be required to display the digital sign clearly, continuously, and conspicuously on the relevant pages or screens under the proposed rule. To be clear and conspicuous, the digital sign must be displayed in a continuous manner, near the top of the relevant page or screen, in close proximity to the IDI's name. Display of the digital sign at the footer of the relevant page or a similar location would not satisfy the clear and conspicuous standard.

It may be helpful to consumers if IDIs link the digital sign to the FDIC's online BankFind tool. Such a link would take the consumer to FDIC's BankFind web page and make consumer due diligence easier than it is currently, which in turn would help consumers differentiate IDIs from non-banks.[20] This is not a requirement under the proposed rule, however, and IDIs would have the discretion to include such a link when displaying the digital sign.

Digital Sign Design

The FDIC recognizes that IDIs may not as easily display the official FDIC sign, described above, on websites and application pages and is therefore proposing to require a digital sign that would be an abbreviated version of the official sign. The FDIC expects that a digital sign would prominently bear the name of the FDIC and the statement that insured deposits are backed by the full faith and credit of the U.S. Government. The proposed rule does not include, and the FDIC is soliciting comment on, a design for the digital sign that includes these elements.

Digital Deposit-Taking Channels Are Not Advertisements

The FDIC does not intend for the proposed digital sign requirement to overlap with the general advertising statement requirements that apply to IDIs. As discussed above, the proposed digital sign would be displayed on an IDI's homepage, landing and login pages, and transactional pages involving insured deposits. The FDIC views these pages as environments where the customer may interact directly with the IDI, rather than as ''advertisements'' as defined in the rule's advertising statement requirements.[21] To the extent these pages can be considered ''advertisements,'' the inclusion of the digital sign on these pages would make clear that the IDI is insured by the FDIC, making use of the official advertising statement unnecessary under proposed § 328.6(d)(10). IDIs, however, would remain responsible for complying with the official advertising statement requirements for other qualifying advertisements, including those contained on other web pages.

Non-Deposit Digital Signage Requirements When Non-Deposit Products and Deposit Products Are Offered Through Same Digital Deposit-Taking Channel

The FDIC believes there is an increased risk of consumer confusion regarding deposit insurance coverage when both deposits and non-deposit products are offered through the same digital deposit-taking channel. Under the proposed rule, if a digital deposit-taking channel offers both access to deposits and non-deposit products, the

[20] The FDIC intends to update its online BankFind page with useful deposit insurance information for consumers as well as instructions on how to use BankFind so consumers could more easily verify that an entity is FDIC-insured.

IDI would be required to clearly and conspicuously display signage indicating that the non-deposit products are: (1) not insured by the FDIC; (2) are not deposits; and (3) may lose value. IDIs would be required to display this non-deposit signage via a one-time notification when consumers initially access such a page. Such notification would provide an initial, prominent display of the non-deposit signage to alert consumers that they are dealing with non-deposit products that are not subject to FDIC-insurance. Moreover, consumers would need to take action to dismiss the notification before accessing the relevant page or screen. This could include, for example, an IDI using a ''pop-up,'' [22] ''speedbump,'' [23] or ''overlay'' [24] that displays a notification to the consumer that the consumer must dismiss before accessing the content related to non-deposit products.

In addition, the proposed rule would require the continuous display of the non-deposit signage on each page relating to non-deposit products and prohibit displaying the non-deposit signage in close proximity to the digital FDIC sign. The FDIC would expect the non-deposit signage to be in a prominent place, in an appropriate size, and displayed in a continuous manner for a consumer accessing the page to notice.[25] The FDIC believes, however, that institutions should have flexibility in the way they market non-deposit products and is not proposing specific design or size requirements for this non-deposit signage.

Automated Teller Machines and Similar Devices

Section 328.4 of the proposed rule governs signage requirements for IDIs' automated teller machines (ATMs) and other remote electronic facilities that receive deposits. The FDIC seeks to ensure that depositors receive necessary disclosures regarding deposit insurance as banks continue to devise new ways to provide services outside of physical branches. The proposed rule intends to capture banking kiosks and other devices currently defined as ''Remote Service Facilities'' [26] that receive deposits. This section of the proposed rule is not intended to address online and mobile banking channels, which are considered ''digital deposit-taking channels'' under the proposed rule.

Under current regulations governing ATMs and like devices, IDIs have the option to display the physical official FDIC sign. The FDIC believes, however, that accurate signage across digital, mobile, and physical banking channels is critical to providing clear information on deposit insurance coverage to depositors. The proposed rule would require display of the official FDIC sign on IDIs' ATMs and like devices. The FDIC recognizes that requiring a physical sign may lead to formatting issues, maintenance costs, and difficulty in updating devices when signage requirements change. In order to accommodate those concerns, the proposed rule would require the electronic display of the official sign on the ATM or like device.

The proposed rule provides that the official FDIC sign must be electronically displayed clearly and conspicuously. ATMs and like devices must, at a minimum, display the official FDIC sign on the home page or screen and each transaction page or screen relating to deposits.

While ATMs and similar devices offer less of an opportunity to physically separate deposit products from non-deposit products, the proposed rule nevertheless distinguishes these products to reduce the potential for consumer confusion. Clear signage can be important in this setting because customers often interact with ATMs alone, including when bank branches are otherwise closed, without an opportunity to ask clarifying questions or for a bank representative to ensure that customers fully understand disclosures. As such, the proposed rule would require electronic non-deposit signs where an ATM or like device both receives deposits for an IDI and offers access to non-deposit products.[27] The ATM or like device would be required to clearly, continuously, and conspicuously display electronic disclosures indicating that non-deposit products: are not insured by the FDIC; are not deposits; and may lose value. The proposed rule would require the display of these disclosures on each transaction page or screen relating to non-deposit products.

Official Advertising Statement for IDIs

The FDIC is proposing limited amendments to the advertisement statement requirements. The proposed rule would expand IDIs' options for use of a short advertising statement.

Currently, IDIs must include the official advertising statement in all advertisements that promote deposit products. The term advertisement means a commercial message in any medium that is designed to attract public attention or patronage to a product or business.[28] The FDIC views this definition to include advertising published through social media channels.

The current regulation allows IDIs to use the short title ''Member of FDIC,'' ''Member FDIC,'' or a reproduction of the symbol of the corporation (defined in § 328.2(b)). In addition to these options, to provide additional flexibility, the proposed rule would allow the use of ''FDIC-insured.''

The FDIC also proposes to make a technical correction to the reference to the deposit insurance limit found in paragraph (d)(10) of the current regulation, which states that ''deposits or depositors are insured by the Federal Deposit Insurance Corporation to at least $100,000 for each depositor.'' As a technical correction, the proposed rule would instead reference the standard maximum deposit insurance amount defined in § 330.1 of the FDIC's regulations, currently $250,000.

Misrepresentations and Material Omissions by Any Person

The FDIC believes that it may be beneficial to provide further clarity on the application of the misrepresentation statute in specific situations where consumers may be misled as to whether an entity is insured by the FDIC or the nature and extent of deposit insurance coverage. The FDIC is proposing to amend subpart B to expressly address these situations, making clear when specific statements or omissions constitute a misrepresentation under section 18(a)(4).

Use of the Official Advertising Statement or FDIC-Associated Terms or Images

Consumers have historically identified the use of the official advertising statement (such as ''Member FDIC'') and FDIC-Associated Terms or FDIC-Associated Images to signify that they are dealing with an IDI and will

[22] A ''pop-up'' refers to a screen generated when a consumer clicks on particular hyperlink.

[23] A ''speedbump'' refers to an intermediate page that appears, requiring the user to take action to transition to the next page.

[24] An ''overlay'' refers to a content box that appears on a web page or screen and obscures the background content.

[25] Some IDIs currently display non-deposit disclosures in small font near the bottom of web pages and application screens. Consumers are unlikely to notice such disclosures and may mistakenly believe that non-deposits products are covered by FDIC-insurance. Such display of non-deposit disclosures would not satisfy the clear, continuous, and conspicuous display requirement of the proposed rule.

[26] ''Remote Service Facility'' includes any automated teller machine, cash dispensing machine, point-of-sale terminal, or other remote electronic facility where deposits are received. 12 CFR 328.2(a)(1)(ii).

[27] The FDIC would not view postage stamps sold at ATMs to require these disclosures.

[28] 12 CFR 328.3(a), (c).

receive the protection of deposit insurance. As noted above, however, the official advertising statement and FDIC-Associated Terms and FDIC-Associated Images have increasingly been used by non-banks that purport to deposit their customers' funds at IDIs. The FDIC believes that use of the official advertisement or FDIC-Associated Terms or FDIC-Associated Images in such instances presents a high risk of confusing consumers as to whether they are dealing with an IDI and whether deposit insurance applies to their funds.

To address this risk, the proposed rule would amend § 328.102(a) to clarify specific circumstances under which use of the official advertising statement, FDIC-Associated Terms, or FDIC-Associated Images by a non-bank would constitute a misrepresentation of insured status. The FDIC believes that use of the official advertising statement, FDIC-Associated Terms, or FDIC-Associated Images by a non-bank may inaccurately imply that the non-bank is FDIC-insured. For example, a non-bank's use of the ''Member FDIC'' logo on its website or in its marketing materials would be a misrepresentation unless that logo is next to the name of one or more IDIs. As another example, a non-bank's use of either the official FDIC sign or the digital sign that IDIs would be required to display through their digital deposit-taking channels (under proposed § 328.5) would be a misrepresentation if it inaccurately implies that the non-bank is insured by the FDIC and backed by the full faith and credit of the U.S. government. Similarly, a non-bank's use of FDIC-Associated Terms in statements suggesting that the non-bank is insured by the FDIC would constitute a misrepresentation.[29]

Failure To Disclose That a Person Is a Non-Bank Is a Material Omission When a Statement Is Made Regarding Deposit Insurance

Non-banks that purport to deposit their customers' funds at IDIs sometimes make statements regarding deposit insurance coverage for those funds. Absent additional context, such statements misrepresent the insured status of the non-bank and suggest that the FDIC's deposit insurance will protect consumers in the event of the non-bank's insolvency. To minimize risk of consumer confusion, the proposed rule provides that if a non-bank makes statements regarding deposit insurance for its customers, it is a material omission for the non-bank to fail to clearly and conspicuously disclose that it is not itself an FDIC-insured institution and that the FDIC's deposit insurance coverage only protects against the failure of an FDIC-insured depository institution. In the FDIC's view, this additional disclosure is necessary to prevent consumers from misinterpreting a non-bank's assertions regarding deposit insurance coverage. The FDIC notes that some non-banks already include such language on their websites, often identifying the partner IDI through which banking services are provided.[30] The proposed rule does not prescribe specific disclosure language; however, it explains that a statement that a person is not an FDIC-insured bank and deposit insurance covers the failure of an insured bank would be considered a clear statement for purposes of this provision. This approach gives non-banks that wish to make statements regarding deposit insurance coverage some flexibility in how they communicate the required information.

Failure To State That Non-Deposit Products Are Not Insured by the FDIC Is a Material Omission When a Statement Is Made Regarding Deposit Insurance

The FDIC's experience suggests that deposits and non-deposit products are increasingly being offered to consumers in ways that fail to distinguish which products are insured by the FDIC. For instance, marketing materials might emphasize the deposit insurance protection that applies to some products while failing to make clear that not all of the products offered are FDIC-insured. In other instances, firms have represented to their consumers that non-deposit products are eligible for deposit insurance coverage, which has led consumers to believe, mistakenly, that their money or investments are protected by deposit insurance. The FDIC believes that where banks or non-banks make statements regarding deposit insurance in a context where deposits and non-deposit products are involved, additional information is necessary to ensure that consumers understand which products are subject to deposit insurance. To prevent consumer confusion, the proposed rule provides that if a person makes statements regarding deposit insurance in a context that involves both deposits and non-deposit products, it is a material omission to fail to disclose that non-deposit products: are not insured by the FDIC; are not deposits; and may lose value. For example, if a non-bank's website offered customers the option to have their funds deposited at an IDI and protected by deposit insurance or invested in non-deposit products, it would be a material omission if the non-bank's website failed to state that the non-deposit products are not insured by the FDIC, are not deposits, and may lose value.

Failure To State That Requirements Apply To Pass-Through Deposit Insurance

The FDIC has a long history of providing ''pass-through'' deposit insurance coverage, meaning that deposits placed at an IDI by a party on behalf of one or more owners are insured as if deposited directly at the IDI by the owner(s). Pass-through insurance allows each owner of the funds in such an arrangement to be separately insured up to the statutory deposit insurance limit, currently $250,000, even if the total deposit of all owners (in the aggregate) exceeds the $250,000 limit. Pass-through insurance only applies, however, if certain regulatory requirements are satisfied.[31]

Arrangements that rely on pass-through insurance have become increasingly common, with non-banks often claiming to provide the protection of pass-through deposit insurance for consumers' funds. Such representations, however, may be inaccurate and mislead consumers and fail to apprise them of the risk they face in the event that the pass-through deposit insurance requirements have not been satisfied. If the pass-through requirements are not met, consumers' funds may not be fully insured in the event the IDI where the funds have been deposited were to fail. The FDIC believes that where parties make statements regarding the application of pass-through deposit insurance, additional disclosure is necessary to ensure that consumers are aware of this risk.

[29] These examples are intended to be illustrative, rather than an exhaustive list of ways in which a non-bank might misrepresent its insured status. Any use of the official advertising statement, FDIC-Associated Terms, or FDIC-Associated Images that inaccurately states or implies that the non-bank is insured by the FDIC would violate the proposed rule.

[30] For example, ''ABC Co. is not an FDIC-insured depository institution; banking services provided by XYZ Bank, Member FDIC.''

[31] *See* 12 CFR 330.5, 330.7. For pass-through deposit insurance to apply: (1) the deposit account records of the IDI must disclose a basis for pass-through coverage, such as a custodial or agency relationship; (2) the identities and interests of the actual owners of the funds must be ascertainable either from the records of the IDI or records maintained in good faith and in the regular course of business by another party; and (3) the relationship that provides the basis for pass-through deposit insurance coverage must be genuine, with the deposited funds actually owned by the named owners. Additional requirements apply to arrangements involving multiple levels of relationships.

The proposed rule provides that if a person makes statements regarding pass-through deposit insurance for its customers' funds, it is a material omission to fail to clearly and conspicuously disclose that certain conditions must be satisfied for pass-through deposit insurance coverage to apply. The proposed rule would not require a person making a statement regarding pass-through deposit insurance to list the specific conditions that must be satisfied; simply referencing that conditions must be satisfied would be sufficient under the proposed rule. The proposed rule also does not prescribe specific disclosure language, providing flexibility in how parties may wish to express the necessary information. For example, if a website for a financial product were to state that consumers' funds are eligible for pass-through deposit insurance, it would be a material omission to fail to clearly and conspicuously state that certain conditions must be satisfied in order for pass-through insurance to apply.

Policies and Procedures for IDIs

As described in this document, the FDIC is proposing changes to (1) its signage and advertising statement requirements for IDIs under subpart A and (2) clarifications to the misrepresentations rule under subpart B. The proposed rule would require IDIs to establish written policies and procedures related to these requirements that are commensurate with the nature, size, complexity, scope, and potential risk of the deposit-taking activities of the institution. As part of these policies and procedures, IDIs would also need to include, as appropriate, provisions related to monitoring and evaluating activities of persons that provide deposit-related services to the IDI or offer IDI's deposit-related products or services to other parties.

Signs, Advertising Statement, and Misrepresentations

Such policies and procedures could include, for example, measures that an IDI would take to ensure compliance with the proposed sign and advertising requirements when the IDI changes its advertising strategy or engages with, or expands into, new physical or digital deposit-taking channels. For example, this could include, if applicable, establishing procedures to ensure that the IDI's technology (*e.g.,* websites and mobile applications) is capable of implementing the proposed sign and advertisement statement requirements across all digital deposit-taking channels.

Ultimately, an institution's policies and procedures would need to be commensurate with the nature, size, complexity, scope, and potential risk of its deposit-taking activities. For instance, an IDI that offers an array of non-deposit products and engages with consumers through a variety of digital channels would be expected to have more detailed and sophisticated policies and procedures in place than a traditional community bank that has a smaller presence in such products and banking channels.

Certain Third Party Relationships

The FDIC recognizes that IDIs have been increasingly entering into business relationships with non-bank third parties to provide banking products and other financial services to new customers and expand the IDIs' access to deposits. For example, IDIs can connect with third-party fintech companies or non-financial enterprises via application programming interfaces (APIs) in a business relationships often referred to as banking as a service (BaaS). In such cases, third parties make available certain IDI products and services to offer those products and services directly to customers. As part of these relationships, third parties often use marketing materials that may include representations about the availability of FDIC insurance for certain products. In essence, from the customer's perspective, the third parties perform the same functions that the bank would typically perform through its own deposit-taking channels (*e.g.,* branches, which were contemplated under section 18(a)(1) of the FDI Act).[32]

To the extent a third party has a business relationships with, and is serving as a deposit-taking channel for, an IDI, sound risk management would compel the IDI to be aware of the activities of the third party to ensure that the availability of deposit insurance is not being misrepresented. As such, under the proposed rule, and as appropriate, IDIs would establish policies and procedures that include provisions related to the deposit-related services that a third party provides to the IDI or deposit-related products or services offered by the third party to other parties. These policies and procedures would include, as appropriate, provisions related to monitoring and evaluating whether such third parties are in compliance with subpart B. Having policies and procedures in place relating to certain third party relationships is critical to mitigating the risks of consumer harm and confusion, consistent with the statutory purpose underlying section 18(a) of the FDI Act, and the FDIC's mission to maintain and promote public confidence in the banking system.

To the extent an IDI has a business relationship with a third party that provides deposit related services, it would include reasonable provisions in its policies and procedures to ensure the marketing and advertising materials provided to prospective depositors by that third party do not misrepresent the insurability of financial products. This includes, for example, policies related to training staff to review the marketing and advertising materials to evaluate whether such materials contain misrepresentations about deposit insurance.

Further, as appropriate to the potential risk, an IDI should consider policies and procedures related to steps that the IDI might take to mitigate its risk were the third party to misrepresent deposit insurance and therefore cause potential consumer confusion and harm about a product provided by the IDI.

The policies and procedures related to certain third parties would be commensurate with the nature, size, complexity, scope, and potential risk of the deposit-taking activities. With regard to third party relationships, IDIs would be expected to focus on the relationships that pose a higher degree of risk to consumers. For example, there may be third parties that have long-standing, well-established, relationships with the IDI such that the third party has been offering products and services on the IDI's behalf for many years. Moreover, during this time, the third party has been appropriately representing deposit insurance. In other cases, the IDI may be involved in nascent relationships that are less established, and involve novel arrangements such that consumers may not fully appreciate how deposit insurance may or may not apply to the IDI products and services that are being offered. Assuming all other relevant factors are equal, it would be reasonable for an IDI to view the former relationship as lower risk vis-à-vis the latter, which would be considered higher risk. Accordingly, in this instance, it would be appropriate for an IDI to focus its policies and procedures on the higher-risk relationship, as the activities performed via that relationship pose a higher risk of deposit insurance misrepresentation and potential consumer harm.

It would also be prudent for policies and procedures to include ensuring that

[32] 12 U.S.C. 1828(a)(1).

third parties that provide marketing or joint marketing services, web and other electronic channel design, or similar services, are aware of the IDIs compliance policies under part 328.

Reservation of Authority

The proposed rule also provides that the FDIC would reserve the authority to take appropriate actions, including supervisory or enforcement actions, against any person that violates part 328. The existence of adequate policies and procedures would not preclude the FDIC from taking actions against IDIs or third parties to address violations.

Crypto-Assets

Among other things, part 328 currently prohibits any person from representing or implying that any Uninsured Financial Product is insured or guaranteed by the FDIC.[33] This prohibition applies to advertisements, publications, and other disseminations of information. The FDIC has recently noted a number of misrepresentations of insurance coverage and crypto-assets,[34] and believes that part 328 should be amended to make clear that representations concerning crypto-assets fall within its scope. Accordingly, the proposed rule would amend the definitions of ''Non-Deposit Product'' and ''Uninsured Financial Product'' in subpart B to include crypto-assets and define crypto-asset as ''any digital asset implemented using cryptographic techniques.'' This would include a digital asset that is a digital representation of value that functions as a medium of exchange, a unit of account, and, or a store of value; as well as a digital asset that has an equivalent value in and is convertible to real currency, or that acts as a substitute for real currency and is not legal tender.

The proposed rule also includes crypto-assets in subpart A's definition of ''non-deposit product,'' using the definition of ''crypto-asset'' described above. Accordingly, the non-deposit sign requirements proposed in subpart A would apply to crypto-assets. For example, if an IDI's ATM offered customers the ability to purchase crypto-assets, the ATM would be required to clearly, continuously, and conspicuously display disclosures indicating that the crypto-assets: are not insured by the FDIC; are not deposits; and may lose value.

Expected Effects

Costs

The costs of the proposed rule would be incurred by IDIs, as well as some non-bank entities that may need to update disclosures or marketing materials. This section addresses these two groups separately.

Costs to IDIs

According to data from recent Reports of Condition and Income (Call Reports), the FDIC insures the deposits of 4,780 IDIs operating approximately 80 thousand branches in the United States.[35] These IDIs are currently subject to the existing requirements of part 328, so the costs incurred by these IDIs by the proposed rule would be limited to activities to ensure compliance with the new provisions in the proposed rule and ameliorated by the extent to which IDIs are already complying with the new provisions. These activities include updating the display of FDIC signs in both physical and digital locations where deposits are normally received (including ATMs and websites), creating and maintaining signs for non-deposit products, segregating areas related to the sale of non-deposit products from areas where insured deposits are normally received, and ensuring that FDIC signs are not displayed in close proximity with non-deposit product signs.

Data on the costs of updating the displays of signs and segregating physical areas within bank premises are unavailable, but the FDIC expects these costs would depend on the number of branches operated by each IDI as well as the complexities of each IDI's branches. The FDIC expects that larger banks are more likely to have branches that are nontraditional, complex, and/or offer both deposit and non-deposit products. For purposes of the proposed rule, the FDIC estimates that IDIs with less than $10 billion in assets would spend approximately one hour per year to complete these activities at each branch while IDIs with at least $10 billion in total consolidated assets (assets) would spend approximately two hours per year per branch, for a total annual burden of approximately 120 thousand hours per year across all IDIs[36] at an annual cost of approximately $10 million.[37]

The costs of complying with the proposed rule's requirements for digital deposit-taking channels would also depend on the complexities of each IDI's digital deposit-taking operations. The FDIC expects that larger banks are more likely to have more complex digital operations or offer both deposit and non-deposit products through their digital deposit-taking operations. For purposes of the proposed rule, the FDIC estimates that, on average, IDIs would incur a one-time burden of sixty hours to update their digital operations to incorporate the requirements in the proposed rule, at an approximately cost of $23 million for the industry.[38] The FDIC also estimates that, in years subsequent to the enactment of the proposed rule, IDIs with less than $10 billion in assets would spend approximately ten additional hours per year to comply with the digital deposit-taking operation requirements of the proposed rule, while IDIs with at least $10 billion in assets would spend approximately twenty additional hours per year, at an annual cost of approximately $4 million for the industry.[39]

Finally, all IDIs must update their policies and procedures to comply with the proposed rule. These policies and procedures would include, as appropriate, provisions related to monitoring and evaluating whether certain third parties are in compliance with subpart B. The FDIC recognizes that the costs to implement and maintain these policies and procedures will vary across IDIs in ways that depend on the specifics of each IDI's operations or relationships with certain third parties. For purposes of the proposed rule, the FDIC estimates that, on average, IDIs would incur a one-time

[33] ''Uninsured Financial Product'' is currently defined to include non-deposit products, hybrid products, investments, securities, obligations, certificates, shares, or financial products other than insured deposits.

[34] *See* FDIC Press Release PR–60–2022, *FDIC Issues Cease and Desist Letters to Five Companies for Making Crypto-Related False or Misleading Representations About Deposit Insurance* (Aug. 19, 2022).

[35] Call Reports as of June 30, 2022.

[36] According to Call Reports as of June 30, 2022, there were 4,619 IDIs with assets less than $10 billion operating 33,895 branches and 161 IDIs with assets at least $10 billion operating 45,372 branches.

[37] Dollar costs for this analysis are based on a $81.12 total hourly cost of compensation, a weighted average of the 75th percentile hourly wages reported by the Bureau of Labor Statistics (BLS) National Industry-Specific Occupational Employment and Wage Estimates (OEWS) across five occupational groups in the Depository Credit Intermediation sector, as of May 2021, and adjusted by 1.51 to include non-wage compensation and 1.08 to account for the change in the seasonally adjusted Employment Cost Index for the Credit Intermediation and Related Activities sector (NAICS Code 522) between March 2021 and June 2022. For this analysis, the FDIC uses the following estimated occupational burden weights and occupational hourly labor costs: 14.4 percent for executives and managers at $132.10 per hour, 4.3 percent for lawyers at $163.63 per hour, 36.5 percent for compliance officers at $63.78 per hour, 25.5 percent for IT professionals at $101.32 per hour, and 19.3 percent for clerical workers at $37.34 per hour.

[38] According to Call Reports as of June 30, 2022. $23 million = 4,780 IDIs × 60 hours per IDI × $81.12 per hour.

[39] According to Call Reports as of June 30, 2022. $4 million = 4,619 IDIs × 10 hours per IDI × $81.12 per hour + 161 IDIs × 20 hours per IDI × $81.12 per hour.

burden of eighty hours to update their policies and procedures to incorporate the requirements in the proposed rule, at an approximately cost of $31 million for the industry.[40] The FDIC also estimates that, in years subsequent to the enactment of the proposed rule, IDIs would spend, on average, approximately seventeen additional hours per year to ensure that their policies and procedures maintain compliance with the proposed rule,[41] at an annual cost of approximately $7 million for the industry.[42] Based on the preceding analysis, the FDIC expects that, if the proposed rule were to be adopted, the banking industry would incur approximately $64 million in the first year after adoption and approximately $21 million in each subsequent year to comply with the proposed amendments to part 328.

Costs to Non-Bank Entities

The FDIC does not have direct data on the number of non-bank entities that would be affected by the proposed rule. FDIC staff believe that the non-bank entities affected by the requirement would generally be classified in the following North American Industry Classification System (NAICS) industries: Miscellaneous Financial Investment Activities (NAICS Code 523999), Financial Transaction Processing, Reserve & Clearinghouse Activities (NAICS Code 522320), Computer System Design and Related Services (NAICS Code 5415), and Investment Advice (NAICS Code 523930). According to recent Census data, there were 144,556 firms in these NAICS industries in 2019, the most recent year for which such data is available.[43] However, not all of these firms enter into agreements with IDIs or otherwise engage in operations related to insured deposits; FDIC staff believe that the number of non-bank entities engaged in such operations would be considerably less than the number of IDIs. For purposes of the proposed rule, the FDIC estimates that the number of affected non-bank entities would be approximately one percent of firms in the NAICS industries listed above. Therefore, the FDIC estimates that approximately 1,500 non-bank entities would be affected by the proposed rule.

Nonbanks have been statutorily prohibited from falsely representing that uninsured financial products are FDIC-insured for many years. Thus, the proposed rule would not create a new prohibition on such misrepresentations, but would clarify the types of communications that can materially misrepresent deposit insurance coverage. The nonbank entities affected by the proposed rule may need to update their disclosures and marketing materials to ensure that they neither mis-use the FDIC's official sign or any FDIC-associated terms or images, nor omit or fail to clearly and conspicuously disclose material information that could lead to a reasonable consumer being unable to understand the extent or manner of deposit insurance provided. For purposes of the proposed rule, the FDIC estimates that, on average, each nonbank entity would spend an additional thirty minutes per year to comply with the proposed amendments to subpart B., for a total cost of approximately $60 thousand per year across all nonbank entities affected by the rule.[44]

Benefits

Provided that affected entities are not already complying with certain aspects of the proposed rule, it would, if adopted, produce benefits for the banking industry as well as the general public by providing clarity, and requiring affected entities to provide such clarity, to consumers about the extent to which or the manner in which products are insured by the FDIC. This clarity would help consumers to more clearly understand when they are conducting business with IDIs and when their funds are protected by the FDIC's deposit insurance, thereby helping them avoid incurring financial losses as a result of investing in products they mistakenly thought were FDIC-insured. The proposed rule would reduce ambiguity about the nature of deposit insurance in situations where non-deposit products are offered by IDIs, where insured deposits are advertised by non-bank entities, or where both non-deposit products and deposit products are offered at the same premise. The proposed rule would also extend these benefits to digital deposit-taking channels where physical segregation is not possible. The proposed rule would also require the clear, conspicuous, and consistent use of the official FDIC sign and symbol in both physical and digital locations. These requirements would facilitate consumers' recognition of the FDIC's guarantee and reassure them of the nature of deposit insurance for those products. This effect will reinforce the role of FDIC deposit insurance and bolster confidence in the U.S. banking sector.

As discussed previously, the proposed rule would further clarify the FDIC's procedures for evaluating potential violations of section 18(a)(4). The proposed rule would generally be consistent with existing practices used by the FDIC with respect to these matters. Furthermore, the proposed rule, if adopted, would not affect the application of related criminal prohibitions under 18 U.S.C. 709. Therefore, the FDIC believes that this aspect of the proposed rule is unlikely to have any significant effect on formal or informal enforcement of the section 18(a)(4) prohibitions.

By providing the clarity described above, the FDIC believes the proposed rule would curtail instances in which IDIs or non-bank entities potentially misuse or misrepresent the FDIC's name or logo.[45] When such an instance is made public,[46] the resulting public discourse may increase consumer uncertainty as to whether their own funds are protected by the FDIC's deposit insurance. Consumers' uncertainty as to the safety of their funds may weaken the confidence that underpins banks and our nation's broader financial system. The proposed rule would reduce the frequency of these types of instances going forward. The FDIC does not have the data to quantity the cost savings of this effect, but expects that the reduction in such instances would strengthen public confidence in the FDIC deposit insurance and the nation's banking system.

The FDIC invites comments on all aspects of this Expected Effects section. In particular, are there any effects of the proposed rule that have not been identified?

Alternatives Considered

The FDIC has considered a number of alternatives to the proposed rule that could meet its objectives in this rulemaking, including proposals

[40] According to Call Reports as of June 30, 2022. $31 million = 4,780 IDIs × 80 hours per IDI × $81.12 per hour.

[41] The FDIC estimates that twelve of the seventeen hours are recordkeeping costs under the Paperwork Reduction Act. The five remaining hours are regulatory costs of compliance that are not under the Paperwork Reduction Act.

[42] According to Call Reports as of June 30, 2022. $7 million = 4,780 IDIs × 17 hours per IDI × $81.12 per hour.

[43] (1,110 + 3,163 + 120,070 + 20,213 = 144,556) 2019 County Business Patterns. See number of firms *available at: https://www.census.gov/data/tables/2019/econ/susb/2019-susb-annual.html,* last retrieved on June 30, 2022.

[44] $7 million = 1,500 non-bank entities × 0.5 hours per IDI × $81.12 per hour.

[45] There have been at least 165 such instances recently—see FDIC 2019 Annual Report, p. 38 and FDIC 2020 Annual Report, p. 47.

[46] See, for example, a recent incident of a misrepresentation of FDIC deposit insurance status at *https://www.federalreserve.gov/newsevents/pressreleases/files/bcreg20220728a1.pdf.*

suggested by commenters in response to the 2020 and 2021 RFIs. Some of these alternatives are described below. For the reasons described, the FDIC views the proposed rule as the most appropriate and effective means of achieving its policy objectives with respect to part 328.

Alternatives to Digital Official Sign for Digital Deposit-Taking Channels

With respect to digital deposit-taking channels, the FDIC considered alternatives to the digital official sign required by the proposed rule, including plain text signage and disclosure requirements.[47] As discussed above, the proposed digital sign is intended to quickly and visually convey to consumers that they are dealing directly with an IDI rather than a non-bank entity. This distinction is critical to understanding the risks a consumer faces, and the FDIC believes that it warrants a requirement for consistent visual signage. Plain text signage or disclosures would not achieve this objective as effectively.

Official Advertising Statement Requirements—Allow ''One-Click-Away'' Disclosures

Some commenters recommended that the FDIC adopt a ''one click away'' approach for electronic or digital advertisements (where the advertising statement may not be immediately visible to consumers but could be reached through one mouse click) in order to permit greater flexibility in advertising formats.[48] The FDIC believes that the proposed rule better meets its objectives, as a ''one click away'' approach places the burden on consumers to obtain the necessary information and makes it less likely that they will do so. In addition, the advertising statement options available to IDIs under the proposed rule allow significant flexibility in advertising formats, as IDIs could use short titles including ''Member of FDIC,'' ''Member FDIC,'' or ''FDIC-insured.'' The FDIC believes that these options would be sufficient to permit advertising flexibility.

[47] *See e.g.,* Hancock Whitney Bank Comment Letter to 2021 RFI (May 24, 2021); Kasasa Comment Letter to 2020 RFI (March 24, 2020) (stating that the official sign should not be required on an IDI's website or mobile applications but suggests requiring, at minimum, the FDIC advertising statement on certain pages).

[48] *See* Hancock Whitney Bank Comment Letter to 2021 RFI (May 24, 2021); American Bankers Association and Bank Policy Institute joint comment letter to 2021 RFI (May 21, 2021); Kasasa Comment Letter to 2020 RFI (March 24, 2020).

Administrative Law Matters

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency, in connection with a proposed rule, to prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of a proposed rule on small entities.[49] However, a regulatory flexibility analysis is not required if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The Small Business Administration (SBA) has defined ''small entities'' to include banking organizations with total assets of less than or equal to $750 million.[50] Generally, the FDIC considers a significant effect to be a quantified effect in excess of 5 percent of total annual salaries and benefits per institution, or 2.5 percent of total noninterest expenses. The FDIC believes that effects in excess of these thresholds typically represent significant effects for FDIC-supervised institutions. For the reasons described below, the FDIC certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

As described in the Expected Effects section, the proposed rule is expected to affect all institutions whose deposits are insured by the FDIC, as well as non-bank entities who may potentially use the official FDIC sign, advertising statements, or otherwise make representations that their products are insured or guaranteed by the FDIC. According to recent Call Reports, there are 4,780 FDIC-insured IDIs.[51] Of these, approximately 3,394 would be considered small entities for the purposes of RFA.[52] These small IDIs operate approximately 13 thousand deposit-taking offices. The number of deposit-taking offices for each IDI range from 1 to 21. As discussed in the Expected Effects section, the FDIC expects affected IDIs with less than $10 billion in assets, which are likely to have less complex deposit-taking operations and fewer offices than larger IDIs, would spend, on average, 60 hours to update their digital operations, 80 hours to implement policies and procedures, and seven hours to update physical signage at branches in the first year. At average labor costs of $81.12 per hour, the expected first-year costs of complying with the proposed rule would average less than a percent of the small IDIs' total annual salaries and benefits. These expected first-year costs would exceed five percent of the total annual salaries and benefits for only 20 small IDIs (comprising less than one percent of the total number of affected small IDIs). For subsequent years, the costs of maintaining compliance are even smaller. Thus, the proposed rule would not significantly affect a substantial numbers of small IDIs.

As described in the Expected Effects section, the FDIC estimates that 1,500 non-bank entities would be affected by this proposed rule. The FDIC does not have data on the number of non-bank entities that would be considered small entities for the purposes of RFA. As a conservative estimate, the FDIC assumes all 1,500 affected non-bank entities are small. As discussed in the Expected Effects section, the FDIC estimates that each non-bank entity would incur an additional 30 minutes per year to comply with the proposed amendments to subpart B. At an estimated compensation rate of $81.12, the expected costs of complying with the proposed rule would be less than $100 per year per non-bank small entity.

The proposed rule may also affect private individuals who may potentially misuse the FDIC name or logo or may potentially misrepresent the nature of deposit insurance. Private individuals are not considered ''small entities'' under the RFA.

Given that the expected costs of the proposed rule would be relatively small, the FDIC certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities. The FDIC invites comments on all aspects of the supporting information provided in this RFA section. In particular, would this proposed rule have any significant effects on small entities that the FDIC has not identified?

Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), the FDIC may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control

[49] 5 U.S.C. 601 *et seq.*

[50] The SBA defines a small banking organization as having $750 million or less in assets, where an organization's ''assets are determined by averaging the assets reported on its four quarterly financial statements for the preceding year.'' See 13 CFR 121.201 (as amended by 87 FR 18627, effective May 2, 2022). In its determination, the ''SBA counts the receipts, employees, or other measure of size of the concern whose size is at issue and all of its domestic and foreign affiliates.'' See 13 CFR 121.103. Following these regulations, the FDIC uses a covered entity's affiliated and acquired assets, averaged over the preceding four quarters, to determine whether the covered entity is ''small'' for the purposes of RFA.

[51] FDIC Call Reports, June 30, 2020.

[52] *Id.*

number. Certain provisions of the proposed rule contain ''collection of information'' requirements within the meaning of the PRA.[53] The information collection requirements (IC) contained in this notice of proposed rulemaking have been submitted to OMB for review and approval by FDIC under section 3507(d) of the PRA and § 1320.11 of OMB's implementing regulations (5 CFR part 1320) as a new information collection.

Title of Proposed Information Collection: Disclosure, Recordkeeping and Reporting Requirements Related to FDIC's Official Sign and Advertising Requirements, False Advertising, Misrepresentation of Insured Status, and Misuse of the FDIC's Name or Logo.

OMB Control Number: 3064–[NEW].

Affected Public: Businesses or other for-profit.

Respondents: Any FDIC-insured depository institution and persons that provide deposit-related services to insured depository institutions or offer insured depository institution's deposit-related products or services to other parties.

Estimated Annual Burden:

The proposed rule contains the following ten (10) information collection requirements:

1. *Signs within Institution Premises—Banks <$10B, 12 CFR 328.3 (Third-Party Disclosure; Mandatory).* Proposed § 328.3 would impose PRA third-party disclosure burden governing signage within the premises of insured depository institutions. This burden is associated with the display of signage for non-deposit products, segregating areas offering non-deposit products, and the use of electronic media. The FDIC believes the hourly burden for these activities differ among respondents. For purposes of PRA, the FDIC would split the burden into two information collection categories: one for banks with less than $10 billion in total consolidated assets (assets) and one for banks with at least $10 billion in assets. This IC captures the burden for the former group.

2. *Signs within Institution Premises—Banks >$10B, 12 CFR 328.3 (Third-Party Disclosure; Mandatory).* Proposed § 328.3 would impose PRA third-party disclosure burden governing signage within the premises of insured depository institutions. This burden is associated with the display of signage for non-deposit products, segregating areas offering non-deposit products, and the use of electronic media. The FDIC believes the hourly burden for these activities differ among respondents. For purposes of PRA, the FDIC would split the burden into two ICs: one for banks with less than $10 billion in total consolidated assets (assets) and one for banks with at least $10 billion in assets. This IC captures the burden for the latter group.

3. *Signage for ATMs and Digital Deposit-taking Channels—Implementation, 12 CFR 328.4 and 328.5 (Third-Party Disclosure; Mandatory).* Proposed §§ 328.4 and 328.5 would impose PRA third-party disclosure burden governing signs for ATMs as well as digital deposit-taking channels. This burden is associated with the display of signage for both deposit and non-deposit products. The FDIC believes banks will incur burdens in the first year to update their digital channels to incorporate the amended requirements in the proposed rule. This IC captures the burden for these implementation activities.

4. *Signage for ATMs and Digital Deposit-taking Channels—Banks <$10B–Ongoing, 12 CFR 328.4 and 328.5 (Third-Party Disclosure; Mandatory).* Proposed §§ 328.4 and 328.5 would impose PRA third-party disclosure burden governing signs for ATMs as well as digital deposit-taking channels. This burden is associated with the display of signage for deposit and non-deposit products. The FDIC believes that, in years subsequent to implementation, banks would incur ongoing burdens to update and maintain their digital channels to ensure continual compliance with the requirements in the proposed rule. For purposes of PRA, the FDIC would split this ongoing burden into two ICs: one for banks with less than $10 billion in total consolidated assets (assets) and one for banks with at least $10 billion in assets. This IC captures the burden for the former group.

5. *Signage for ATMs and Digital Deposit-taking Channels—Banks ≥$10B–Ongoing, 12 CFR 328.4 and 328.5 (Third-Party Disclosure; Mandatory).* Proposed §§ 328.4 and 328.5 would impose PRA third-party disclosure burden governing signs for ATMs as well as digital deposit-taking channels. This burden is associated with the display of signage for deposit and non-deposit products. The FDIC believes that, in years subsequent to implementation, banks would incur ongoing burdens to update and maintain their digital channels to ensure continual compliance with the requirements in the proposed rule. For purposes of PRA, the FDIC would split the burden into two ICs: one for banks with less than $10 billion in total consolidated assets (assets) and one for banks with at least $10 billion in assets. This IC captures the burden for the latter group.

6. *Policies and Procedures—Implementation, 12 CFR 328.8 (Recordkeeping; Mandatory).* Proposed § 328.8 would require IDIs to establish and maintain written policies and procedures to achieve compliance with part 328 including provisions related to monitor and evaluate the activities of persons that provide deposit-related services to the IDI or offer the IDI's deposit-related products or services to other parties. The FDIC believes the hourly burden for these activities can be categorized into two distinct ICs covering (1) implementation burdens incurred in the first year in which the policies and procedures are implemented and (2) ongoing burden incurred every subsequent year to maintain compliance. This IC captures the implementation burden.

7. *Policies and Procedures—Ongoing, 12 CFR 328.8 (Recordkeeping; Mandatory).* Proposed § 328.8 would require IDIs to establish and maintain written policies and procedures to achieve compliance with part 328 including provisions related to monitoring and evaluating the activities of persons that provide deposit-related services to the Insured Depository Institution or offer the Insured Depository Institution's deposit-related products or services to other parties. The FDIC believes the hourly burden for these activities can be categorized into two distinct ICs covering (1) implementation burdens incurred in the first year in which the policies and procedures are implemented and (2) ongoing burden incurred every subsequent year to maintain compliance. This IC captures the ongoing burden.

8. *Insured Depository Institution Relationships—Implementation 12 CFR 328.102(b)(5) (Third-Party Disclosure; Mandatory).* Proposed § 328.102(b)(5) would require covered non-bank entities to ensure that their public statements regarding deposit insurance comply with the requirements in part 328. The FDIC believes the hourly burden for these activities can be categorized into two distinct ICs covering (1) implementation burdens incurred in the first year in which the public statements are amended and (2) ongoing burden incurred every subsequent year to ensure continual compliance. This IC captures the implementation burden.

9. *Insured Depository Institution Relationships—Ongoing 12 CFR*

[53] Information collection is defined under OMB's regulations at 5 CFR 1320(c). Certain requirements in part 328 for public disclosure of the FDIC name and/or logo are not information collections. *See* 5 CFR 1320(c)(2).

328.102(b)(5) (Third-Party Disclosure; Mandatory). Proposed § 328.102(b)(5) would require covered non-bank entities to ensure that their public statements regarding deposit insurance comply with the requirements in part 328. The FDIC believes the hourly burden for these activities can be categorized into two distinct ICs covering (1) implementation burdens incurred in the first year in which the public statements are amended and (2) ongoing burden incurred every subsequent year to ensure continual compliance. This IC captures the ongoing burden.

10. *Request for Consent to Use Non-English Language Advertising Statement—12 CFR 328.3(f), proposed 12 CFR 328.6(f) (Reporting; Required to Obtain or Retain a Benefit).* Existing § 328.3(f), which the proposed rule moves to § 328.6(f), requires IDIs to obtain prior written approval of the FDIC before using a non-English equivalent of the official FDIC advertising statement in an advertisement.

Methodology and Assumptions

Estimated Annual Number of Respondents

ICs 1–7 and IC 10 capture PRA burdens incurred by insured depository institutions (IDIs). According to recent Reports of Condition and Income (Call Reports), the FDIC supervised approximately 4,780 insured depository institutions (FDIC-supervised IDIs).[54] These include 161 IDIs with assets at least $10 billion and 4,619 IDIs entities with assets less than $10 billion. Of these, 3,394 IDIs are considered small entities for purposes of the Regulatory Flexibility Act.[55]

IC 1 captures PRA burdens incurred by all IDIs with less than $10 billion in assets, and IC 2 captures PRA burdens incurred by all IDIs with at least $10 billion in assets. Using the Call Report data summarized above, FDIC estimates 4,169 annual respondents for IC 1 and 161 annual respondents for IC 2.

ICs 3 and 6 capture implementation burdens incurred by all 4,780 IDIs. Implementation burdens are incurred in the first year after the proposed rule would become effective. Given that this information collection request (ICR) covers PRA burdens over three years, FDIC annualize the counts of respondents by dividing the total number of respondents by three. Thus, FDIC estimates 1,593 annual respondents for ICs 3 and 6.

ICs 4, 5, and 7 capture the ongoing PRA burdens incurred by the 4,169 IDIs with less than $10 billion in assets, the 161 IDIs with at least $10 billion in assets, and all 4,780 IDIs, respectively. Ongoing burdens are incurred in two of the three years after the proposed rule would become effective. FDIC annualizes the counts of respondents accordingly. Thus, FDIC estimates 3,080 annual respondents for IC 4, 107 annual respondents for IC 5 and 3,187 annual respondents for IC 7.

ICs 8 and 9 capture PRA requirements incurred by non-bank entities. The FDIC does not have direct data on the number of non-bank entities that would be subject to part 328. FDIC assumes that the affected non-bank entities would generally be classified in the following North American Industry Classification System (NAICS) industries: Miscellaneous Financial Investment Activities (NAICS Code 523999), Financial Transaction Processing, Reserve & Clearinghouse Activities (NAICS Code 522320), Computer System Design and Related Services (NAICS Code 5415), and Investment Advice (NAICS Code 523930). According to recent Census data, there were 144,556 firms in these NAICS industries in 2019, the most recent year for which such data is available.[56] However, not all of these firms enter into agreements with IDIs or otherwise engage in operations related to insured deposits; FDIC assumes that the number of non-bank entities engaged in such operations would be considerably less than the number of IDIs. For purposes of this estimation, the FDIC assumes that the number of covered non-bank entities would be approximately one percent of firms in the NAICS industries listed above. Therefore, FDIC estimates that approximately 1,500 non-bank entities would incur burdens associated with part 328. ICs 8 and 9 are implementation and ongoing burdens, respectively. FDIC annualizes the count of respondents accordingly. Thus, FDIC estimates 500 annual respondents for IC 8 and 1,000 annual respondents for IC 9.

IC 10 captures PRA requirements incurred by IDIs that submit requests to the FDIC for the use of a non-English equivalent of the official FDIC advertising statement. The FDIC does not have data on the historical annual number of such requests submitted. However, the FDIC has not handled such a request since at least January 1, 2021 and believes it is unlikely that such a request from an IDI would be received within the next three years. Since OMB's system of record for PRA burdens does not allow non-positive respondent counts, FDIC uses an annual respondent of one for IC 10 to preserve the estimated burden calculations.

Estimated Annual Number of Responses per Respondent

ICs 1 and 2 capture the activities that respondents undertake at each of their branches to comply with the PRA requirements in 12 CFR 328.3. For purposes of this ICR, FDIC designates the activities at a single branch as a single response by the respondent. According to recent Call Reports, IDIs with assets less than $10 billion operate approximately 7 branches each, on average, while IDIs with assets of at least $10 billion have approximately 282 branches each, on average.[57] Accordingly, FDIC estimates 7 responses per year for IC 1 and 282 responses per year for IC 2.

For ICs 3–10, the activities that respondents undergo throughout the year to comply with the PRA requirements in each IC can all be considered part of a single annual response to that IC. Therefore, FDIC uses one as the number of annual responses per respondent for these ICs.

Estimated Burden Hours per Response

ICs 1 and 2 capture the third-party disclosure burden of ensuring that signage within the premises of insured depository institutions comply with part 328. Data on this burden are unavailable. The FDIC assumes that larger banks are more likely to have branches that are nontraditional, complex, and/or offer both deposit and non-deposit products. While smaller IDIs are more likely to operate simple branches that offer only deposit products and may not require extensive revisions of signage, those that do may require updates to their designated areas. For purposes of this ICR, FDIC

[54] *See* FDIC Call Reports, June 30, 2022.

[55] The SBA defines a small banking organization as having $750 million or less in assets, where an organization's ''assets are determined by averaging the assets reported on its four quarterly financial statements for the preceding year.'' See 13 CFR 121.201 (as amended by 87 FR 18627, effective May 2, 2022). In its determination, the ''SBA counts the receipts, employees, or other measure of size of the concern whose size is at issue and all of its domestic and foreign affiliates.'' See 13 CFR 121.103. Following these regulations, the FDIC uses an IDI's affiliated and acquired assets, averaged over the preceding four quarters, to determine whether the IDI is ''small'' for the purposes of RFA.

[56] (1,110 + 3,163 + 120,070 + 20,213 = 144,556) 2019 County Business Patterns. See number of firms at *https://www.census.gov/data/tables/2019/econ/susb/2019-susb-annual.html,* last retrieved on June 30, 2022.

[57] According to Call Reports as of June 30, 2022, there were 4,619 banks with assets less than $10 billion operating 33,895 branches and 161 IDIs with assets at least $10 billion operating 45,372 branches.

estimates the burden would be approximately one hour per branch, on average, for institutions with less than $10 billion in assets and approximately two hours per branch, on average, for institutions with at least $10 billion in assets. Accordingly, FDIC estimates burdens as one hour per response for IC 1 and two hours per response for IC 2.

ICs 3, 4, and 5 capture the third-party disclosure burden of ensuring that signs for ATMs and digital deposit-taking channels with part 328. Data on this burden are unavailable. The FDIC assumes that larger banks are more likely to have more complex digital operations or offer both deposit and non-deposit products through their digital deposit-taking operations. However, these larger banks may also have permanent IT teams in place that could facilitate and/or reduce the hourly burden of these changes. Conversely, for smaller banks relying on third-party web service providers, many may be seeking compliance through the same channel as others, which could create a backlog of work on the third party web service providers, making it so other small banks experience a delay in compliance timelines. For purposes of this ICR, FDIC assumes that each IDI will spend 60 hours, on average, in the first year to implement the changes to its ATM and digital deposit-taking channels to comply with part 328. In subsequent years, IDIs with less than $10 billion in assets would spend approximately 10 additional hours per year, on average, to maintain ongoing compliance, while IDIs with at least $10 billion in assets would spend approximately 20 additional hours per year, on average, to maintain ongoing compliance. As such, FDIC estimates burdens as 60 hours per response for IC 3, 10 hours per response for IC 4, and 20 hours per response for IC 5.

ICs 6 and 7 capture the recordkeeping burden of ensuring that the IDIs' policies and procedures comply with part 328. FDIC assumes the recordkeeping burden imposed relates to documenting the development of policies and procedures by compliance officers and senior management that would be appropriate to the institution's risk profile. This program would then be reviewed, revised, and then approved by the board of directors or other executives at the institution. In addition, part 238 requires that IDIs monitor and evaluate certain third parties to ensure that these third parties are also in compliance with part 328. Additional recordkeeping burden would be incurred in documenting the results of such monitoring activities. Data on the hourly burden of these activities are unavailable. For purposes of this ICR, the FDIC assumes that each IDI, on average, would spend approximately 80 hours in the first year to establish and/or implement policies and approximately 12 hours in each subsequent year to revise and update these documents. FDIC estimates burdens as 80 hours per response for IC 6 and 12 hours per response for IC 7.

ICs 8 and 9 capture the burden of ensuring that covered non-bank entities' third-party disclosures comply with part 328. Data on this burden are unavailable. The FDIC assumes each covered non-bank entity, on average, would spend approximately two and one-half hours in the first year to implement these procedures and approximately one hour in each subsequent year to revise and maintain ongoing compliance. FDIC estimates burdens as 2.5 hours per response for IC 8 and 1 hour per response for IC 9.[58]

IC 10 captures the reporting burden incurred when an IDI requests approval from the FDIC to use the non-English equivalent of the official advertising statement in any of its advertisements. The FDIC believes that an IDI would spend approximately two hours per year, on average, to prepare and submit such requests.

Estimated Annual Burden Summary

The estimated PRA burdens for the proposed rule are summarized in the *Summary of Estimated Annual Burden* table below. For each IC, the burden table lists the estimated annual number of responses per respondent and estimated time per response, as described in the sections above. Note that the counts of annual respondents for ICs 3–9 have been annualized to reflect a three year PRA cycle in which respondents incur implementation costs in the first year and ongoing costs in the second and third years.

SUMMARY OF ESTIMATED ANNUAL BURDEN

Information collection (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Time per response (HH:MM)	Annual burden (Hours)
1. Signs within Institution Premises—Banks <$10B, 12 CFR 328.3 (Mandatory).	Third-Party Disclosure (Annual).	4619	7	1:00	32,333
2. Signs within Institution Premises—Banks ≥$10B, 12 CFR 328.3 (Mandatory).	Third-Party Disclosure (Annual).	161	282	2:00	90,804
3. Signage for ATMs and Digital Deposit-taking Channels—Implementation, 12 CFR 328.4 and 328.5 (Mandatory).	Third-Party Disclosure (Annual).	1593	1	60:00	95,580
4. Signage for ATMs and Digital Deposit-taking Channels—Banks <$10B–Ongoing, 12 CFR 328.4 and 328.5 (Mandatory).	Third-Party Disclosure (Annual).	3080	1	10:00	30,800
5. Signage for ATMs and Digital Deposit-taking Channels—Banks ≥$10B–Ongoing, 12 CFR 328.4 and 328.5 (Mandatory).	Third-Party Disclosure (Annual).	107	1	20:00	2,140
6. Policies and Procedures—Implementation, 12 CFR 328.8 (Mandatory).	Recordkeeping (Annual).	1593	1	80:00	127,440
7. Policies and Procedures—Ongoing, 12 CFR 328.8 (Mandatory).	Recordkeeping (Annual).	3187	1	12:00	38,244

[58] Note that these hourly burden estimates are higher than the corresponding estimates in the notice and request for comment published in the **Federal Register** on September 8, 2022. The increase reflects the additional requirements in the proposed rule's amendments to 12 CFR 328.102(b)(5).

SUMMARY OF ESTIMATED ANNUAL BURDEN—Continued

Information collection (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Time per response (HH:MM)	Annual burden (Hours)
8. Insured Depository Institution Relationships—Implementation 12 CFR 328.102(b)(5) (Mandatory).	Third-Party Disclosure (Annual).	500	1	2:30	1,250
9. Insured Depository Institution Relationships—Ongoing 12 CFR 328.102(b)(5) (Mandatory).	Third-Party Disclosure (Annual).	1000	1	1:00	1,000
10. Request for Consent to Use Non-English Language Advertising Statement—existing 12 CFR 328.3(f), proposed 12 CFR 328.6(f) (Required to Obtain or Retain a Benefit).	Reporting (On occasion).	1	1	2:00	2
Total Annual Burden (Hours)	.....	.....	.....	.....	*419,593*

Source: FDIC.

Note: The annual burden estimate for a given collection is calculated in two steps. First, the total number of annual responses is calculated as the whole number closest to the product of the annual number of respondents and the annual number of responses per respondent. Then, the total number of annual responses is multiplied by the time per response and rounded to the nearest hour to obtain the estimated annual burden for that collection. This rounding ensures the annual burden hours in the table are consistent with the values recorded in the OMB's regulatory tracking system.

Comments are invited on:

- Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;
- The accuracy of the agency's estimate of the burden of the collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected;
- Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and
- Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Riegle Community Development and Regulatory Improvement Act

Section 302 of the Riegle Community Development and Regulatory Improvement Act of 1994 (RCDRIA) requires that the Federal banking agencies, including the FDIC, in determining the effective date and administrative compliance requirements of new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions, consider, consistent with principles of safety and soundness and the public interest, any administrative burdens that such regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the benefits of such regulations subject to certain exceptions, new regulations and amendments to regulations prescribed by a Federal banking agency which impose additional reporting, disclosures, or other new requirements on insured depository institutions shall take effect on the first day of a calendar quarter which begins on or after the date on which the regulations are published in final form.

Plain Language

Section 722 of the Gramm-Leach-Bliley Act requires the Federal banking agencies to use plain language in all proposed and final rulemakings published in the **Federal Register** after January 1, 2000. The FDIC invites your comments on how to make this proposal easier to understand. For example:

- Has the FDIC organized the material to suit your needs? If not, how could the material be better organized?
- Are the requirements in the proposed regulation clearly stated? If not, how could the regulation be stated more clearly?
- Does the proposed regulation contain language or jargon that is unclear? If so, which language requires clarification?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the regulation easier to understand?

Request for Comment

The FDIC invites comment on all aspects of this proposed rulemaking. In particular, the FDIC seeks feedback on the scope of the proposed rule and its requirements, and responses to the following specific questions:

Physical Signage

(1) Are there any aspects of the proposed rule's on-premises signage requirements that would be challenging to satisfy in a non-traditional footprint branch? How could the proposed rule be modified to better accommodate signage needs in such branches while also satisfying the FDIC's objectives?

(2) With respect to the proposed rule's non-deposit signage requirements, are there better alternative methods by which IDIs might help consumers distinguish insured deposits from non-deposit products?

(3) Would it be beneficial to consumers to standardize the design of the proposed rule's non-deposit signage? If a standard design were required, which design elements would minimize any potential challenges associated with integrating it into an IDI's other non-deposit product marketing materials?

Digital Channels

(4) Are there any particular aspects of a potential design or the placement of the digital sign that might improve its presentation or readability for consumers, or minimize the any potential technical challenges of introducing this sign into digital interfaces?

(5) Would it be beneficial to consumers to require the digital sign on other pages in addition to the homepage, application, landing, login, and transactional pages of an IDI's digital channels, including websites and mobile applications?

(6) Should the proposed rule require, rather than permit, IDIs to link the digital sign to the FDIC BankFind tool? Would IDIs face any unique technological challenges in complying with such a requirement?

(7) Does the proposed rule sufficiently address the risk of confusion where

consumers interact with deposits and non-deposit products through the same digital channels? Are there any additional or alternative requirements that would draw a clear distinction between deposits and non-deposit products on digital channels?

ATMs and Similar Devices

(8) Does the proposed rule's requirement to display the digital version of the FDIC official sign on ATMs and similar devices present technical challenges? If so, are there ways to address those challenges while still displaying clear signage on deposit insurance coverage for consumers?

(9) Do the proposed rule's disclosure requirements for ATMs and similar devices sufficiently differentiate between deposits and non-deposit products? If not, please suggest better alternative methods.

(10) Given potential requirements for signs in physical branches, ATMs, and digital channels, how long would it take to revise systems and process for the purposes of complying with a rule; what should the compliance date(s) for the rule be?

IDI Policies and Procedures

(11) With respect to the proposed requirement for IDI's to establish policies and procedures to comply with part 328, are there additional, or more specific, criteria that institutions should consider as part of its policies and procedures?

Official Advertising Statement

(12) In addition to ''FDIC-insured'', are there other options for the short advertising statement that the proposed rule should allow?

Misrepresentations and Material Omissions

(13) Are there additional practices or scenarios that the FDIC should clarify as being misrepresentations of deposit insurance?

Non-Deposit Products

(14) Is the proposed definition of crypto-asset in subparts A and B appropriate?

List of Subjects in 12 CFR Part 328

Advertising, Bank deposit insurance, Savings associations, Signs and symbols.

Authority and Issuance

For the reasons stated in the preamble, the Federal Deposit Insurance Corporation proposes to amend 12 CFR part 328 as follows:

PART 328—ADVERTISEMENT OF MEMBERSHIP, FALSE ADVERTISING, MISREPRESENTATION OF INSURED STATUS, AND MISUSE OF THE FDIC'S LOGO

■ 1. The authority citation for part 328 continues to read as follows:

Authority: 12 U.S.C. 1818, 1819 (Tenth), 1820(c), 1828(a).

■ 2. Revise subpart A to read as follows:

Subpart A—Advertisement of Membership

Sec.

§ 328.0 Purpose.

Subpart A of this part describes the official sign and advertising statement and prescribes their use by insured depository institutions, as well as other signs to prevent customer confusion in the event non-deposit products are offered by an insured depository institution. Subpart A applies to insured depository institutions, including insured branches of foreign banks, but does not apply to non-insured offices or branches of insured depository institutions located in foreign countries.

§ 328.1 Definitions.

Branch has the same meaning as the term ''domestic branch'' as set forth under section 3(*o*) of the Federal Deposit Insurance Act, 12 U.S.C. 1813(*o*).

Corporation means the Federal Deposit Insurance Corporation.

Crypto-asset means any digital asset implemented using cryptographic techniques.

Deposit has the same meaning as set forth under section 3(*l*) of the Federal Deposit Insurance Act, 12 U.S.C. 1813(*l*).

Digital deposit-taking channel means any electronic communications method through which an insured depository institution accepts deposits.

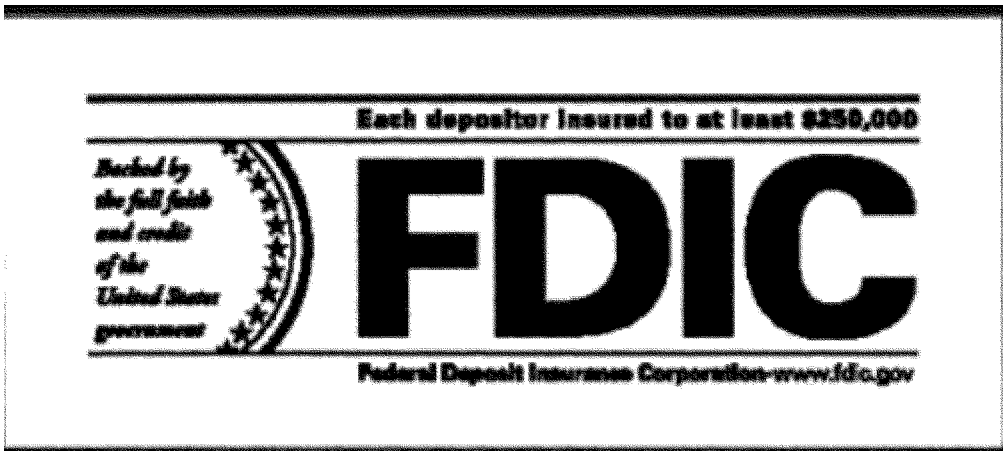
Hybrid product means a product or service that has both deposit product features and non-deposit product features. A sweep account is an example of a hybrid product.

Insured depository institution has the same meaning as set forth under section 3(c)(2) of the Federal Deposit Insurance Act, 12 U.S.C. 1813(c)(2).

Non-deposit product means any product that is not a ''deposit'', including, but not limited to: stocks, bonds, government and municipal securities, mutual funds, annuities (fixed and variable), life insurance policies (whole and variable), savings bonds, and crypto-assets. For purposes of this definition, a credit product is not a non-deposit product.

§ 328.2 Official sign.

(a) *Design.* The official sign has the following design:



(b) *Symbol.* The ''symbol'' of the Corporation, as used in this subpart, shall be that portion of the official sign consisting of ''FDIC'' and the two lines of smaller type above and below ''FDIC.''

(c) *Procuring signage.* An insured depository institution may procure the official sign from the Corporation for official use at no charge. Information on obtaining the official sign is posted on the FDIC's internet website, *https://www.fdic.gov.* Alternatively, insured depository institutions may, at their expense, procure from commercial suppliers signs that vary from the official sign in size, color, or material. Any insured depository institution which has promptly submitted a written request for an official sign to the Corporation shall not be deemed to have violated this subpart by failing to display the official sign, unless the insured depository institution fails to display the official sign after receipt thereof.

(d) *Required changes in signage.* The Corporation may require any insured depository institution, upon at least thirty (30) days' written notice, to change the wording of the official sign in a manner deemed necessary for the protection of depositors or others.

§ 328.3 Signs within institution premises and offering of non-deposit products within institution premises.

(a) *Scope.* This section governs signage within the premises of insured depository institutions and the offering of non-deposit products within the premises of insured depository institutions.

(b) *Display of official sign.* Insured depository institutions must continuously, clearly, and conspicuously display the official sign in its principal place of business and all of its branches (except branches excluded from the scope of this subpart under § 328.0) in the manner described in this paragraph (b).

(1) *Deposits received at teller windows or stations.* If deposits are usually and normally received at teller windows or stations, the insured depository institution must display the official sign:

(i) At each teller window or station where deposits are usually and normally received, in a size of 7″ by 3″ or larger with black lettering on a gold background; or

(ii) If the insured depository institution does not offer non-deposit products on the premises, at one or more locations visible from the teller windows or stations in a manner that ensures a copy of the official sign is large enough so as to be legible from anywhere in that area.

(2) *Deposits received in areas other than teller windows or stations.* If insured deposits are usually and normally received in areas of the premises other than teller windows or stations, the insured depository institution must display the official sign in one or more locations in a manner that ensures a copy of the official sign is large enough so as to be legible from anywhere in those areas.

(3) *Other locations within the premises.* An insured depository institution may display the official sign in locations at the institution other than those required by this section, except for areas where non-deposit products are offered.

(4) *Varied signs.* An insured depository institution may display signs that vary from the official sign in size, color, or material at any location where display of the official sign is required or permitted under this paragraph. However, any such varied sign that is displayed in locations where display of the official sign is required must not be smaller in size than the official sign, must have the same color for the text and graphics, and includes the same content.

(5) *Newly insured institutions.* An insured depository institution shall display the official sign as described in this section no later than its twenty-first calendar day of operation as an insured depository institution, unless the institution promptly requested the official sign from the Corporation, but did not receive it before that date.

(a) *Non-deposit products offered on IDI premises*—(1) *Segregated areas.* If non-deposit products are offered within the premises, those products must be physically segregated from areas where insured deposits are usually and normally accepted. The institution must identify areas where activities related to the sale of non-deposit investment products occur and clearly delineate and distinguish those areas from the areas where insured deposit-taking activities occur.

(2) *Non-deposit signage.* At each location within the premises where non-deposit products are offered, an insured depository institution must continuously, clearly, and conspicuously display signage indicating that the non-deposit products: are not insured by the FDIC; are not deposits and may lose value. Such signage may not be displayed in close proximity to the official sign.

(d) *Electronic media.* Insured depository institutions may use electronic media to display the official sign and non-deposit sign required by this section.

§ 328.4 Signage for automated teller machines and like devices.

(a) *Scope.* This section governs signage for IDI's automated teller machines or other remote electronic facilities that receive deposits.

(b) *Display of official sign.* An IDI's automated teller machine or like device that receives deposits for an insured

depository institution must clearly, continuously, and conspicuously display a digital version of the official sign on its home page or screen and on each transaction page or screen relating to deposits.

(c) *Non-deposit signage.* If an IDI's automated teller machine or like device receives deposits for an insured depository institution and offers access to non-deposit products, the machine must clearly, continuously, and conspicuously display electronic disclosures indicating that such non-deposit products: are not insured by the FDIC; are not deposits; and may lose value. These disclosures must be displayed on each transaction page or screen relating to non-deposit products.

§ 328.5 Signs for digital deposit-taking channels.

(a) *Scope.* This section governs signage for digital deposit-taking channels, including insured depository institutions' websites and web-based or mobile applications that offer the ability to make deposits electronically and access to deposits at insured depository institutions.

(b) *Design.* The digital sign required by the provisions of this section has the following design: [Image of sign for digital deposit-taking channels that FDIC expects would prominently bear the name of the FDIC and the statement that insured deposits are backed by the full faith and credit of the U.S. Government TBD]

(c) *Display of digital sign.* An insured depository institution must clearly, continuously and conspicuously display the digital sign specified in paragraph (b) of this section on its digital deposit taking channels in the following pages or screens:

(1) The initial or homepage of the website or application;

(2) Landing or login pages; and

(3) Pages where the customer may transact with deposits.

(4) A digital sign continuously displayed near the top of the relevant page or screen in close proximity to the IDI's name would be considered clear and conspicuous.

(d) *Non-deposit signage.* If a digital deposit-taking channel offers both access to deposits at an insured depository institution and non-deposit products, the insured depository institution must clearly and conspicuously display signage indicating that the non-deposit products: are not insured by the FDIC; are not deposits and may lose value. This signage must be displayed:

(1) Via a one-time notification that is dismissed by an action of the user, when the page is initially accessed; and

(2) Continuously on each page relating to non-deposit products. This non-deposit signage may not be displayed in close proximity to the digital sign required by paragraph (c) of this section.

§ 328.6 Official advertising statement requirements.

(a) *Advertisement defined.* The term ''advertisement,'' as used in this subpart, shall mean a commercial message, in any medium, that is designed to attract public attention or patronage to a product or business.

(b) *Official advertising statement.* The official advertising statement shall be in substance as follows: ''Member of the Federal Deposit Insurance Corporation.''

(1) *Optional short title and symbol.* The short title ''Member of FDIC,'' ''Member FDIC,'' ''FDIC-insured,'' or a reproduction of the symbol of the Corporation (as described in § 328.2(b)), may be used by insured depository institutions at their option as the official advertising statement.

(2) *Size and print.* The official advertising statement shall be of such size and print to be clearly legible. If the symbol of the Corporation is used as the official advertising statement, and the symbol must be reduced to such proportions that the two lines of smaller type above and below ''FDIC'' are indistinct and illegible, those lines of smaller type may be blocked out or dropped.

(c) *Use of official advertising statement in advertisements*—(1) *General requirement.* Except as provided in paragraph (d) of this section, each insured depository institution shall include the official advertising statement prescribed in paragraph (b) of this section in all advertisements that either promote deposit products and services or promote non-specific banking products and services offered by the institution. For purposes of this section, an advertisement promotes non-specific banking products and services if it includes the name of the insured depository institution but does not list or describe particular products or services offered by the institution. An example of such an advertisement would be, ''Anytown Bank, offering a full range of banking services.''

(2) *Foreign depository institutions.* When a foreign depository institution has both insured and noninsured U.S. branches, the depository institution must also identify which branches are insured and which branches are not insured in all of its advertisements requiring use of the official advertising statement.

(3) *Newly insured institutions.* A depository institution shall include the official advertising statement in its advertisements no later than its twenty-first day of operation as an insured depository institution.

(d) *Types of advertisements which do not require the official advertising statement.* The following types of advertisements do not require use of the official advertising statement:

(1) Statements of condition and reports of condition of an insured depository institution which are required to be published by State or Federal law;

(2) Insured depository institution supplies such as stationery (except when used for circular letters), envelopes, deposit slips, checks, drafts, signature cards, deposit passbooks, certificates of deposit, etc.;

(3) Signs or plates in the insured depository institution offices or attached to the building or buildings in which such offices are located;

(4) Listings in directories;

(5) Advertisements not setting forth the name of the insured depository institution;

(6) Entries in a depository institution directory, provided the name of the insured depository institution is listed on any page in the directory with a symbol or other descriptive matter indicating it is a member of the Federal Deposit Insurance Corporation;

(7) Joint or group advertisements of depository institution services where the names of insured depository institutions and noninsured institutions are listed and form a part of such advertisements;

(8) Advertisements by radio or television, other than display advertisements, which do not exceed thirty (30) seconds in time;

(9) Advertisements which are of the type or character that make it impractical to include the official advertising statement, including, but not limited to, promotional items such as calendars, matchbooks, pens, pencils, and key chains; and

(10) Advertisements which contain a statement to the effect that the depository institution is a member of the Federal Deposit Insurance Corporation, or that the depository institution is insured by the Federal Deposit Insurance Corporation, or that its deposits or depositors are insured by the Federal Deposit Insurance Corporation to at least the standard maximum deposit insurance amount (as defined in § 330.1(o)) for each depositor.

(e) *Restrictions on using the official advertising statement when advertising non-deposit products*—(1) *Non-deposit product advertisements.* Except as provided in paragraph (e)(3) of this section, an insured depository institution shall not include the official advertising statement, or any other statement or symbol which implies or suggests the existence of Federal deposit insurance, in any advertisement relating solely to non-deposit products.

(2) *Hybrid product advertisements.* Except as provided in paragraph (e)(3) of this section, an insured depository institution shall not include the official advertising statement, or any other statement or symbol which implies or suggests the existence of Federal deposit insurance, in any advertisement relating solely to hybrid products.

(3) *Mixed advertisements.* In advertisements containing information about both insured deposit products and non-deposit products or hybrid products, an insured depository institution shall clearly segregate the official advertising statement or any similar statement from that portion of the advertisement that relates to the non-deposit products.

(f) *Official advertising statement in non-English language.* The non-English equivalent of the official advertising statement may be used in any advertisement, provided that the translation has had the prior written approval of the Corporation.

§ 328.7 Prohibition against receiving deposits at same teller station or window as noninsured institution.

(a) *Prohibition.* An insured depository institution may not receive deposits at any teller station or window where any noninsured institution receives deposits or similar liabilities.

(b) *Exception.* This section does not apply to deposits received at an automated teller machine or other remote electronic facility that receives deposits for an insured depository institution, or to deposits facilitated through a digital deposit-taking channel.

§ 328.8 Policies and Procedures.

(a) *Policies and Procedures.* An Insured Depository Institution must establish and maintain written policies and procedures to achieve compliance with this part. Such policies and procedures must be commensurate with the nature, size, complexity, scope, and potential risk of the deposit-taking activities of the Insured Depository Institution and must include, as appropriate, provisions related to monitoring and evaluating activities of persons that provide deposit-related services to the Insured Depository Institution or offer the Insured Depository Institution's deposit-related products or services to other parties.

(b) *Reservation of authority.* Nothing in this section shall be construed to limit the FDIC's authority to address violations of this part, the FDIC's authority to interpret the rules in this part, or any other authority the FDIC has pursuant to any other laws or regulations.

■ 3. Amend § 328.101 by adding the definitions for ''Crypto-asset'' and ''Deposit'' in alphabetical order, and revising the definitions for ''FDIC-Associated Images'', ''Hybrid Product'', ''Non-Deposit Product'', and ''Uninsured Financial Product'' to read as follows:

Subpart B—False Advertising, Misrepresentation of Insured Status, and Misuse of the FDIC's Name or Logo

§ 328.101 Definitions.

* * * * *

Crypto-asset means any digital asset implemented using cryptographic techniques.

Deposit has the same meaning as set forth under section 3(l) of the Federal Deposit Insurance Act, 12 U.S.C. 1813(l).

* * * * *

FDIC-Associated Images means the Seal of the FDIC, alone or within the letter C of the term FDIC; the Official Sign and Symbol of the FDIC, as set forth in § 328.2; the digital sign set forth in § 328.5; the Official Advertising Statement, as set forth in § 328.6; any similar images; and any other signs and symbols that may represent or imply that any deposit, liability, obligation certificate, or share is insured or guaranteed in whole or in part by the FDIC.

* * * * *

Hybrid Product has the same meaning as set forth under § 328.1.

* * * * *

Non-Deposit Product means any product that is not a ''deposit'', including, but not limited to: stocks, bonds, government and municipal securities, mutual funds, annuities (fixed and variable), life insurance policies (whole and variable), savings bonds, and crypto-assets. For purposes of this definition, a credit product is not a non-deposit product.

* * * * *

Uninsured Financial Product means any Non-Deposit Product, Hybrid-Product, investment, security, obligation, certificate, share, crypto-asset or financial product other than an ''Insured Deposit'' as defined in this section.

■ 4. Amend § 328.102 by adding paragraph (a)(3)(viii) and revising paragraphs (b)(3)(ii), (b)(4)(i), (b)(5), and (b)(6)(ii) to read as follows:

§ 328.102 Prohibition.

(a) * * *

(3) * * *

(viii) Use of FDIC-Associated Terms or FDIC-Associated Images, in a manner that inaccurately states or implies that a person other than an Insured Depository Institution is insured by the FDIC.

(b) * * *

(3) * * *

(ii) The statement omits or fails to clearly and conspicuously disclose material information that would be necessary to prevent a reasonable consumer from being misled, regardless of whether any such consumer was actually misled.

(4) * * *

(i) A person or Uninsured Financial Products are insured or guaranteed by the FDIC;

* * * * *

(5) Without limitation, a statement regarding deposit insurance will be deemed to omit or fail to clearly and conspicuously disclose material information if the absence of such information could lead a reasonable consumer to believe any of the material misrepresentations set forth in paragraph (b)(4) of this section or could otherwise result in a reasonable consumer being unable to understand the extent or manner of deposit insurance provided. Examples of such material information include, but are not limited to, the following:

(i) A statement made by a person other than an Insured Depository Institution that represents or implies that an advertised product is insured by the FDIC that fails to identify the Insured Depository Institution(s) with which the representing party has a direct or indirect business relationship for the placement of deposits and into which the consumer's deposits may be placed;

(ii) A statement made by a person that is not an insured depository institution regarding deposit insurance that fails to clearly and conspicuously disclose that the person is not an FDIC-insured depository institution and that FDIC insurance only covers the failure of the FDIC-insured depository institution. A statement that a person is not an FDIC-insured bank and deposit insurance covers the failure of an insured bank would be considered a clear statement for purposes of this provision.

(iii) A statement made by a person regarding deposit insurance in a context where deposits and non-deposit products are involved that fails to clearly and conspicuously differentiate between Insured Deposits and Non-Deposit Products by disclosing that Non-Deposit Products: are not insured by the FDIC; are not deposits; and may lose value.

(iv) A statement made by a person regarding pass-through deposit insurance coverage that fails to clearly and conspicuously disclose that certain conditions must be satisfied for pass-through deposit insurance coverage to apply.

(6) * * *

(ii) Has been advised by the FDIC in an advisory letter, as provided in § 328.106(a), or has been advised by another governmental or regulatory authority, including, but not limited to, another Federal banking agency, the Federal Trade Commission, the Bureau of Consumer Financial Protection, the U.S. Department of Justice, or a state bank supervisor, that such representations are false or misleading; and

* * * * *

Federal Deposit Insurance Corporation.

By order of the Board of Directors.

Dated at Washington, DC, on December 13, 2022.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2022–27349 Filed 12–20–22; 8:45 am]

BILLING CODE 6714–01–P

CONSUMER PRODUCT SAFETY COMMISSION

14 CFR Part 1421

[Docket No. CPSC–2021–0014]

Notice of Availability and Request for Comment: ''Study of Debris Penetration of Recreational Off-Highway Vehicle (ROV) Proof-of-Concept (POC) Floorboard Guards''

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule; availability of supplemental information.

SUMMARY: The U.S. Consumer Product Safety Commission (Commission or CPSC) is announcing the availability of, and seeking comment on, a report from SEA, Ltd. (SEA), ''Study of Debris Penetration of Recreational Off-Highway Vehicle (ROV) Proof-of-Concept (POC) Floorboard Guards'' (SEA Technical Report). This report is related to CPSC's notice of proposed rulemaking (NPR) regarding off-highway vehicle debris penetration hazards. CPSC contracted with SEA to perform debris penetration tests on POC floorboard guards per the test methods described in the NPR. The SEA Technical Report also evaluates an alternative test method for debris penetration that is proposed in two draft voluntary standards. The SEA testing evaluates the effectiveness of the test methods in addressing the debris penetration hazard and the feasibility of the proposed requirements in the NPR.

DATES: Comments must be received by January 20, 2023.

ADDRESSES: Submit comments, identified by Docket No. CPSC–2021–0014, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *www.regulations.gov.* Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by electronic mail (email), except as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal.

Mail/hand delivery/courier/confidential Written Submissions: Submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: *cpsc-os@cpsc.gov.*

Instructions: All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to *www.regulations.gov.* Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier/confidential written submissions.

Docket: For access to the docket to read background documents or comments received, go to: *www.regulations.gov,* and insert the docket number, CPSC–2021–0014, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Han Lim, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987–2327; email: *hlim@cpsc.gov.*

SUPPLEMENTARY INFORMATION: CPSC is engaged in a rulemaking to address debris penetration hazards associated with ROVs and Utility Task/Terrain Vehicles (UTVs). On July 21, 2022, the Commission published in the **Federal Register** an NPR regarding a Safety Standard for Debris Penetration Hazards, 87 FR 43688.

The NPR proposed test methods to address debris penetration hazards associated with ROVs and UTVs. The Outdoor Power Equipment Institute (OPEI) and Recreational Off-Highway Vehicle Association (ROHVA), two industry groups that represent ROV and UTV manufacturers in the United States, have proposed a different debris penetration test method in two draft voluntary standards.[1] These two draft standards, ANSI/OPEI B71.9–202x and ANSI/ROHVA–1–202x, include a drop test with an impact energy of 355 joules (the ''355 J drop test'') that OPEI and ROHVA assert will address the debris penetration hazard.[2] OPEI and ROHVA proposed this test method as an alternative to the NPR test methods. OPEI and ROHVA assert that the energy level used in the 355 J drop test method is based on the OPEI and ROHVA members' warranty claim and incident data.

CPSC contracted with SEA to perform debris penetration tests on POC floorboard guards per the test methods described in the NPR and the 355 J drop test method in the two draft voluntary standards. The Technical Report, ''Study of Debris Penetration of Recreational Off-highway Vehicle (ROV) Proof-of-Concept (POC) Floorboard Guards,'' completed by SEA in October 2022, provides discussion and test results from testing to the proposed requirements in the NPR, and to the 355 J drop test method proposed in the two draft voluntary standards. SEA conducted this testing to evaluate the feasibility and effectiveness of POC

[1] OPEI balloted the proposed test on August 3, 2022. ROHVA balloted the proposed test on September 8, 2022.

[2] OPEI included the draft proposed drop test procedure in a comment to the ROV/UTV Debris Penetration NPR (pages 29 to 32 in the PDF attachment): *https://www.regulations.gov/comment/CPSC-2021-0014-0191.* The drop test method involves a 2-inch diameter wood penetrator dowel that strikes an ROV/UTV floorboard surface when an 80-pound weight is dropped onto the dowel from 1 meter. The drop weight is dropped in a guided path using a plastic pipe or other means to allow for vertical free fall.

floorboard guards that conform to the proposed requirements in the NPR, as well as to assess the NPR and 355 J drop test methods.

SEA conducted debris penetration tests using full-scale, autonomously driven ROVs. SEA also tested a simulated ROV sled system it previously developed,[3] to evaluate POC floorboard guards' strength and their ability to reduce the debris penetration hazard. Both the sled tests and autonomous ROV were used to simulate an ROV colliding with an embedded tree branch (represented by a wooden dowel).

The sled tests were conducted in accordance with the proposed requirements in the NPR. Specifically, a simulated vehicle was propelled in a straight-line path towards 2-inch and 3-inch diameter wooden dowels at 10, 12, and 14 mph speeds. The report describes how floorboard guards can be designed to prevent debris penetration at 10 mph, as proposed in the NPR. All tests that had POC aluminum floorboard guards that were at least 0.125 inches thick did not have debris penetrations. These POC floorboard guards are thinner than an aftermarket floorboard guard that passed a 10 mph test during the 2021 SEA study, which was 0.170 inch thick. Test results also showed that POC floorboard guards capable of resisting debris penetration at 10 mph were additionally capable of resisting debris penetration at speeds greater than 10 mph. These test results appear to confirm the feasibility of designing floorboard guards that effectively reduce the risk to consumers of debris penetration hazards.

The SEA Technical Report also contains results of sled tests evaluating a commercially available, model year 2022 plastic floorboard that OPEI and ROHVA members indicated conforms to the draft 355 J drop test method. The SEA report compares the impact results at the 355 J energy level per the NPR test condition of a fully loaded vehicle traveling at 10 mph, which is approximately a 10,000 J energy level. The sled speed found to produce an impact energy level equivalent to the 355 J test condition is approximately 2.2 mph. Although no debris penetration of the plastic floorboard occurred at the 2.2 mph test condition, debris penetration did occur at the NPR's 10 mph test condition, as well as at a 6 mph test condition. The 10 mph speed is representative of incidents reviewed by CPSC and SEA staff, and it is reasonable to assume that drivers will operate ROVs and UTVs at these speeds in wooded areas where debris is likely. Thus, the test results indicate that the OPEI/ROHVA proposed 355 J energy drop test method draft requirement does not adequately prevent debris penetration at 10 mph and poses a risk of debris penetration that could cause serious injury or death to ROV and UTV occupants.

The Commission seeks public comment on the SEA Technical Report. The report is available on CPSC's website at: *https://www.cpsc.gov/content/Study-of-Debris-Penetration-of-Recreational-Off-highway-Vehicle-ROV-Proof-of-Concept-POC-Floorboard-Guards.*

Comments must be received by January 20, 2023.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2022–27640 Filed 12–20–22; 8:45 am]

BILLING CODE 6355–01–P

[3] For background information, the following 2021 SEA report describes the development of the autonomous and sled test methods and debris penetration testing of commercially available aftermarket floorboard guards: *https://www.cpsc.gov/content/Study-of-Debris-Penetration-of-Recreational-Off-Highway-Vehicle-ROV-Floorboards.*

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 51

RIN 2900–AR62

Payments Under State Home Care Agreements for Nursing Home Care

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs proposes to amend its State home per diem regulation to provide a new formula for calculating the prevailing rate VA would pay a State home that enters into a State home care agreement to provide nursing home care to eligible veterans.

DATES: Comments must be received on or before February 21, 2023.

ADDRESSES: Comments must be submitted through *www.regulations.gov*. Except as provided below, comments received before the close of the comment period will be available at *www.regulations.gov* for public viewing, inspection, or copying, including any personally identifiable or confidential business information that is included in a comment. We post the comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov.* VA will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm the individual. VA encourages 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. Any public comment received after the comment period's closing date is considered late and will not be considered in the final rulemaking.

FOR FURTHER INFORMATION CONTACT: Lisa Minor, National Director, Facilities Based Care, Geriatrics and Extended Care, 12GEC, Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 632–8320. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

I. Background

The State homes program is the largest provider of long-term care for our Nation's veterans with more than 162 State homes across all 50 states and Puerto Rico, totaling over 30,000 beds. They provide skilled nursing care, domiciliary care, and adult day health care (ADHC) to both veterans and non-veterans. Each State home is owned, operated, and managed by each State's government. In order to qualify for VA per diem payments, a State home facility must be formally recognized and certified by VA as meeting the requirements and standards (*e.g.,* quality of life, quality of care, physical environment, etc.) necessary to receive such payments. After certification, VA reviews each State home annually to ensure continued compliance with VA's requirements and standards.

As it pertains to nursing home care, VA pays State homes a per diem for each eligible veteran who receives nursing home care from a State home. There are two types of per diem rates that VA may pay a State home for providing nursing home care: a basic rate for veterans who meet the State nursing home per diem eligibility criteria or a prevailing rate for certain veterans with service-connected disabilities for whom the State provides nursing home care pursuant to a State home care agreement (SHCA). This rulemaking proposes changes that would affect the prevailing rate for nursing home care, not the basic rate.

II. Authority

VA has authority to pay State homes for providing nursing home care to

eligible veterans under title 38 of the United States Code (U.S.C.), sections 1741 through 1745. Section 1745(a) sets forth VA's ability to enter into contracts or agreements with State homes to pay for nursing home care provided to eligible veterans within such homes. Section 1745(a)(2) further states that the payments by VA to State homes under such contracts or agreements shall be based on a formula, developed by the Secretary in consultation with the State home, to adequately reimburse the State home for the care.

Current § 51.41 of title 38 of the Code of Federal Regulations (CFR) implements VA's authority under section 1745 to enter into contracts or agreements with State homes for nursing home care provided to eligible veterans. Paragraph (a) provides that VA and State homes may enter into both contracts and agreements, but each veteran's care will be paid through only one of these two instruments. We are not proposing any changes to paragraph (a) in this rulemaking. Paragraph (b) addresses payment to State homes by VA when the State home provides care under a contract. We are not proposing any changes to paragraph (b) in this rulemaking. Paragraph (c) addresses payment to State homes by VA when the State home provides care under a SHCA. Specifically, paragraph (c) provides the formula for calculating the prevailing rate. We are proposing changes to paragraph (c) in this rulemaking by:

- Listing the current steps used to calculate the prevailing rate in subparagraphs and labeling them.
- Establishing a baseline fiscal year from the current prevailing rate and the Market Basket rate.
- Adding an additional step of applying the Market Basket rate to track with increased costs in a new subparagraph.
- Revising the note.
- Making a few technical corrections (*i.e.,* grammatic changes).

III. Current § 51.41(c)(1): Formula Used To Calculate Prevailing Rates

Currently, the prevailing rate is specific to each State home and is published each year on VA's website. Veterans Affairs, *Geriatrics and Extended Care, https://www.va.gov/geriatrics/pages/State_Veterans_Home_Program_per_diem.asp,* last updated October 6, 2022. The prevailing rate is based on Centers for Medicare and Medicaid Services (CMS) case-mix levels. A case-mix is a classification system; the distribution of patients into categories reflecting differences in severity of illness or resource consumption. Centers for Medicare and Medicaid Services, *Glossary, https://www.cms.gov/apps/glossary/default.asp?Letter=C&Language=English,* last modified May 14, 2006. VA began using two CMS case-mix data sets in 2013: Resource Utilization Groups (RUG), which applies to metropolitan areas, and Skilled Nursing Facility Prospective Payment System (SNF–PPS), which applies to rural areas. See 77 FR 72738 (December 6, 2012).

Current § 51.41(c)(1) outlines the formula for calculating payments. The first step is to determine whether the RUG or SNF–PPS case-mix level applies. The next step is to compute the daily rate for each State home by following this formula:

- Multiply the labor component by the State home wage index for each of the applicable case-mix levels.
- Add to that amount the non-labor component.
- Divide the sum of the results of these calculations by the number of applicable case-mix levels.
- Add to this quotient the amount based on the CMS payment schedule for physician services. The amount for physician services, based on information published by CMS, is the average hourly rate for all physicians, with the rate modified by the applicable urban or rural geographic index for physician work, then multiplied by 12, then divided by the number of days in the year.

The current note to § 51.41(c)(1) further explains, in pertinent part, that the amount calculated under this formula reflects the prevailing rate payable in the geographic area in which the State home is located for nursing home care furnished in a non-VA nursing home.

IV. Changes to the CMS Case-Mix Classification System

In July 2018, CMS finalized a new case-mix classification system, the Patient Driven Payment Model (PDPM), which replaced the RUG and SNF–PPS case-mix classification systems. It became effective on October 1, 2019. Centers for Medicare and Medicaid Services, *Patient Driven Payment Model Overview, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM,* last modified July 29, 2022. As a result of changes by CMS to their case-mix classification systems (RUG and SNF–PPS), VA is now revising its payment formula in § 51.41(c)(1).

Consistent with the requirement in 38 U.S.C. 1745(a)(2) to consult with State homes in developing the payment formula for nursing home care provided through SHCAs, VA consulted with the National Association of State Veterans Homes (NASVH) in June of 2019 on whether VA should adopt CMS's PDPM formula, or if not, what formula should be utilized. VA, (2019), *Prevailing Rate Consultation State Home Per Diem (SHPD).* Denver, CO. VA and NASVH agreed that it would not be appropriate to use the PDPM formula. Primarily, VA will not adopt the PDPM formula because this formula is focused on incentivizing providers to take on new patients, which is not an issue VA faces with State homes that provide nursing home care. An additional reason is that the PDPM model is specific to the needs of CMS facilities, rather than State homes. For example, under Medicare, CMS only pays for the first 100 days of skilled nursing home care. After which, the patient's care must be paid for by another source (*i.e.,* private, insurance, Medicaid), or the patient is discharged. This does not apply to State homes. In many cases, State homes provide nursing home care to our veterans for the remainder of their lives.

Further, 31 percent of the State homes that provide nursing home care to eligible veterans are not subject to the CMS PDPM formula as they are not certified by CMS and do not receive CMS payments. After consultation with NASVH, VA determined to instead propose revising the current formula as explained further below.

V. Changes to the Prevailing Rate

We propose to keep the current formula described in § 51.41(c)(1) to create a baseline rate and then add, at the end, a provision for using the CMS Skilled Nursing Facilities (SNF) Market Basket increase to account for annual increases that will reflect price inflation facing providers in the provision of medical services. The CMS SNF Market Basket increase rates are published in the **Federal Register** on an annual basis. In 2023, the CMS SNF Market Basket rate increase was 5.1% percent. See 87 FR 47502 (August 3, 2022).

The CMS SNF Market Basket is a fixed-weight index. Generally, a market basket is a group of products designed to track the performance of a specific market segment and determine inflation levels. Thus, the CMS SNF Market Basket increase measures the price changes of a permanent mix of goods and services used by nursing homes between two set dates. They are used to update payments and cost limits in the various CMS payment systems and reflect price inflation facing providers in the provision of medical services. Centers for Medicare and Medicaid

Services, *Market Basket Definitions and General Information, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/info.pdf.*

VA believes that the CMS SNF Market Basket rate would more accurately reflect actual costs than would an alternate method such as a component of the Consumer Price Index (CPI). The CMS SNF Market Basket rate is adjusted annually based on price changes in goods and services specifically identified as being utilized in nursing home care, while other measures such as the CPI reflect price changes in goods and services in the general medical services field.

VI. Rates for Fiscal Year (FY) 2020 Through 2023

CMS's new payment model PDPM became effective in FY 2020. Therefore, we established an agreement with CMS to obtain average market basket data needed to continue providing an annual per diem rate until this rulemaking is finalized. Thus, for FY 2020 through 2023, we have and will continue to use the average market basket data provided by CMS to calculate the per diem rate that we are currently using.

VII. Rates for FY 2024

We plan to use our new formula in FY 2024. In determining the baseline for this formula, we would use the rate for FY 2023 because we anticipate this rulemaking to be finalized and effective on or before October 1, 2023, which is the first day of FY 2024. If that changes due to delays in the rulemaking process, we will ensure that we receive the necessary CMS data to continue our current formula until the rule becomes effective, and we will ensure the correct FY used for the baseline is appropriately and accurately referenced in the amended regulation.

VIII. Regulation Text Changes to § 51.41(c)

First, we propose a nonsubstantive revision of changing the title of § 51.41(c) from ''*Payments under State home care agreements.*'' to ''*Payments for nursing home care under State home care agreements.*'' This change clarifies that subparagraph (c) only applies to State nursing homes.

We also propose to revise § 51.41(c) by making the term ''agreements'' in State home care agreements singular to ensure consistency with 38 U.S.C. 1745, and with revisions of 38 CFR part 51. 83 FR 61250 (November 28, 2018). Thus, we would revise the sentence that currently states, ''State home care agreements under this section will provide for payments at the rate determined by the following formula'' to instead state ''A State home care agreement for nursing home care under this section will provide for payments at the rate determined by the following formula.''

We also propose to reorganize § 51.41(c)(1) by breaking apart the steps of the formula and putting them into a list for easier readability. The steps will be listed in proposed § 51.41(c)(1)(i) through (ii).

Section 51.41(c)(1)(i) would require that one would determine which case-mix applies, the RUG or SNF–PPS. We also propose to change the name of the case-mix level used for rural areas in § 51.41(c)(1)(i). Currently, it states Skilled Nursing Prospective Payment System. We propose to change it to Skilled Nursing Facility Prospective Payment System. The word ''facility'' was evidently left off through an inadvertent oversight since the rulemaking that placed this name in the regulation did not explain an intended deviation from the proper title. By making this correction, the name will align with the name that CMS uses.

Proposed § 51.41(c)(1)(ii) would require that one compute the daily rate for each State home, using the formula described above. The formula would be listed in proposed paragraphs (c)(1)(ii)(A) through (E). As previously explained, paragraphs (c)(1)(ii)(A) through (D) are substantively identical to the current formula, but merely listed out for ease of readability.

Proposed paragraph (c)(1)(ii)(E) would include the new calculation to the formula and would provide that one would multiply the current per diem baseline by the CMS SNF Market Basket increase in effect as of the fiscal year in which the final rule becomes effective to obtain the reference total per diem baseline rate from which subsequent fiscal year per diem rates will be calculated. For calculation of SNF per diem rates for subsequent fiscal years VA will apply the CMS SNF Market Basket increase to the total per diem baseline each year.

Lastly, we propose to amend the note in § 51.41(c) by clarifying that the first sentence is applicable to State homes. Additionally, we propose to add a sentence stating that the amount calculated under the new formula applies to both new and existing facilities with SHCAs.

IX. Technical and Grammatic Corrections to Part 51

We also propose to correct technical errors in 38 CFR 51.70 and 51.300. Section 51.70(n) erroneously refers to § 51.110(d)(2)(ii); however, the reference should be to § 51.110(e)(2)(ii). Therefore, we propose to revise § 51.70(n) by removing ''51.110(d)(2)(ii)'' and in its place inserting ''51.110(e)(2)(ii)''.

Section 51.110(d) refers to Version 2.0 of the Centers for Medicare and Medicaid Services (CMS) Resident Assessment Instrument Minimum Data Set. The reference should be Version 3.0 as noted in § 51.110(b)(1). The prior amendment stated the change and explained the rationale. 77 FR 26183 (May 3, 2012). We propose to correct this inadvertent oversight by changing ''Version 2.0'' to ''Version 3.0'' in § 51.110(d).

Section 51.300(d)(3) refers to paragraphs (a)(2)(i) through (vii) of this section. However, the reference should be to paragraphs (d)(2)(i) through (vii), which lists the circumstances requiring the documentation to which paragraph (d)(3) refers. We propose to revise § 51.300(d)(3) by removing ''(a)(2)(i) through (vii)'', and in its place inserting ''(d)(2)(i) through (vii)''.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866.

VA's impact analysis can be found as a supporting document at *https://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its Regulatory Impact Analysis (RIA) are available on VA's website at *https://www.va.gov/orpm/,* by following the link for ''VA Regulations Published From FY 2004 Through Fiscal Year to Date.''

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory

Flexibility Act (5 U.S.C. 601–612). The rulemaking would revise the formula VA uses to calculate the per diem it pays State homes for nursing home care of certain veterans. The effect of the rule would be to change VA payments to State homes. Therefore, this rule only affects veterans and State homes.

All State homes are owned, operated, and managed by State governments, except for a small number operated by entities under contract with State governments. Neither these contractors nor State governments are small entities as defined in 5 U.S.C. 601. State homes subject to this proposed rulemaking are State homes that are currently under a State home care agreement, those that enter into a new agreement, and any facility that begins an agreement for the first time. The effect of the rule would impose no direct costs on the State homes. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, or tribal governments, or on the private sector.

Paperwork Reduction Act

Although this action relates to provisions constituting collections of information at 38 CFR 51.41, under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), no new or proposed revised collections of information would be associated with this proposed rule. The information collection requirements for § 51.41(e) are currently approved by the Office of Management and Budget (OMB) and have been assigned OMB control numbers 2900–0091 and 2900–0160.

List of Subjects in 38 CFR Part 51

Administrative practice and procedure; Claims; Adult Day Health Care; Domiciliary, Dental health; Government contracts; Grant programs—health; Grant programs—veterans; Health care; Health facilities; Health professions; Health records; Mental health programs; Nursing homes; Reporting and recordkeeping requirements; Travel and transportation expenses; Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on December 13, 2022, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Consuela Benjamin,

Regulation Development Coordinator Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons described in the preamble, Department of Veterans Affairs proposes to amend 38 CFR part 51 as follows:

PART 51—PER DIEM FOR NURSING HOME, DOMICILIARY, OR ADULT DAY HEALTH CARE OF VETERANS IN STATE HOMES

■ 1. The authority citation for part 51 continues to read as follows:

Authority: 38 U.S.C. 101, 501, 1710, 1720, 1741–1743, 1745, and as follows.

* * * * *

■ 2. In § 51.41 revise the introductory text of paragraph (c) and paragraph (c)(1) and the Note under paragraph (c)(1) to read as follows:

§ 51.41 Contracts and State home care agreements for certain veterans with service-connected disabilities.

* * * * *

(c) *Payments for nursing home care under State home care agreements.*

(1) State homes must sign an agreement to receive payment from VA for providing care to certain eligible veterans under a State home care agreement. A State home care agreement for nursing home care under this section will provide for payments at the rate determined by the following formula.

(i) Determine whether the Resource Utilization Groups (RUG) or Skilled Nursing Facility Prospective Payment System (SNF–PPS) applies.

For State Homes in a metropolitan statistical area, use the published fiscal year Centers for Medicare and Medicaid Services (CMS) RUG case-mix levels for the applicable metropolitan statistical area.

For State Homes in a rural area, use the published fiscal year CMS SNF–PPS case-mix levels for the applicable rural area.

(ii) Compute the daily rate for each State home, using the following formula in the order described:

(A) Multiply the labor component by the State home wage index for each of the applicable case-mix levels.

(B) Add to that amount the non-labor component.

(C) Divide the sum of the results of these calculations by the number of applicable case-mix levels.

(D) Add to this quotient the amount based on the CMS payment schedule for physician services. The amount for physician services, based on information published by CMS, is the average hourly rate for all physicians, with the rate modified by the applicable urban or rural geographic index for physician work, then multiplied by 12, then divided by the number of days in the year. The resulting sum is the per diem baseline rate for the State home.

(E) Multiply the per diem baseline rate from the previous year by the CMS Skilled Nursing Facilities (SNF) Market Basket increase in effect as of [Date 30 days after date of publication of Final Rule in the **Federal Register**]. The sum establishes the reference total per diem baseline rate from which subsequent fiscal year per diem rates will be calculated. For calculation of SNF per diem rates for subsequent fiscal years VA will apply the CMS SNF Market Basket increase to the total per diem each year.

Note to paragraph (c)(1): The amount calculated under this formula reflects the prevailing rate payable in the geographic area in which the State home is located for nursing home care furnished in a State home. The amount calculated under this formula applies to both new and existing facilities with State home care agreements. Further, the formula for establishing these rates includes CMS information that is published in the **Federal Register** every year and is effective beginning October 1 for the entire fiscal year. Accordingly, VA will adjust the rates annually.

* * * * *

§ 51.70 [Amended]

■ 3. In § 51.70(n), removing the term ''51.110(d)(2)(ii)'', and adding in its place, the term ''51.110(e)(2)(ii)''.

§ 51.110 [Amended]

■ 4. In § 51.110(d), removing the term ''Version 2.0'', and adding in its place, the term ''Version 3.0''.

§ 51.300 [Amended]

■ 5. In § 51.300(d)(3), removing the term ''(a)(2)(i) through (vii)'', and adding in its place, the term ''(d)(2)(i) through (vii)''.

[FR Doc. 2022–27436 Filed 12–20–22; 8:45 am]

BILLING CODE 8320–01–P

Notices

Federal Register
Vol. 87, No. 244
Wednesday, December 21, 2022

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Temporary Bridge Funding Opportunity Program

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the extension of a currently approved information collection, Temporary Bridge Funding Opportunity Program.

DATES: Comments must be received in writing on or before February 21, 2023 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to contact listed under **FOR FURTHER INFORMATION CONTACT**.

Comments submitted in response to this notice may be made available to the public through relevant websites and upon request. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, 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. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

The public may inspect the draft supporting statement and/or comments received at the Sydney R. Yates Federal Building, 1400 Independence Ave., Washington, DC, Room 3NW Yates during normal business hours. Visitors are encouraged to call ahead to 800–832–1355 to facilitate entry to the building. The public may request an electronic copy of the draft supporting statement and/or any comments received be sent via return email. Requests should be emailed to the contact listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Kevin Naranjo, Cooperative Forestry, Wood Innovations, 404–673–3482, *kevin.naranjo@usda.gov,* or via facsimile 202–205–1271. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339 twenty-four hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Title: Temporary Bridge Funding Opportunity Program.

OMB Number: 0596–0255.

Expiration Date of Approval: 05/31/2023.

Type of Request: Extension with no revision of a currently approved information collection.

Abstract: USDA Forest Service is delivering the Temporary Bridge Funding Opportunity (TBFO) Program as part of the Bipartisan Infrastructure Law. Section 40804(b)5 of the Infrastructure Investment and Jobs Act Public Law 117–58 (11/15/2021) directs the Forest Service to provide funding for States and Indian Tribes to establish rental programs for portable skidder bridges, bridge mats, or other temporary water crossing structures, to minimize stream bed disturbance on non-Federal land and Federal land. The need and process to collect information from State and Indian Tribe applicants is detailed in 2 CFR part 200 and Forest Service Handbook 1509.11, Chapter 20, which prescribes administrative requirements and processes applicable to all Forest Service domestic Federal Financial Assistance awards to States and Indian Tribes. In particular, collection of information is necessary to ascertain the required needs of applicants to initiate a temporary bridge program to protect water resources and reduce water quality degradation during forestry related operations requiring temporary water resource crossings. Information collected will be reviewed by Forest Service staff to evaluate eligibility and proposed activities of the applicant.

Affected Public: State and Tribal Government.

Estimate of Burden per Response: 6.5 hours.

Estimated Annual Number of Respondents: 50.

Estimated Annual Number of Responses per Respondent: 1

Estimated Total Annual Burden on Respondents: 325 hours.

Comment is Invited:

Comment is invited on: (1) whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the Agency, including whether the information will have practical or scientific utility; (2) the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission request toward Office of Management and Budget approval.

Jaelith Hall-Rivera,

Deputy Chief, State & Private Forestry.

[FR Doc. 2022–27674 Filed 12–20–22; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Virginia 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 Virginia Advisory Committee

(Committee) will hold a web meeting via Zoom on Monday, January 23, 2023, at 2 p.m. Eastern Time. The purpose of the meeting is to discuss progress on its draft report on police oversight and accountability in Virginia.

DATES: The meeting will be held on: Monday, January 23, 2023, at 2 p.m. Eastern Time.

Registration: *https://tinyurl.com/228ccv34.*

Join by Phone: 1–833–435–1820; Meeting ID: 160 843 5494#.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at *mwojnaroski@usccr.gov* or 1–202–618–4158.

SUPPLEMENTARY INFORMATION: Members of the public may listen to this discussion through the above call-in number (audio only) or online registration link (audio/visual). An open comment period will be provided to allow members of the public to make a statement as time allows. 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. Individuals who are deaf, deafblind, and/or hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to 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.*

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, Virginia 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

I. Welcome & Roll Call
II. Approval of Minutes
III. Announcements and Updates
IV. Discussion: Report Draft
V. Next Steps
VI. Public Comments
VII. Adjournment

Dated: December 16, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–27701 Filed 12–20–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the South Dakota Advisory Committee; Cancellation

AGENCY: Commission on Civil Rights

ACTION: Notice; cancellation of meeting dates.

SUMMARY: The Commission on Civil Rights published a notice in the **Federal Register** concerning a meeting of the South Dakota Advisory Committee. The following meetings are cancelled: Monday, January 9, 2023, and Monday, February 13, 2023; both at 3:30 p.m. (CT). The notice is in the **Federal Register** of Tuesday, November 1, 2022, in FR Doc. 2022–23714, in the first, second, and third columns of page 65742.

FOR FURTHER INFORMATION CONTACT: Mallory Trachtenberg, 202–809–9618, *mtrachtenberg@usccr.gov.*

Dated: December 16, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–27704 Filed 12–20–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Texas Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that the Texas Advisory Committee (Committee) will hold a series of meetings via ZoomGov on the following dates and times listed below. These virtual business meetings are for the purpose of debriefing testimony and plan for future panels.

DATES: These meetings will be held on:

- Wednesday, January 18, 2023, from 12:00 p.m.–1:00 p.m. CT
- Wednesday, February 15, 2023, from 12:00 p.m.–1:00 p.m. CT
- Tuesday, March 14, 2023, from 12:00 p.m.–1:00 p.m. CT

ADDRESSES: Zoom Link to Join:

- Wednesday, January 18th: *https://www.zoomgov.com/meeting/register/vJItc-iqrTIoGo1YPedD9YBW9WIxMkal01k.*
- Wednesday, February 15th: *https://www.zoomgov.com/meeting/register/vJItfu6sqzgiEpgscKLF43smP8eIq4_Oe90.*
- Tuesday, March 14th: *https://www.zoomgov.com/meeting/register/vJIsduuupzIqEzZ78fhqGnpBPteYyLayWbA.*

FOR FURTHER INFORMATION CONTACT: Brooke Peery, Designated Federal Officer (DFO) at *bpeery@usccr.gov* or by phone at (202) 701–1376. 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.

SUPPLEMENTARY INFORMATION: Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be emailed to Brooke Peery (DFO) at *bpeery@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzkoAAA.*

Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call
II. Approval of Minutes
III. Committee Discussion
IV. Public Comment
V. Adjournment

Dated: December 16, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–27700 Filed 12–20–22; 8:45 am]

BILLING CODE 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 Construction Questionnaire for the Building Permit Official (SOC–QBPO)

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite 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. Public comments were previously requested via the **Federal Register** on October 13, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau, Commerce.

Title: Survey of Construction Questionnaire for the Building Permit Official (SOC–QBPO).

OMB Control Number: 0607–0125.

Form Number(s): SOC–QBPO.

Type of Request: Regular submission, request for an extension, without change, of a currently approved collection.

Number of Respondents: 1,000.

Average Hours per Response: 15 minutes.

Burden Hours: 250.

Needs and Uses: The U.S. Census Bureau is requesting an extension of the currently approved collection for the Survey of Construction Questionnaire for the Building Permit Official (SOC–QBPO). The information collected on the SOC–QBPO is necessary to carry out the sampling for the Survey of Housing Starts, Sales and Completions (OMB number 0607–0110), also known as the Survey of Construction (SOC). Government agencies and private companies use statistics from the SOC to monitor and evaluate the large and dynamic housing construction industry.

The SOC–QBPO is an electronic questionnaire. The field representatives (FRs) either call or visit the respondents to enter their survey responses into a laptop computer using the Computer Assisted Personal Interviewing (CAPI) software formatted for the SOC–QBPO. The overall length of the interview will not change, and the sample size will only receive a minor downward adjustment.

The Census Bureau FRs use the SOC–QBPO to obtain information on the operating procedures of a permit office. This enables them to locate, classify, list, and sample building permits for residential construction. These permits are used as the basis for the sample selected for SOC. The Census Bureau also uses the information to verify and update the geographic coverage of permit offices.

Failure to collect this information would make it difficult, if not impossible, to accurately classify and sample building permits for the SOC. Data for two principal economic indicators are produced from the SOC: New Residential Construction (housing starts and housing completions) and New Residential Sales. Government agencies use these statistics to evaluate economic policy, measure progress towards the national housing goal, make policy decisions, and formulate legislation. For example, the Board of Governors of the Federal Reserve System uses data from this survey to evaluate the effect of interest rates in this interest-rate sensitive area of the economy. The Bureau of Economic Analysis (BEA) uses the data in developing the Gross Domestic Product (GDP). The private sector and other data users from Department of Housing and Urban Development (HUD) and the National Association of Home Builders (NAHB) use the information for estimating the demand for housing, building materials and the many products used in new housing and to schedule production, distribution, and sales efforts. The financial community uses the data to estimate the demand for short-term (construction loans) and long-term (mortgages) borrowing.

Affected Public: State, local, or Tribal government.

Frequency: Annually.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, United States Code, sections 131 and 182.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

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 and entering either the title of the collection or the OMB Control Number 0607–0125.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–27708 Filed 12–20–22; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–62–2022]

Foreign-Trade Zone (FTZ) 163—Ponce, Puerto Rico; Notification of Proposed Production Activity, Global Manufacturing LLC, (Mattresses and Box Springs), Ponce, Puerto Rico

CODEZOL, C.D., grantee of FTZ 163, submitted a notification of proposed production activity to the FTZ Board (the Board) on behalf of Global Manufacturing LLC, located in Ponce, Puerto Rico within FTZ 163. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on December 8, 2022.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/component(s) and specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via *www.trade.gov/ftz.*

The proposed finished products include mattresses with inner springs, box springs, and bunkettes—one layer of pre-cut wood with a layer of fabric (duty rate ranges from duty-free to 3%).

The proposed foreign-status materials and components include: knitted fabrics in rolls and pre-cut composed of (98.5% polyester and 1.5% elastane/100% polyester/96% polyester and 4% metallic); woven fabrics in rolls and pre-cut composed of 80 percent polyester and 20 percent polypropylene; polyurethane foam in rolls and pre-cut; memory foam in rolls and precut; 100% polyester non-woven felt pad sheets used to upholster the interior of the mattress; innerspring units (with uncovered and covered inner springs); pre-cut pine wood; steel wire; and, steel mesh (duty rate ranges from duty-free to 14.9%. The request indicates that inner spring units and pre-cut pine wood are

subject to antidumping/countervailing duty (AD/CVD) orders if imported from certain countries. The Board's regulations (15 CFR 400.14(e)) require that merchandise subject to AD/CVD orders, or items which would be otherwise subject to suspension of liquidation under AD/CVD procedures if they entered U.S. customs territory, be admitted to the zone in privileged foreign (PF) status (19 CFR 146.41). The request also indicates that certain materials/components are subject to duties under Section 232 of the Trade Expansion Act of 1962 (Section 232) or Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 232 and Section 301 decisions require subject merchandise to be admitted to FTZs in PF status.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is January 30, 2023.

A copy of the notification will be available for public inspection in the ''Online FTZ Information System'' section of the Board's website.

For further information, contact Diane Finver at *Diane.Finver@trade.gov.*

Dated: December 15, 2022.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2022–27691 Filed 12–20–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–61–2022]

Foreign-Trade Zone (FTZ) 61—San Juan, Puerto Rico; Notification of Proposed Production Activity, Boehringer Ingelheim Animal Health Puerto Rico LLC, (Pharmaceutical Products/Canine), Barceloneta, Puerto Rico

Boehringer Ingelheim Animal Health Puerto Rico LLC submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Barceloneta, Puerto Rico within Subzone 61AC. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on December 13, 2022.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via *www.trade.gov/ftz.* The proposed finished product(s) would be added to the production authority that the Board previously approved for the operation, as reflected on the Board's website.

The proposed finished products include medicament that treats fleas and ticks in finished (packaged) and semi-finished (unpackaged) chewable tablets for canines (duty rate is duty-free).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is January 30, 2023.

A copy of the notification will be available for public inspection in the ''Online FTZ Information System'' section of the Board's website.

For further information, contact Juanita Chen at *juanita.chen@trade.gov.*

Dated: December 15, 2022.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2022–27690 Filed 12–20–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–094]

Refillable Stainless Steel Kegs From the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review, Rescission of Review in Part; 2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that certain producers/exporters of refillable stainless steel kegs (kegs) from the People's Republic of China (China) received countervailable subsidies during the period of review (POR) from January 1, 2020, through December 31, 2020. In addition, we are rescinding the review with respect to 35 companies. Interested parties are invited to comment on these preliminary results.

DATES: Applicable December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Theodore Pearson, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2631.

Background

On February 4, 2022, Commerce published the notice of initiation of an administrative review of the countervailing duty (CVD) order on kegs from China.[1] On August 1, 2022, Commerce extended the deadline for the preliminary results of this administrative review by 105 days, until December 16, 2022.[2]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[3] A list of topics discussed in the Preliminary Decision Memorandum is included as the 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 *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The products covered by the order are kegs. For a complete description of the scope, *see* the Preliminary Decision Memorandum.[4]

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each subsidy program found countervailable, we preliminarily find that there is a subsidy, (*i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific).[5] For a full description of the methodology underlying our

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 87 FR 6487 (February 4, 2022) (*Initiation Notice*).

[2] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review; 2020,'' dated August 1, 2022.

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Countervailing Duty Administrative Review, Rescission of Review in Part, 2020: Refillable Stainless Steel Kegs from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See* Preliminary Decision Memorandum.

[5] *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.

conclusions, including our reliance, in part, on adverse facts available pursuant to sections 776(a) and (b) of the Act, *see* the Preliminary Decision Memorandum.

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation. Commerce received a timely-filed withdrawal request with respect to 37 companies from American Keg Company (the petitioner).[6] Of the 37 companies, two companies, Guangzhou Jingye Machinery Co., Ltd. (Jingye) and Guangzhou Ulix Industrial & Trading Co., Ltd. (Ulix), filed requests for review of themselves which were not withdrawn.[7] Because the withdrawal request from the petitioner was timely filed, and no other parties requested a review of the other 35 companies, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this review of the Order with respect to the 35 companies. For a complete list of the companies, *see* Appendix to the Preliminary Decision Memorandum.

Preliminary Rate for Non-Selected Companies Under Review

There are two companies, Jingye and Ulix, for which a review was requested and not rescinded, and which were not selected as mandatory respondents or found to be cross-owned with a mandatory respondent. The statute and Commerce's regulations do not directly address the establishment of rates to be applied to companies not selected for individual examination where Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of the Act, which provides the basis for calculating the all-others rate in an investigation.

Section 705(c)(5)(A)(i) of the Act instructs Commerce, as a general rule, to calculate an all-others rate equal to the weighted average of the countervailable subsidy rates established for exporters and/or producers individually examined, excluding any rates that are zero, *de minimis,* or based entirely on facts available. In this review, the preliminary rate calculated for Ningbo Master International Trade Co., Ltd. (Ningbo Master), the sole mandatory respondent, was not zero, *de minimis,* or based entirely on facts available. Therefore, for the companies for which a review was requested that were not selected as mandatory company respondents, and for which Commerce did not receive a timely request for withdrawal of review, Commerce based the preliminary subsidy rate on the preliminary rate calculated for Ningbo Master.

Preliminary Results of Review

We preliminarily find the following net countervailable subsidy rates for the period January 1, 2020, through December 31, 2020, are as follows:

Manufacturer/exporter	Subsidy rate (percent *ad valorem*)
Ningbo Master International Trade Co., Ltd[8]	5.13
Review-Specific Average Rate Applicable to the Following Companies[9]	
Guangzhou Jingye Machinery Co., Ltd	5.13
Guangzhou Ulix Industrial & Trading Co., Ltd	5.13

Disclosure and Public Comment

We will disclose to parties in this review, the calculations performed for these preliminary results within five days after the date of publication of this notice.[10] Interested parties case briefs no later than 30 days after the date of publication of these preliminary results of review.[11] Rebuttals to case briefs may be filed no later than seven days after the case briefs are filed, and all rebuttal comments must be limited to comments raised in the case briefs.[12] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information until further notice.[13]

Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this review are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically using ACCESS. An electronically-filed request must be received successfully, and in its entirety, by ACCESS by 5:00 p.m. Eastern Time, within 30 days after the date of publication of this notice. Hearing 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, parties will be notified of the date and time for the hearing to be determined.

Unless extended, we intend to issue the final results of this administrative review, which will include the results of our analysis of the issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Cash Deposit Requirements

Pursuant to section 751(a)(2)(C) of the Act, Commerce intends, upon publication of the final results, to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the respondents listed above on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review. If the rate calculated in the final results is zero or *de minim*is, no cash deposit will be required on shipments of the subject merchandise entered or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review.

For all non-reviewed firms, CBP will continue to collect cash deposits of estimated countervailing duties at the all-others rate or the most recent company-specific rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Assessment Rates

In accordance with 19 CFR 351.221(b)(4)(i), we preliminarily

[6] *See* Petitioner's Letter, ''Withdrawal of Request for Administrative Review,'' dated April 20, 2022.

[7] *See* Ulix and Jingye's Letter, ''Request for Administrative Review,'' dated January 3, 2022.

[8] Cross-owned affiliates are: Ningbo Major Draft Beer Equipment Co., Ltd. and Zhejiang Major Technology Co., Ltd.

[9] This rate is based on the rate for the respondent that was selected for individual review, excluding rates that are zero, *de minimis,* or based entirely on facts available. *See* section 735(c)(5)(A) of the Act.

[10] *See* 19 CFR 351.224(b).

[11] *See* 19 CFR 351.309(c).

[12] *See* 19 CFR 351.309(d).

[13] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 29615 (May 18, 2020); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

assigned subsidy rates in the amounts shown above for the producers/exporters shown above. Upon completion of the administrative review, consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), Commerce shall determine, and CBP shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

For the companies for which this review is rescinded, we will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2020, through December 31, 2020, in accordance with 19 CFR 351.212(c)(l)(i).

Notification to Interested Parties

These preliminary results and notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: December 14, 2022.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2022–27688 Filed 12–20–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–112, C–570–113]

Certain Collated Steel Staples From the People's Republic of China: Initiation of Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In response to a request from KYOCERA SENCO Industrial Tools, Inc. (Senco), the Department of Commerce (Commerce) is initiating country-wide circumvention inquiries to determine whether imports of certain collated steel staples (collated staples), which are completed in Thailand or Vietnam using parts and components from the People's Republic of China (China), are circumventing the antidumping duty (AD) and countervailing duty (CVD) orders on collated staples from China.

DATES: Applicable December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Brian Smith (Thailand) or Shane Subler (Vietnam), Office VIII, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1766 and (202) 482–2000, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 15, 2022, pursuant to section 781(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.226(c), Senco filed a circumvention inquiry request alleging that collated staples completed in Thailand or Vietnam using parts and components manufactured in China are circumventing the orders [1] and, accordingly, should be included within the scope of the orders.[2]

Scope of the Orders

The merchandise covered by these *Orders* is certain collated steel staples. Merchandise covered by these *Orders* is currently classifiable under subheading 8305.20.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). While the HTSUS subheading and ASTM specification are provided for convenience and for customs purposes, the written description of the subject merchandise is dispositive. *See* the Initiation Memorandum for further discussion.[3]

Merchandise Subject to the Circumvention Inquiries

The circumvention inquiries cover collated staples that have been completed in Thailand or Vietnam, using parts and components from China, that are then subsequently exported from Thailand or Vietnam to the United States.

Initiation of Circumvention Inquiries

Section 351.226(d) of Commerce's regulations states that if Commerce determines that a request for a circumvention inquiry satisfies the requirements of 19 CFR 351.226(c), then Commerce ''will accept the request and initiate a circumvention inquiry.'' Section 351.226(c)(1) of Commerce's regulations, in turn, requires that each request for a circumvention inquiry allege ''that the elements necessary for a circumvention determination under section 781 of the Act exist'' and be ''accompanied by information reasonably available to the interested party supporting these allegations.'' Senco alleged circumvention pursuant to section 781(b) of the Act (merchandise completed or assembled in other foreign countries).

According to section 781(b)(1) of the Act, after taking into account any advice provided by the U.S. International Trade Commission (ITC) under section 781(e) of the Act, Commerce may find merchandise imported into the United States to be covered by the scope of an order if: (A) merchandise imported into the United States is of the same class or kind as any merchandise produced in a foreign country that is the subject of an AD order or finding or a CVD order; (B) before importation into the United States, such imported merchandise is completed or assembled in another foreign country from merchandise which is subject to the order or finding

[1] *See Certain Collated Steel Staples from the People's Republic of China: Antidumping Duty Order,* 85 FR 43815 (July 20, 2020); and *Certain Collated Steel Staples from the People's Republic of China: Countervailing Duty Order,* 85 FR 43813 (July 20, 2020) (collectively, *Orders*).

[2] *See* Senco's Letters, ''Request for Anticircumvention Inquiry Pursuant to Section 781(b) of the Tariff Act of 1930, as Amended,'' dated November 15, 2022 (Vietnam Circumvention Inquiry Request); and ''Request for Anticircumvention Inquiry Pursuant to Section 781(b) of the Tariff Act of 1930, as Amended,'' dated November 15, 2022 (Thailand Circumvention Inquiry Request).

[3] *See* Memorandum, ''Certain Collated Steel Staples from the People's Republic of China: Initiation of Circumvention Inquiries on Antidumping and Countervailing Duty Orders,'' dated concurrently with, and hereby adopted by, this notice (Initiation Memorandum).

or is produced in the foreign country with respect to which such order or finding applies; (C) the process of assembly or completion in the foreign country referred to in subparagraph (B) is minor or insignificant; (D) the value of the merchandise produced in the foreign country to which the AD (or CVD) order applies is a significant portion of the total value of the merchandise exported to the United States; and (E) the administering authority determines that action is appropriate to prevent evasion of such order or finding.

In determining whether the process of assembly or completion in a foreign country is minor or insignificant under section 781(b)(1)(C) of the Act, section 781(b)(2) of the Act directs Commerce to consider: (A) the level of investment in the foreign country; (B) the level of research and development in the foreign country; (C) the nature of the production process in the foreign country; (D) the extent of production facilities in the foreign country; and (E) whether the value of processing performed in the foreign country represents a small proportion of the value of the merchandise imported into the United States.

In addition, section 781(b)(3) of the Act sets forth additional factors to consider in determining whether to include merchandise assembled or completed in a foreign country within the scope of an AD or CVD order. Specifically, Commerce shall take into account such factors as: (A) the pattern of trade, including sourcing patterns; (B) whether the manufacturer or exporter of the merchandise that was shipped to the foreign country for completion or assembly is affiliated with the person in the foreign country who assembles or completes the merchandise that is subsequently imported into the United States; and (C) whether imports into the foreign country of the merchandise that was completed or assembled have increased after the initiation of the investigation which resulted in the issuance of the order or finding.

Based on our analysis of Senco's circumvention inquiry requests, we determined that Senco satisfied the criteria under 19 CFR 351.226(c), and thus, pursuant to 19 CFR 351.226(d)(1)(ii), we have accepted the request and are initiating the requested circumvention inquiries of the *Orders.* For a full discussion of the basis for our decision to initiate the requested circumvention inquiries, *see* the Initiation Memorandum. Moreover, as explained in the Initiation Memorandum, based on the information provided by Senco, we have initiated country-wide circumvention inquiries. Commerce has taken this approach in prior circumvention inquiries where the facts warranted initiation on a country-wide basis.[4]

Consistent with the approach taken in prior circumvention inquiries that Commerce initiated on a country-wide basis, we intend to solicit information from certain companies in Thailand and Vietnam concerning their production of collated staples and their shipments thereof to the United States. A company's failure to completely respond to Commerce's requests for information may result in the application of partial or total facts available, pursuant to section 776(a) of the Act, which may include adverse inferences, pursuant to section 776(b) of the Act.

For companion AD and CVD proceedings, ''the Secretary will initiate and conduct a single inquiry with respect to the product at issue for both orders only on the record of the antidumping proceeding.'' [5] Further, ''{o}nce the Secretary issues a final circumvention determination on the record of the antidumping duty proceeding, the Secretary will include a copy of that determination on the record of the countervailing duty proceeding.'' [6] Accordingly, once Commerce concludes this circumvention inquiry, Commerce intends to place its final circumvention determination on the record of the companion CVD proceedings.

Suspension of Liquidation

Pursuant to 19 CFR 351.226(l)(1), Commerce will notify U.S. Customs and Border Protection (CBP) of its initiation of the requested circumvention inquiries and direct CBP to continue the suspension of liquidation of entries of products subject to the circumvention inquiries that were already subject to the suspension of liquidation and to apply the cash deposit rate that would be applicable if the products were determined to be covered by the scope of the *Orders.* Should Commerce issue preliminary or final circumvention determinations, Commerce will follow the suspension of liquidation rules under 19 CFR 351.226(l)(2)–(4).

Notification to Interested Parties

In accordance with 19 CFR 351.226(d) and section 781(b) of the Act, Commerce has determined that Senco's request for circumvention inquiries satisfies the requirements of 19 CFR 351.226(c). Accordingly, Commerce is notifying all interested parties of the initiation of circumvention inquiries to determine whether U.S. imports of collated staples that have been completed in, and exported from, Thailand or Vietnam using parts and components manufactured in China, are circumventing the *Orders.* We included a description of the products that are subject to the circumvention inquiries, and an explanation of the reasons for Commerce's decision to initiate these inquiries, in the accompanying Initiation Memorandum.[7] In accordance with 19 CFR 351.226(e)(1), Commerce intends to issue its preliminary determinations in these circumvention proceedings no later than 150 days from the date of publication of this notice in the **Federal Register**.

This notice is published in accordance with section 781(b) of the Act and 19 CFR 351.226(d)(1)(ii).

Dated: December 14, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Circumvention Initiation Memo

[FR Doc. 2022–27692 Filed 12–20–22; 8:45 am]

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[4] *See, e.g., Certain Corrosion-Resistant Steel Products from the Republic of Korea and Taiwan: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,* 83 FR 37785 (August 2, 2018); *Carbon Steel Butt-Weld Pipe Fittings from the People's Republic of China: Initiation of Anti-Circumvention Inquiry on the Antidumping Duty Order,* 82 FR 40556, 40560 (August 25, 2017) (stating at initiation that Commerce would evaluate the extent to which a country-wide finding applicable to all exports might be warranted); and *Certain Corrosion-Resistant Steel Products from the People's Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,* 81 FR 79454, 79458 (November 14, 2016) (stating at initiation that Commerce would evaluate the extent to which a country-wide finding applicable to all exports might be warranted).

[5] *See* 19 CFR 351.226(m)(2).

[6] *Id.*

[7] *See* Initiation Memorandum.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–896]

Magnesium Metal From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that there were no shipments of merchandise subject to the antidumping duty (AD) order on magnesium metal from the People's Republic of China (China) during the period of review (POR), April 1, 2021, through March 31, 2022, from Tianjin Magnesium International Co., Ltd. (TMI) and Tianjin Magnesium Metal Co., Ltd. (TMM). We invite interested parties to comment on these preliminary results.

DATES: Applicable December 21, 2022.

FOR FURTHER INFORMATION CONTACT: John Conniff, 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) 482–1009.

SUPPLEMENTARY INFORMATION:

Background

On April 1, 2022, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the AD order on magnesium metal from China for the POR.[1] On April 15, 2022, we received a timely request from US Magnesium LLC (the petitioner).[2] On May 16, 2022, TMI and TMM, upon which the petitioner requested a review, objected to the request on the basis that they had not sold merchandise in the United States for more than ten years.[3] On June 9, 2022, in response to the petitioner's request, we initiated an administrative review of the *Order* with respect to TMI and TMM, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.221(c)(1)(i).[4]

Scope of the Order

The product covered by the *Order* is magnesium metal from China, which includes primary and secondary alloy magnesium metal, regardless of chemistry, raw material source, form, shape, or size. Magnesium is a metal or alloy containing by weight primarily the element magnesium. Primary magnesium is produced by decomposing raw materials into magnesium metal. Secondary magnesium is produced by recycling magnesium-based scrap into magnesium metal. The magnesium covered by the *Order* includes blends of primary and secondary magnesium.

The subject merchandise includes the following alloy magnesium metal products made from primary and/or secondary magnesium including, without limitation, magnesium cast into ingots, slabs, rounds, billets, and other shapes; magnesium ground, chipped, crushed, or machined into rasping, granules, turnings, chips, powder, briquettes, and other shapes; and products that contain 50 percent or greater, but less than 99.8 percent, magnesium, by weight, and that have been entered into the United States as conforming to an ''ASTM Specification for Magnesium Alloy'' [5] and are thus outside the scope of the existing antidumping orders on magnesium from China (generally referred to as ''alloy'' magnesium).

The scope of the *Order* excludes: (1) all forms of pure magnesium, including chemical combinations of magnesium and other material(s) in which the pure magnesium content is 50 percent or greater, but less than 99.8 percent, by weight, that do not conform to an ''ASTM Specification for Magnesium Alloy''; [6] (2) magnesium that is in liquid or molten form; and (3) mixtures containing 90 percent or less magnesium in granular or powder form by weight and one or more of certain non-magnesium granular materials to make magnesium-based reagent mixtures, including lime, calcium metal, calcium silicon, calcium carbide, calcium carbonate, carbon, slag coagulants, fluorspar, nephaline syenite, feldspar, alumina (Al203), calcium aluminate, soda ash, hydrocarbons, graphite, coke, silicon, rare earth metals/mischmetal, cryolite, silica/fly ash, magnesium oxide, periclase, ferroalloys, dolomite lime, and colemanite.[7] The merchandise subject to this *Order* is classifiable under items 8104.19.00, and 8104.30.00 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS items are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Preliminary Determination of No Shipments

We received timely submissions from TMI and TMM certifying that they did not have sales, shipments, or exports of subject merchandise to the United States during the POR.[8] On June 15, 2022, we requested U.S. Customs and Border Protection (CBP) entry data of subject merchandise imported into the United States during the POR, and exported by TMM or TMI.[9] This query returned no entries during the POR.[10] Additionally, on June 21, 2022, Commerce submitted a no-shipments inquiry to CBP with regard to TMI and TMM, to which CBP did not respond with any contrary information by the expiration of the 10-day deadline on July 1, 2022.[11]

Accordingly, and consistent with our practice, we preliminarily determine that TMI and TMM had no shipments and, therefore, no reviewable entries

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review and Join Annual Inquiry Service List,* 87 FR 19075 (April 1, 2022); *see also Notice of Antidumping Duty Order: Magnesium Metal from the People's Republic of China,* 70 FR 19928 (April 15, 2005) (*Order*).

[2] *See* Petitioner's Letter, ''Magnesium Metal from the People's Republic of China/Request for Administrative Review,'' dated April 15, 2022.

[3] *See* TMI and TMM's Letter, ''Magnesium Metal from the People's Republic of China; A–570–896; Objection to Request for Review,'' dated May 16, 2022.

[4] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 87 FR 35165 (June 9, 2022).

[5] The meaning of this term is the same as that used by the American Society for Testing and Materials in its Annual Book for ASTM Standards: Volume 01.02 Aluminum and Magnesium Alloys.

[6] The material is already covered by existing antidumping orders. *See Notice of Antidumping Duty Orders: Pure Magnesium from the People's Republic of China, the Russian Federation and Ukraine; Notice of Amended Final Determination of Sales at Less Than Fair Value: Antidumping Duty Investigation of Pure Magnesium from the Russian Federation,* 60 FR 25691 (May 12, 1995); *see also Antidumping Duty Order: Pure Magnesium in Granular Form from the People's Republic of China,* 66 FR 57936 (November 19, 2001).

[7] This third exclusion for magnesium-based reagent mixtures is based on the exclusion for reagent mixtures in the 2000–2001 investigations of magnesium from China, Israel, and Russia. *See Final Determination of Sales at Less Than Fair Value: Pure Magnesium in Granular Form from the People's Republic of China,* 66 FR 49345 (September 27, 2001); *see also Final Determination of Sales at Less Than Fair Value: Pure Magnesium from Israel,* 66 FR 49349 (September 27, 2001); and *Final Determination of Sales at Not Less Than Fair Value: Pure Magnesium from the Russian Federation,* 66 FR 49347 (September 27, 2001). These mixtures are not magnesium alloys, because they are not combined in liquid form and cast into the same ingot.

[8] *See* TMI's Letter, ''Magnesium Metal from the People's Republic of China; A–570–896; No Shipment Certification,'' dated June 13, 2022; *see also* TMM's Letter, ''Magnesium Metal from the People's Republic of China; A–570–896; No Shipment Certification,'' dated June 13, 2022.

[9] *See* Memorandum, ''Release of U.S. Customs and Border Protection Data,'' dated July 5, 2022, at Attachment 1.

[10] *Id.* at Attachment 2.

[11] *Id.* at 1 and Attachment 3.

during the POR. In addition, we find it is not appropriate to rescind the review with respect to these companies, but rather to complete the review with respect to TMI and TMM and issue appropriate instructions to CBP based on the final results of the review, consistent with our practice in non-market economy (NME) cases.[12]

Disclosure and Public Comment

Because Commerce has not calculated weighted-average dumping margins for these preliminary results, there are no calculations to disclose to interested parties.

Interested parties are invited to comment on these preliminary results of the 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 in the **Federal Register**. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the deadline for filing case briefs.[13] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each brief: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[14] Executive summaries should be limited to five pages total, including footnotes.[15] Case and rebuttal briefs should be filed using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS).[16] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[17]

Pursuant to 19 CFR 351.310(c), any interested party may request a hearing within 30 days of the date of publication of this notice in the **Federal Register**. 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, by the deadline noted above. If a hearing is requested, Commerce will notify interested parties of the hearing date and time. Requests for a hearing should contain: (1) the requesting party's name, address, and telephone number; (2) the number of individuals from the requesting party's firm that will attend the hearing; and (3) a list of issues the party intends to discuss at the hearing. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs.

Unless we extend the deadline for the final results of this review, we intend to issue the final results of this administrative review, including the results of our analysis of issues raised by the parties in their briefs, within 120 days of the date of publication of this notice in the **Federal Register**.[18]

Assessment Rates

Upon issuance of the final results of this review, Commerce will determine, and CBP will assess, antidumping duties on all appropriate entries covered by this review.[19] Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication). Pursuant to Commerce's practice in NME cases, if we continue to determine in the final results that TMI and TMM had no shipments of subject merchandise, any suspended entries of subject merchandise during the POR from these companies will be liquidated at the China-wide rate.[20]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of review, as provided for by section 751(a)(2)(C) of the Act: (1) For TMI, which claimed no shipments, the cash deposit rate will remain unchanged from the rate assigned to TMI in the most recently completed review of the company; (2) for previously investigated or reviewed Chinese and non-Chinese exporters who are not under review in this segment of the proceeding but who have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate (including TMM, which claimed no shipments, but has not been found to be separate from China-wide entity), the cash deposit rate will be China-wide rate of 141.49 percent; 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 Chinese exporter(s) that supplied that non-Chinese exporter. 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)(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

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: December 14, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–27689 Filed 12–20–22; 8:45 am]

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[12] *See Glycine from the People's Republic of China: Final Results of Antidumping Duty Administrative Review 2014–2015,* 81 FR 72567 (October 20, 2016), and the ''Assessment Rates'' section, below.

[13] *See* 19 CFR 351.309(d).

[14] S*ee* 19 CFR 351.309(c)(2) and (d)(2).

[15] *Id.*

[16] *See* 19 CFR 351.303.

[17] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[18] *See* section 751(a)(3)(A) of the Act; *see also* 19 CFR 351.213(h)(1).

[19] *See* 19 CFR 351.212(b)(1).

[20] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC456]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Marine Site Characterization Surveys Offshore of North Carolina and South Carolina

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

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible renewal.

SUMMARY: NMFS has received a request from TerraSond Limited (TerraSond) for authorization to take marine mammals incidental to marine site characterization surveys in federal waters offshore of North Carolina and South Carolina in the Bureau of Ocean Energy Management (BOEM) Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf (Lease) Areas OCS–A 0545 and OCS–A 0546 (also referred to [by BOEM] as the ''Carolina Long Bay Lease Areas.'' Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-time, one-year renewal that could be issued under certain circumstances and if all requirements are met, as described in Request for Public Comments at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorization and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than January 20, 2023.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service and should be submitted via email to *ITP.taylor@noaa.gov.*

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. All comments received are a part of the public record and will generally be posted online at *www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Jessica Taylor, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed IHA is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review. We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA request.

Summary of Request

On September 19, 2022, NMFS received a request from TerraSond for an IHA to take marine mammals incidental to marine site characterization surveys in federal waters offshore of North Carolina and South Carolina in the Bureau of Ocean Energy Management (BOEM) Lease Areas OCS–A 0545 and 0546. Following NMFS' review of the application, TerraSond submitted revised applications on October 14, 2022 and October 17, 2022. The application was deemed adequate and complete on November 9, 2022. TerraSond's request is for take of small numbers of 18 species of marine mammals by Level B harassment only. Neither TerraSond nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Proposed Activity

Overview

TerraSond proposes to conduct marine site characterization surveys in the BOEM Lease Areas OCS–A 0545 and 0546 in federal waters offshore of North Carolina and South Carolina to support the development of offshore wind farm technology. TerraSond's proposed site characterization survey activities, specifically high-resolution geophysical (HRG) surveys, have the potential to result in incidental take of marine mammals in the form of Level B behavioral harassment.

Dates and Duration

HRG surveys are planned to commence as early as February 1, 2023 and last for a minimum of 6–8 months (or through January 31, 2024) for a total of approximately 180 active survey days (Table 1) over the course of the 1 year period of effectiveness for the proposed IHA. A ''survey day'' is defined as a 24-hour (hr) activity period in which active acoustic sound sources are used. This schedule is inclusive of any inclement weather downtime and crew transfers. Up to 2 HRG survey vessels may be active at one time. The number of anticipated active survey days in a phase (see Table 1) was calculated by

dividing the total vessel trackline length by the approximate vessel survey distance per day with active HRG equipment. It is expected that each vessel would cover approximately 100 kilometers (km) per day at a speed of 1.8 meters/second (m/s). The project would consist of three phases, including up to 3 possible tow configurations (Table 1).

TABLE 1—PROPOSED NUMBER OF SURVEY DAYS AND DISTANCES FOR EACH PHASE [1]

Survey phase	Total approximate vessel trackline (km)	Approximate vessel distance per day (km)	Active survey days
Phase 1	4,054	100	41
Phase 2	1,400	100	14
Phase 3	12,488	100	125

[1] Up to two survey vessels may actively survey over a 24-hour period.

Specific Geographic Region

TerraSond's survey activities would occur in BOEM Lease Areas OCS–A 0545 and 0546, approximately 34–56 km offshore of Cape Fear, North Carolina (Figure 1). The proposed survey area is offshore of North Carolina and South Carolina in federal waters, and covers an area of approximately 445.4 square kilometers (km^2). Water depths within the proposed survey area range from 20–35 meters (m) (66–115 feet (ft)).

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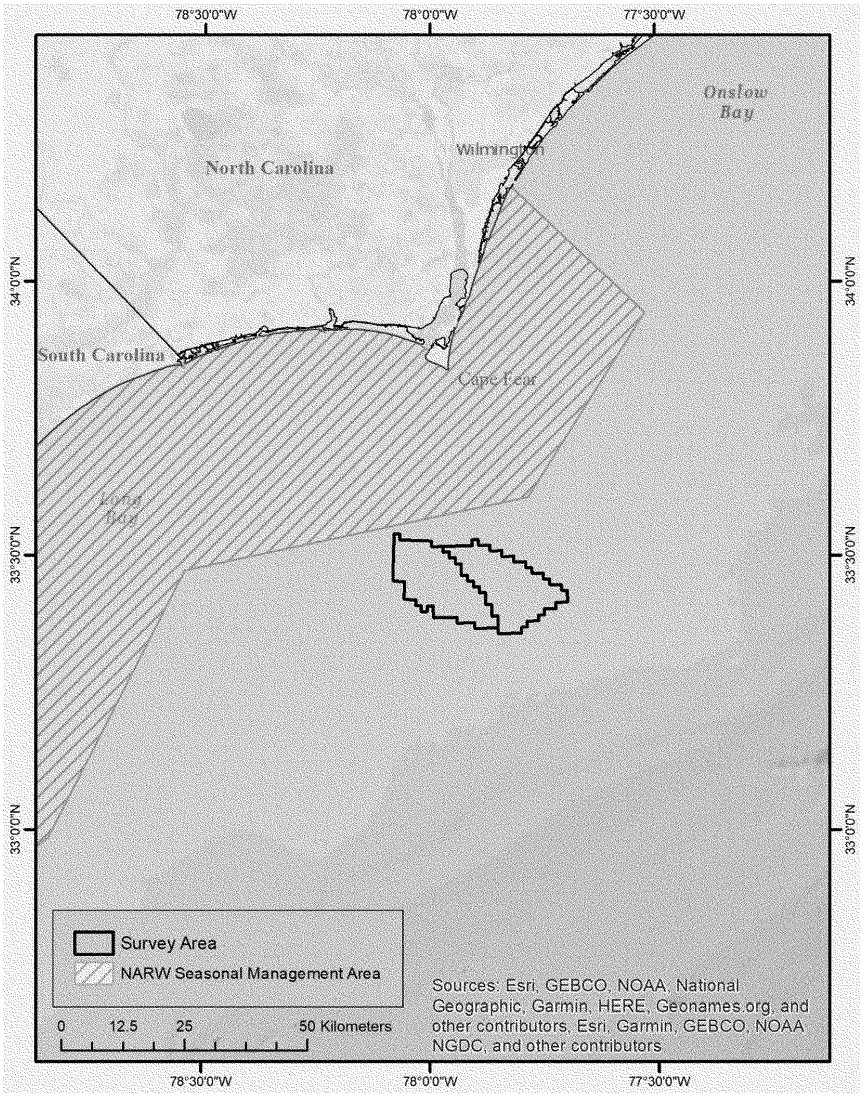

Figure 1. Proposed Survey Area

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Detailed Description of Specific Activity

TerraSond proposes to conduct HRG surveys to acquire data on the bathymetry, seafloor morphology, subsurface geology, environmental/biological sites, seafloor obstructions, soil conditions, and locations of any man-made, historical, or archaeological resources in BOEM Lease Areas OCS–A 0545 and 0546 to support offshore wind energy development. HRG surveys will include the use of seafloor mapping equipment with operating frequencies above 180 kilohertz (kHz) (*e.g.,* side-scan sonar (SSS), multibeam echosounders (MBES)); magnetometers and gradiometers that have no acoustic output; and shallow- to medium-penetration sub-bottom profiling (SBP) equipment (*e.g.,* parametric sonars, sparkers) with operating frequencies below 180 kHz. No deep-penetration SBP surveys (*e.g.,* airgun or bubble gun surveys) will be conducted.

TerraSond also proposes to conduct geotechnical surveys, including the use of vibracores and seabed core penetrations tests (CPTs). Vibracoring and CPT may be conducted from the geophysical survey vessel or by an additional geotechnical vessel. NMFS does not expect geotechnical sampling activities to present reasonably anticipated risk of causing incidental take of marine mammals, and these activities are not discussed further in this notice.

As described earlier, TerraSond's proposed HRG surveys will consist of three phases consisting of differing tow configurations of the sparker. Phase 1 may take place concurrently with Phases 2 and 3, and multiple vessels may be used for each stage. Phase 1 would involve the use of a single source vessel towing one sparker source composed of two ''decks'' of 400 electrode tips each stacked on top of each other. Phase 2 would be a brief period of survey work for Research and Development (R&D) purposes, involving the use of a single source vessel towing three of the same sparker sources with a horizontal separation between the sources of 150 m. The three sources would operate independently while collecting geophysical data along separate lines. Phase 3 would involve a single vessel towing two of the same sparker sources described in Phase 1 with a horizontal separation between the sources of 30 m. As described in Phase 2, the two sources would operate independently of each other while collecting geophysical data along two separate lines. Phase 3 activities may occur simultaneously with Phase 1 and 2 activities.

TerraSond proposes to use the following acoustic source during HRG survey activities at sounds levels that have the potential to result in Level B harassment of marine mammals:

- Medium penetration SBPs (sparkers) are used to map deep subsurface stratigraphy as needed. Sparkers create acoustic pulses from 50 Hz to 4 kHz omnidirectionally from the source, and are considered to be impulsive sources. Sparkers are typically towed behind the vessel with adjacent hydrophone arrays to receive the return signals.

Operation of the following survey equipment types is not reasonably expected to result in take of marine mammals and will not be discussed further beyond the brief summaries provided below:

- Parametric SBPs are used to provide high data density in sub-bottom profiles that are typically required for cable routes, very shallow water, and archaeological surveys. Parametric SPBs are usually mounted on a pole, either over the side of the vessel or through a moon pool in the bottom of the hull. Crocker and Fratantonio (2016) does not provide relevant measurements or source data for parametric SBPs, however, some source information is provided by the manufacturer. For the proposed project, the SBP used would generate short, very narrow-beam sound pulses at relatively high frequencies (generally around 85 to 115 kHz). The narrow beam width significantly reduces the potential for exposure while the high frequencies of the source are rapidly attenuated in seawater. Given the narrow beam width and relatively high frequency. NMFS does not reasonably expect there to be potential for marine mammals to be exposed to the signal;
- Ultra-short baseline (USBL) positioning systems are used to provide high accuracy ranges by measuring the time between the acoustic pulses transmitted by vessel transceiver and a transponder (or beacon) necessary to produce the acoustic profile. USBLs are expected to produce extremely small acoustic propagation distances in their typical operating configuration, and therefore marine mammals are highly unlikely to be exposed;
- Multibeam echosounders (MBES) are used to determine water depths and general bottom topography. MBES sonar systems project sonar pulses in several angled beams from a transducer mounted to a ship's hull. The beams radiate out from the transducer in a fan-shaped pattern orthogonally to the ship's direction. The proposed MBES (Reson T50 Dual Head) has an operating frequency >180 kHz (200–400 kHz) and, therefore, is outside the general hearing range of marine mammals; and
- Side scan sonars (SSS) are used for seabed sediment classification purposes and to identify natural and man-made acoustic targets on the seafloor. The sonar device emits conical or fan-shaped pulses down toward the seafloor in multiple beams at a wide angle, perpendicular to the path of the sensor through the water column. The proposed SSS has an operating frequency >180 kHz (300–600 kHz) and, therefore, is outside the general hearing range of marine mammals.

Table 2 identifies representative survey equipment with the potential to result in exposure and take of marine mammals. TerraSond plans to use the Applied Acoustics UHRS 400 + 400, which is essentially two of the same Applied Acoustic Dura-Spark sources (Crocker and Fratantonio, 2016) stacked on top of each other creating two ''decks'' to the sparker. The decks will not be discharged simultaneously. Instead, they will be used in an alternating ''flip-flop'' pattern. Thus, for all of the described source configurations, the maximum power expected when discharging the sparker source (single deck) will be 800 Joules (J). Crocker and Fratantonio (2016) measured the Applied Acoustics Dura-Spark, but did not provide data for an energy setting near 800 J (for a 400-tip configuration, Crocker and Fratantonio (2016) provide measurements at 500 and 2,000 J). Therefore, TerraSond proposes to use a similar alternative system, which was measured with an input voltage of 750 J, as a surrogate. NMFS concurs with this selection, which is described in Table 2.

TABLE 2—REPRESENTATIVE SURVEY EQUIPMENT EXPECTED TO RESULT IN TAKE OF MARINE MAMMALS

Equipment type	System	Operating frequency range (kHz)	Source level (dB Pk)	Source level (dB RMS)	Pulse duration (ms)	Beamwidth (degrees)	Pulse repetition rate (seconds)
Sparker	Applied Acoustics Dura-Spark UHRS 400 + 400, 800 tips total, up to 1,400 J [1].	0.3–1.2	213	203	1.1	180 (Omni)	0.25

kHz = kilohertz; dB = decibel; Pk = peak; RMS = root mean square; J = joule
[1] SIG ELC 820 sparker 750 J used as a proxy (Crocker and Fratantonio, 2016) as the AA Dura-spark was not measured with an energy of 800 J

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting sections).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, incorporated here by reference, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS' website (*https://www.fisheries.noaa.gov/find-species*).

Table 3 lists all species or stocks for which take is expected and proposed to be authorized for this activity, and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no serious injury or mortality is anticipated or proposed to be authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species or stocks and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All stocks managed under the MMPA in this region are assessed in NMFS' U.S. Atlantic and Gulf of Mexico SARs. All values presented in Table 3 are the most recent available at the time of publication (2021 SARs) and are available online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*).

TABLE 3—MARINE MAMMAL SPECIES [6] LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Order Artiodactyla Cetartiodactyla—Infraorder Cetacea—Mysticeti (baleen whales)						
Family Balaenidae:						
North Atlantic right whale	*Eubalaena glacialis*	Western Atlantic	E, D, Y	368 (0; 364; 2019) [5]	0.7	7.7
Family Balaenopteridae (rorquals):						
Fin whale	*Balaenoptera physalus*	Western North Atlantic	E, D, Y	6,802 (0.24; 5,573; 2016)	11	1.8
Humpback whale	*Megaptera novaeangliae*	Gulf of Maine	-, -, Y	1,396 (0; 1,380; 2016)	22	12.15
Odontoceti (toothed whales, dolphins, and porpoises)						
Family Physeteridae:						
Sperm whale	*Physeter macrocephalus*	North Atlantic	E, D, Y	4,349 (0.28; 3,451; 2016)	3.9	0
Family Ziphiidae (beaked whales):						
Cuvier's beaked whale	*Ziphius cavirostris*	Western North Atlantic	-, -, N	5,744 (0.36, 4,282, 2019)	43	0.2
Mesoplodont whales	*Mesoplodon spp*	Western North Atlantic	-, -, N	3,513 (0.63, UNK, 2004)	UNK	7
Family Delphinidae:						
Short-finned pilot whale	*Globicephala macrorhynchus*	Western North Atlantic	-, -, Y	28,924 (0.24; 23,637; 2016).	236	136
Long-finned pilot whale	*Globicephala melas*	Western North Atlantic	-, -, N	39,215 (0.30; 30,627; 2016).	306	29
Atlantic spotted dolphin	*Stenella frontalis*	Western North Atlantic	-, -, N	39,921 (0.27; 32,032; 2016).	320	0
Bottlenose dolphin	*Tursiops truncatus*	Southern Migratory Coastal	-, -, Y	3,751 (0.6, 2,353, 2016)	23	0–18.3
Bottlenose dolphin	*Tursiops truncatus*	Western North Atlantic Offshore	-, -, N	62,851 (0.23; 51,914; 2016).	519	28
Common dolphin	*Delphinus delphis*	Western North Atlantic	-, -, N	172,974 (0.21; 145,216; 2016).	1,452	390
Rough-toothed dolphin	*Steno bredanensis*	Western North Atlantic	-, -, N	136 (1, 67, 2016)	172	0

TABLE 3—MARINE MAMMAL SPECIES[6] LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES—Continued

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N)[1]	Stock abundance (CV, N_{min}, most recent abundance survey)[2]	PBR	Annual M/SI[3]
Family Phocoenidae (porpoises):						
Harbor porpoise	*Phocoena phocoena*	Gulf of Maine/Bay of Fundy	-, -, N	95,543 (0.31; 74,034; 2016).	851	164
Order Carnivora—Pinnipedia						
Family Phocidae (earless seals):						
Harbor seal	*Phoca vitulina*	Western North Atlantic	-, -, N	61,336 (0.08; 57,637; 2018).	1,729	339
Gray seal[4]	*Halichoerus grypus*	Western North Atlantic	-, -, N	27,300 (0.22; 22,785; 2016).	1,389	4,453

[1] ESA status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.* CV is the coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable.

[3] These values, found in NMFS' SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike).

[4] NMFS' stock abundance estimate (and associated PBR value) applies to the U.S. population only. Total stock abundance (including animals in Canada) is approximately 451,431. The annual M/SI value given is for the total stock.

[5] The draft 2022 SARs have yet to be released; however, NMFS has updated its species web page to recognize the population estimate for North Atlantic right whales (NARW) is now below 350 animals (*https://www.fisheries.noaa.gov/species/north-atlantic-right-whale*).

[6] Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (*https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies/*; Committee on Taxonomy (2022)).

As indicated above, all 18 species (with 19 managed stocks) in Table 3 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur. All species that could potentially occur in the proposed survey area are included in Table 5 of the IHA application. While the blue whale (*Balaenoptera musculus*), minke whale *(Balaenoptera acutorostrata),* sei whale (*Balaenoptera borealis*), Risso's dolphin (*Grampus griseus*), Atlantic white-sided dolphin *(Lagenorhynchus acutus),* Clymene dolphin (*Stenella Clymene*), dwarf sperm whale *(Kogia sima),* pygmy sperm whale *(Kogia breviceps),* false killer whale *(Pseudorca crassidens),* Fraser's dolphin *(Lagenodelphis hosei),* killer whale *(Orcinus orca),* melon-headed whale *(Peponocephala electra),* northern bottlenose whale *(hyperoodon ampullatus),* pantropical spotted dolphin *(Stenella attenuate),* Risso's Dolphin *(Grampus griseus),* pygmy killer whale *(Feresa attenuate),* spinner dolphin *(Stenella longirostris*), striped dolphin *(Stenella coeruleoalba),* white-beaked dolphin *(Lagenorhynchus albirotris),* harp seal *(Pagophilus groenlandicus),* and hooded seal *(Cystophora cristata)* have been reported in the area, the temporal and/or spatial occurrence of these species is such that take is not expected to occur, and they are not discussed further.

Below is a description of the species that have the highest likelihood of occurring in the project area and are, thus, expected to potentially be taken by the proposed activities as well as further detail informing the baseline for select species (*i.e.,* information regarding current Unusual Mortality Events (UMEs) and important habitat areas).

North Atlantic Right Whale

The North Atlantic right whale (NARW) ranges from calving grounds in the southeastern United States to feeding grounds in New England waters and into Canadian waters (Hayes *et al.,* 2022). Surveys have demonstrated the existence of seven areas where NARWs congregate seasonally: the coastal waters of the southeastern United States, the Great South Channel, Jordan Basin, Georges Basin along the northeastern edge of Georges Bank, Cape Cod and Massachusetts Bays, the Bay of Fundy, and the Roseway Basin on the Scotian Shelf (Hayes *et al.,* 2018). NMFS has designated two critical habitat areas for the NARW under the ESA: The Gulf of Maine/Georges Bank region, and the southeast calving grounds from Cape Fear, North Carolina to Cape Canaveral, Florida (81 FR 4837, January 27, 2016). The southeast calving grounds critical habitat overlaps with the proposed survey area.

New England and Canadian waters are important feeding habitats for NARWs. Since 2010, NARWs have reduced their use of summer feeding habitats in the Great South Channel and Bay of Fundy, while increasing their use of habitat within Cape Cod Bay as well as a region south of Martha's Vineyard and Nantucket Islands (Stone *et al.,* 2017; Mayo *et al.,* 2018; Ganley *et al.,* 2019; Record *et al.,* 2019; Meyer-Gutbrod *et al.,* 2021). This shift is likely due to changes in oceanographic conditions and food supply as dense patches of zooplankton are necessary for efficient foraging (Mayo and Marx, 1990; Record *et al.,* 2019). NARW use of habitats such as in the Gulf of St. Lawrence, southern New England waters, and the mid-Atlantic waters of the United States have also increased over time (Davis *et al.,* 2017; Davis and Brillant, 2019; Crowe *et al.,* 2021; Quintana-Rizzo *et al.,* 2021).

In the late fall months (*e.g.,* October), NARWs are generally thought to depart from the feeding grounds in the North Atlantic and move south to their calving grounds off Georgia and Florida. However, recent research indicates our understanding of their movement patterns remains incomplete, and not all of the population undergoes a consistent annual migration (Davis *et al.,* 2017). Females may remain in the feeding grounds during the winter in the years preceding and following the birth of a calf to increase their energy stores while juvenile and adult males may move to southern wintering grounds after years of abundant prey in northern feeding areas (Gowan *et al.,* 2019). Passive acoustic studies have demonstrated the year-round presence of NARWs in New Jersey (Whitt *et al.,* 2013) and Virginia (Salisbury *et al.,* 2016), and Hodge *et al.* (2015) made acoustic detections of NARWs off of Georgia and North Carolina in seven months of the year.

NARWs are most common in the proposed survey area in the spring (late March) during their northern migration and in the fall (October and November) during their southern migration (NMFS, 2017).

NARW movements within and between habitats are extensive. A NARW Biologically Important Area (BIA) for migration overlaps the proposed survey area and spans approximately 269,488 km^2 in size from Florida through Massachusetts, encompassing the waters of the continental shelf offshore the east coast of the United States (LaBrecque *et al.,* 2015). NARW movements may include seasonal migrations between northern feeding grounds and southern breeding grounds as well as movements between feeding habitats (Quintana-Rizzo *et al.,* 2021). NARWs generally use the offshore waters of North Carolina and South Carolina during seasonal movements north and south between their feeding and breeding grounds (Knowlton *et al.,* 2002; Firestone *et al.,* 2008), and have been observed in waters offshore North Carolina from October through December, as well as February and March, a timeframe that aligns with the migratory timeframe for this species (Knowlton *et al.,* 2002). The Right Whale Sightings Advisory System reports shows 12 visual records of NARWs offshore of North Carolina and South Carolina since January 2020 (NMFS, 2022c).

Since 2010, the western NARW population has been in decline (Pace *et al.,* 2017), with a 40 percent decrease in calving rate (Kraus *et al.,* 2016). In 2018, no new NARW calves were documented in their calving grounds; this represented the first time since annual NOAA aerial surveys began in 1989 that no new right whale calves were observed. Eighteen right whale calves were documented in 2021. For the 2022 calving season, 15 NARW calves have been documented. Presently, the best available peer-reviewed population estimate for NARWs is 368 per the 2021 SARs (*https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*). The draft 2022 SARs have yet to be released; however, NMFS has updated its species web page to recognize the population estimate for NARWs is below 350 animals (*https://www.fisheries.noaa.gov/species/north-atlantic-right-whale*).

NMFS vessel speed regulations for NARWs at 50 CFR 224.105 designated nearshore waters of the Mid-Atlantic Bight as Mid-Atlantic U.S. Seasonal Management Areas (SMA) in 2008. SMAs were developed to reduce the threat of collisions between ships and NARWs around their migratory route, feeding grounds, and calving grounds. In an active SMA, vessels 65 ft or longer must travel at a speed of 10 knots (kn) or less to reduce the threat of vessel collisions unless an exception applies. The North Carolina-Georgia coast SMA, spanning 20 nm from shore from Wilmington, NC to Brunswick, GA, overlaps spatially with the proposed survey area (*https://www.fisheries.noaa.gov/national/endangered-species-conservation/reducing-vessel-strikes-north-atlantic-right-whales#seasonal-management-areas---mid-atlantic*). The SMA is active from November 1 through April 30 of each year and may be used by NARWs for migrating or calving. In addition, a NARW reproductive BIA (LaBrecque *et al.,* 2015) overlaps the northwestern corners of both lease areas.

On August 1, 2022, NMFS announced proposed changes to the existing North Atlantic right whale vessel speed regulations to further reduce the likelihood of mortalities and serious injuries to endangered NARW from vessel collisions, which are a leading cause of the species' decline and a primary factor in an ongoing Unusual Mortality Event (87 FR 46921, August 1, 2022). Should a final vessel speed rule be issued and become effective during the effective period of this IHA (or any other MMPA incidental take authorization), the authorization holder would be required to comply with any and all applicable requirements contained within the final rule. Specifically, where measures in any final vessel speed rule are more protective or restrictive than those in this or any other MMPA authorization, authorization holders would be required to comply with the requirements of the rule. Alternatively, where measures in this or any other MMPA authorization are more restrictive or protective than those in any final vessel speed rule, the measures in the MMPA authorization would remain in place. These changes would become effective immediately upon the effective date of any final vessel speed rule and would not require any further action on NMFS's part.

Right Whale Slow Zones are established when NARWs are detected both visually (*i.e.,* Dynamic Management Area) and acoustically (*i.e.,* Acoustic Slow Zone). These are areas where mariners are encouraged to avoid and/or reduce speeds to 10 kn (5.1 m/s) to avoid vessel collisions with NARWs. Slow Zones typically persist for 15 days. More information on these right whale Slow Zones can be found on NMFS' website (*https://www.fisheries.noaa.gov/national/endangered-species-conservation/reducing-vessel-strikes-north-atlantic-right-whales*).

Elevated NARW mortalities have occurred since June 7, 2017 along the U.S. and Canadian coasts. As of October 2022, a total of 34 confirmed dead stranded whales (21 in Canada; 13 in the United States) have been documented. This event has been declared an Unusual Mortality Event (UME), with human interactions, including entanglement in fixed fishing gear and vessel strikes, implicated in at least 16 of the mortalities thus far. More information is available online at: *www.fisheries.noaa.gov/national/marine-life-distress/2017-2019-north-atlantic-right-whale-unusual-mortality-event.*

Humpback Whale

Humpback whales are found worldwide in all oceans. Humpback whales were listed as endangered under the Endangered Species Conservation Act (ESCA) in June 1970. In 1973, the ESA replaced the ESCA, and humpback whales continued to be listed as endangered. On September 8, 2016, NMFS divided the species into 14 distinct population segments (DPS), removed the current species-level listing, and in its place, listed four DPSs as endangered and one DPS as threatened (81 FR 62259; September 8, 2016). The remaining nine DPSs were not listed. The West Indies DPS, which is not listed under the ESA, is the only DPS of humpback whales that is expected to occur in the proposed survey area. Whales occurring in the proposed survey area are not necessarily from the Gulf of Maine feeding population managed as a stock by NMFS. Bettridge *et al.* (2015) estimated the size of the West Indies DPS population at 12,312 (95 percent CI 8,688–15,954) whales in 2004–05, which is consistent with previous population estimates of approximately 10,000–11,000 whales (Stevick *et al.,* 2003; Smith *et al.,* 1999) and the increasing trend for the West Indies DPS (Bettridge *et al.,* 2015).

Humpback whales are highly migratory, traveling between mid to high latitude waters to feed from spring through fall and lower latitude wintering grounds to calve and breed. Humpback whales may traverse deep, pelagic areas while migrating (Baker *et al.,* 1998; Calambokidis *et al.,* 2001; Garrigue *et al.,* 2002). Not all humpback whales from the Gulf of Maine stock migrate to breeding areas during the winter as Swingle *et al.* (1993) noted significant numbers of humpback

whales in mid and high latitude regions during this time.

The proposed survey areas offshore North Carolina and South Carolina are part of a humpback whale migration pathway between the calving/breeding grounds in the south and the feeding grounds in the north (Hayes *et al.,* 2020). Since 1989, juvenile humpback whales have been sighted in the mid-Atlantic coast and offshore North Carolina and South Carolina more frequently during the winter months, with sightings peaking between January and March (Swingle *et al.,* 1993). The mid-Atlantic region likely represents a supplemental winter feeding ground for non-reproductive animals that are not participating in reproductive behavior at the breeding grounds (Barco *et al.,* 2002; Swingle *et al.,* 1993).

The most significant anthropogenic causes of mortality of humpback whales include incidental fishery entanglements, responsible for roughly eight whale mortalities, and vessel collisions, responsible for four mortalities both on average annually from 2013 to 2017 (Hayes *et al.,* 2020). Since January 2016, elevated humpback whale mortalities have occurred along the Atlantic coast from Maine to Florida. This event has been declared a UME. Partial or full necropsy examinations have been conducted on approximately half of the 161 known cases (as of October 7, 2022). Of the whales examined, approximately 50 percent had evidence of human interaction, either ship strike or entanglement. While a portion of the whales have shown evidence of pre-mortem vessel strike, this finding is not consistent across all whales examined and more research is needed. A total of 22 strandings have occurred in North Carolina since 2016. Three previous UMEs involving humpback whales have occurred since 2000, in 2003, 2005, and 2006. More information is available at: *www.fisheries.noaa.gov/national/marine-life-distress/2016–2021-humpback-whale-unusual-mortality-event-along-atlantic-coast.*

Fin Whale

Fin whales have a common occurrence in waters of the U.S. Atlantic Exclusive Economic Zone (EEZ), principally from Cape Hatteras northward with a distribution in both continental shelf and deep water habitats (Hayes *et al.,* 2022). Fin whales are present north of 35-degree latitude in every season and are broadly distributed throughout the western North Atlantic for most of the year although densities vary seasonally (Edwards *et al.,* 2015; Hayes *et al.,* 2022).

Western North Atlantic fin whales typically feed in the Gulf of Maine and the waters surrounding New England, but mating and calving (and general wintering) areas are largely unknown (Hain *et al.,* 1992; Hayes *et al.,* 2022). Calving likely takes place from October through January in the mid-Atlantic region (Hain *et al.,* 1992). New England and Gulf of St. Lawrence waters represent major feeding grounds for fin whales (Hayes *et al.,* 2022). Fin whales can be found offshore of North Carolina and South Carolina year-round, although sighting data indicate that they are most abundant during spring, winter, and summer (Hayes *et al.,* 2022).

The fin whale is federally listed under the ESA as an endangered species and is designated as a strategic stock under the MMPA due to its endangered status under the ESA, uncertain human-caused mortality, and incomplete survey coverage of the stock's defined range. The main threats to fin whales are fishery interactions and vessel collisions (Hayes *et al.,* 2022).

Sperm Whale

The distribution of the sperm whale in the U.S. EEZ occurs on the continental shelf edge, over the continental slope, and into mid-ocean regions (Hayes *et al.,* 2020). The offshore distribution is likely associated with Gulf Stream features (Waring *et al.,* 1993). During the winter, sperm whales are concentrated to the east and northeast of Cape Hatteras (Hayes *et al.,* 2020). In the spring, the distribution shifts northward to east of Delaware and Virginia as well as throughout the central region of the mid-Atlantic Bight and the southern region of George's Bank (Hayes *et al.,* 2020). In summer, the distribution continues to shift northward to the area east and north of George's Bank and the continental shelf south of New England. Sperm whales are most abundant along the continental shelf of the mid-Atlantic during fall (Hayes *et al.,* 2020).

Geographic distribution of sperm whales is likely linked to their social structure and low reproductive rate. The basic social unit of the sperm whale appears to be the mixed school of adult females plus their calves and some juveniles of both sexes, and social bonds may persist for many years (Christal *et al.,* 1998). Other social groupings include nursery, juvenile, bachelor, and bull schools as well as solitary bulls (Best, 1979; Whitehead *et al.,* 1991; Christal *et al.,* 1998). Groupings have distinct geographical ranges with females and juveniles occurring in tropical and sub-tropical waters, and males being more wide-ranging and occurring in northern latitudes (Hayes *et al.,* 2020). The peak breeding season in the northern hemisphere for sperm whales occurs between April and June (Best *et al.,* 1984), and calving grounds likely exist around Cape Hatteras, North Carolina (Costidis *et al.,* 2017). Sperm whale distribution can also vary in response to prey availability, such as squid (Jacquet and Gendron, 2002).

Sperm whales are listed as an endangered species under the ESA, and the North Atlantic stock is considered strategic under the MMPA. The greatest threats to sperm whales include ship strikes (McGillivary *et al.,* 2009; Carrillo and Ritter, 2010), anthropogenic sound (Nowacek *et al.,* 2015), and the potential for climate change to influence variations in spatial distribution and abundance of prey (Hayes *et al.,* 2020).

Cuvier's Beaked Whale

Cuvier's beaked whales occur mainly along the continental shelf edge of the Mid-Atlantic region of the U.S. east coast (CETAP, 1982; Waring *et al.,* 1992; Waring *et al.,* 2001; Hamazaki, 2002; Palka, 2006). They are known to prefer deep, pelagic waters along the continental slope edge, and favor steep underwater geological features such as banks, seamounts, and submarine canyons (NOAA Fisheries, 2022a). Offshore of Cape Hatteras, North Carolina, satellite-tagged beaked whales have demonstrated restricted movement patterns suggesting a resident population (Foley, 2018). Cuvier's beaked whales can be found year-round offshore of North Carolina (Hayes *et al.,* 2020; McLellan *et al.,* 2018; Stainstreet *et al.,* 2017) with a potential to offshore of North Carolina and South Carolina (Roberts *et al.,* 2016). Mass strandings of beaked whales globally have been associated with naval activities (Cox *et al.,* 2006; D'Amico *et al.,* 2009; Fernandez *et al.,* 2005; Filadelfo *et al.,* 2009).

Mesoplodont Whales

The genus, *Mesoplodon,* includes four species of beaked whales: True's beaked whale (*Mesoplodon mirus*), Gervais' beaked whale (*M. europaeus*), Blainville's beaked whale (*M. densirostris*) and Sowerby's beaked whale (*M. bidens*) (Mead, 1989). As these species are difficult to distinguish at sea, much of the available information on the distribution of beaked whales is specific to the genus level (Waring *et al.,* 2008b). Along the U.S. Atlantic coast, *Mesoplodon* beaked whale sightings occur primarily along the continental shelf edge and deeper

oceanic waters (CETAP, 1982; Waring *et al.,* 1992; Tove, 1995; Waring *et al.,* 2001; Hamazaki, 2002; Palka, 2006). As with Cuvier's beaked whales, *Mesoplon* beaked whale distributions have been linked to physical features such as continental slope, canyons, escarpments, and oceanic islands (DoN, 2008; Pitman, 2018). Key areas for *Mesoplodon* whales have been identified along the continental edge of the western North Atlantic with depths down to 5,000 m from Cape Hatteras north to southern Nova Scotia (DoN, 2008). Distribution of individual *Mesoplodon* beaked whale species may vary by water temperature with Blainville's and Gervais' beaked whales occurring in warmer southern waters and Sowerby's and True's beaked whales occurring in cooler northern waters (DoN, 2008). Blainville's, Gervais', and True's beaked whales are expected to occur within the proposed survey area, based upon previous sighting and stranding records (Hayes *et al.,* 2008; Hayes *et al.,* 2010).

Pilot Whale

Two species of pilot whales, long-finned and short-finned, occur in the Western North Atlantic and may be sighted within the proposed study area. These species are difficult to differentiate at sea, and cannot be reliably distinguished during most surveys (Rone and Pace, 2012; Hayes *et al.,* 2021). Pilot whales tend to occur in areas of high relief or submerged banks, and may be associated with the Gulf Stream wall and thermal fronts along the continental shelf edge (Waring *et al.,* 1992). Both species of pilot whale are more generally found along the edge of the continental shelf at depths of 100 to 1,000 m (330 to 3,300 ft) in winter and early spring (CETAP, 1982; Payne and Heinemann, 1993; Abend and Smith 1999; Hamazaki, 2002). During late spring through late fall, they frequently travel into the central and northern Georges Bank, Great South Channel, and northward into the Gulf of Maine (CETAP, 1982; Payne and Heinemann, 1993; Hayes *et al.* 2021). Spatial distributions of long-finned and short-finned pilot whales overlap along the central Atlantic shelf break between New Jersey and southern Georges Bank (Payne and Heinemann, 1993; Hayes *et al.,* 2021). Long-finned pilot whales are more pelagic, and have occasionally stranded as far south as Florida (Hayes *et al.,* 2021).

Short-finned pilot whales prefer tropical, subtropical, and warm temperate waters (Jefferson *et al.* 2015). South of Cape Hatteras, NC, most pilot whale sightings are expected to be short-finned pilot whales (Hayes *et al.,* 2021). The continental shelf break is an important foraging habitat for short-finned pilot whales in the Western North Atlantic. A satellite tagging study of short-finned pilot whales showed whales to concentrate along the shelf break from Cape Hatteras, NC north to Hudson Canyon as well as in shelf break waters south of Cape Lookout, NC (Thorne *et al.,* 2017).

Atlantic Spotted Dolphin

Atlantic spotted dolphins are found in tropical and warm temperate waters along the continental shelf from 10 to 200 m (33 to 650 ft) deep to slope waters greater than 500 m (1,640 ft) (Leatherwood *et al.,* 1976; Hayes *et al.,* 2020). Their range extends from southern New England, south to Gulf of Mexico and the Caribbean to Venezuela (Leatherwood *et al.,* 1976; Perrin *et al.,* 1994; Hayes *et al.,* 2020). This stock regularly occurs in continental shelf waters south of Cape Hatteras and in continental shelf edge and continental slope waters north of this region (Hayes *et al.* 2020).

Two forms, or ecotypes, occur in the Western North Atlantic. A large and heavily spotted ecotype inhabits the continental shelf, usually found inside or near the 200 m isobaths in continental shelf waters south of Cape Hatteras. A smaller, less spotted and offshore ecotype occurs in the continental slope waters of the Western North Atlantic, typically north of Cape Hatteras, North Carolina (Mullin and Fulling, 2003; Hayes *et al.,* 2020). The offshore ecotype and the pantropical spotted dolphin (*Stenella attenuata*) are difficult to differentiate at sea (Hayes *et al.,* 2020). Atlantic spotted dolphins have been observed during 2021 HRG surveys offshore northern North Carolina during the months of September–December (Marine-Ventures, 2022). Spotted dolphins were also observed during all seasons except winter during 2019 digital aerial baseline surveys in a nearby survey area (Normandeau-APEM, 2020).

Bottlenose Dolphin

The bottlenose dolphin populations in the U.S. North Atlantic consist of a complex mosaic of dolphin stocks (Hayes *et al.,* 2021). Two morphologically and genetically distinct bottlenose dolphin ecotypes, coastal and offshore, exist along the North Atlantic coast. The coastal ecotype typically resides in waters less than 20 m (65.6 ft) deep, along the inner continental shelf (within 7.5 km (4.6 miles) of shore) and is further subdivided into seven stocks based largely upon spatial distribution (Hayes *et al.* 2021). North of Cape Hatteras, the offshore and coastal ecotypes are separated by bathymetric contours during the summer. Torres *et al.,* (2003) found dolphins corresponding to the offshore ecotype to typically be found in waters greater than 34 m in depth and greater than 34 km from shore.

Two stocks of bottlenose dolphins may be found in the vicinity of the proposed survey area—the western North Atlantic Offshore Stock (WNAOS), which is comprised of the offshore ecotype, and the Southern Coastal Migratory Stock (SCMS). The SCMS is one of two stocks thought to make broad-scale seasonal migrations in the coastal waters of the Western North Atlantic and occurs from Assateague, Virginia, south to northern Florida (Hayes *et al.,* 2021). Seasonally, SCMS movements indicate they are mostly found in southern North Carolina (Cape Lookout) from October to December; they continue to move farther south from January to March to as far south as northern Florida and move back north to coastal North Carolina from April to June. SCMS bottlenose dolphins occupy waters north of Cape Lookout, North Carolina, to as far north as Chesapeake Bay from July to August. An observed shift in spatial distribution during a summer 2004 survey indicated that the northern boundary for the SCMS may vary from year to year (Hayes *et al.* 2021).

The offshore population consists of one stock (WNAOS) in the western North Atlantic Ocean, is distributed primarily along the outer continental shelf and continental slope, and occurs widely during the spring and summer from Georges Bank to the Florida Keys with late summer and fall incursions as far north the Gulf of Maine depending on water temperatures (Kenney, 1990; Hayes *et al.,* 2020). Although WNAOS dolphins are typically found beyond 34 km from shore, sightings may occur at close at 7.3 km from shore in depths as shallow as 13 m (Garrison *et al.,* 2003; Hayes *et al.,* 2020).

Both the SCMS and WNAOS may occur year-round within the proposed survey area. Bottlenose dolphins were observed during the months of July–November during 2019 HRG surveys offshore of Kitty Hawk, North Carolina, north of the proposed survey area (Tetra-Tech, 2022). Additional digital aerial baseline surveys offshore of Kitty Hawk, North Carolina observed bottlenose dolphins in the months of January and March (Normandeau-APEM, 2020).

Common Dolphin

The common dolphin is found world-wide in temperate to subtropical seas. In the Western North Atlantic, common dolphins are commonly found over the continental shelf between the 200 m and 2,000 m isobaths and over prominent underwater topography and east to the mid-Atlantic Ridge (Doksaeter *et al.,* 2008; Waring *et al.,* 2008a). Common dolphins have been noted to be associated with Gulf Stream features (CETAP, 1982; Selzer and Payne, 1988; Waring *et al.* 1992). The species exhibits seasonal movements, occurring between Cape Hatteras and Georges Bank from mid-January to May, then migrating onto Georges Bank and the Scotian Shelf between mid-summer and fall. During fall, large aggregations occur on Georges Bank (Hain *et al.,* 1981; CETAP, 1982; Payne *et al.,* 1984; Selzer and Payne, 1988; Hayes *et al.* 2020). The species is less common south of Cape Hatteras, although sightings have been reported as far south as the Georgia/South Carolina border (Jefferson *et al.,* 2009; Hayes *et al.* 2020). Common dolphins were also observed off the northern coast of North Carolina during HRG surveys during the months of March and January 2019 (Normandeau-APEM, 2020).

Rough-Toothed Dolphin

Rough-toothed dolphins occur worldwide in warm temperate, subtropical, or tropical waters in a wide range of water depths (West *et al.,* 2011; Hayes *et al.,* 2019). Along the Western Atlantic coast, rough toothed dolphins have been observed from Virginia through Florida with occasional sightings on the continental shelf off North Carolina and Florida (DoN, 2008; OBIS, 2021). Although most vessel sightings of rough-toothed dolphins along the Western Atlantic have occurred in oceanic waters at depths greater than 1,000 m (Hayes *et al.,* 2019), a tagging study conducted by Wells *et al.* (2008) showed rough-toothed dolphins to transit through both deep and shallow waters as well as exhibit dives reaching a maximum of 50 m.

Off North Carolina, rough-toothed dolphins are expected to occur beyond the continental shelf break along the western edge of the Gulf Stream and occasionally more coastal waters (DoN, 2008; OBIS, 2021). According to the Roberts *et al.* (2022) density models, potential occurrence of rough-toothed dolphins increases south of Virginia.

Harbor Porpoise

The harbor porpoise inhabits shallow, coastal waters, often found in bays, estuaries, and harbors. In the western Atlantic, they occur from Cape Hatteras north to Greenland. During summer (July to September), harbor porpoises are concentrated in the northern Gulf of Maine and southern Bay of Fundy region, generally in waters less than 150 m deep with a few sightings in the upper Bay of Fundy and on Georges Bank. During fall (October–December) and spring (April–June), harbor porpoises are widely dispersed from New Jersey to Maine, with lower densities farther north and south (Hayes *et al.,* 2022). They occur from the coastline to deep waters (>1,800 m), although the majority of the population occurs over the continental shelf. The harbor porpoise is likely to occur in the waters of the mid-Atlantic, including North Carolina, during winter months, as this species prefers cold temperate and subarctic waters (Hayes *et al.* 2022). Harbor porpoise generally move out of the Mid-Atlantic during spring, migrating north to the Gulf of Maine. There does not appear to be a temporally coordinated migration or a specific migratory route to and from the Bay of Fundy region (Hayes *et al.* 2022).

Harbor porpoises may occur in the proposed study area during the winter months. One harbor porpoise was sighted in January off the coast of northern North Carolina during HRG surveys in 2019 (Normandeau-APEM, 2020).

Harbor Seal

Harbor seals are the most abundant seals in the waters of the eastern United States and are commonly found in all nearshore waters of the Atlantic Ocean from Newfoundland, Canada southward to northern Florida (Hayes *et al.* 2022). While harbor seals occur year-round north of Cape Cod, they only occur south of Cape Cod (southern New England to New Jersey) during winter migration, typically September through May (Kenney and Vigness-Raposa 2010; Hayes *et al.* 2022). During the summer, most harbor seals can be found north of Massachusetts within the coastal waters of central and northern Maine as well as the Bay of Fundy (Hayes *et al.* 2022).

In recent years, this species has been seen regularly as far south as North Carolina, and regular seasonal haul-out sites of up to 40–60 animals have been documented on the eastern shore of Virginia and the Chesapeake Bay (Jones and Rees 2020). Winter haul-out sites for harbor seals have been identified within the Chesapeake Bay region and Outer Banks, NC beaches; however, sightings as far south as the Carolinas are only occasionally recorded (Hayes *et al.* 2022).

Gray Seal

Gray seals occur on both coasts of the Northern Atlantic Ocean and are divided into three major populations (Hayes *et al.* 2021). The western north Atlantic stock occurs in eastern Canada and the northeastern United States, occasionally as far south as North Carolina. Gray seals inhabit rocky coasts and islands, sandbars, ice shelves and icebergs (Hayes *et al.* 2021). In the United States, gray seals congregate in the summer to give birth at four established colonies in Massachusetts and Maine (Hayes *et al.* 2021). From September through May, they disperse and can be abundant as far south as New Jersey.

Historically, gray seals were absent from North Carolina and South Carolina, however, the range of gray seals appears to be shifting south along the U.S. Atlantic coast (DiGiovanni *et al.,* 2011; Johnson *et al.,* 2015; DiGiovanni *et al.,* 2018). Harbor and gray seals are seen regularly between the fall and spring within the central Atlantic (DoN, 2018; Jones and Rees, 2020). Seals may occur within the proposed study area from November through May (Roberts *et al.,* 2016; Roberts and Halpin, 2022).

Since June 2022, an Unusual Mortality Event (UME) has been declared for Northeast pinnipeds in which elevated numbers of sick and dead harbor seals and gray seals have been documented along the southern and central coast of Maine (NOAA Fisheries, 2022b). Currently, 22 grays seals and 258 harbor seals have stranded. Preliminary sample testing results suggest many affected seals to test positive for avian influenza (NOAA Fisheries, 2022b). NMFS is collaborating with local, state, Federal, international, and tribal partners to gain a better understanding of the cause of this UME. Information on this UME is available online at: *https://www.fisheries.noaa.gov/2022-pinniped-unusual-mortality-event-along-maine-coast.*

The above event was preceded by a different UME occurring between 2018–2020 (closure of the 2018–2020 UME is pending). Additionally, stranded seals have shown clinical signs as far south as Virginia, although not in elevated numbers. Therefore, the UME investigation encompasses all seal strandings from Maine to Virginia. As of March 2020, there has been a total of 3,152 reported strandings (of all species), though only 10 occurred in Virginia while 8 were recorded in Maryland. Full or partial necropsy examinations have been conducted on

some of the seals and samples have been collected for testing. Based on tests conducted thus far, the main pathogen found in the seals is phocine distemper virus. NMFS is performing additional testing to identify any other factors that may be involved in this UME. This UME is non-active and pending closure, and therefore, it is not discussed further in this notice. Information on this UME is available online at: *www.fisheries.noaa.gov/new-england-mid-atlantic/marine-life-distress/2018–2020-pinniped-unusual-mortality-event-along.*

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, etc.). Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 4.

TABLE 4—MARINE MAMMAL HEARING GROUPS

[NMFS, 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, Cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.,* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section provides a discussion of the ways in which components of the specified activity may impact marine mammals and their habitat. Detailed descriptions of the potential effects of similar specified activities have been provided in other recent **Federal Register** notices, including for survey activities using the same methodology, over a similar amount of time, and occurring in the southeast Atlantic region, including the southeast Virginia and North Carolina areas (*e.g.,* 84 FR 31032, June 28, 2019; 85 FR 55415, September 8, 2020; 86 FR 43212, August 6, 2021; 87 FR 25452, April 29, 2022). No significant new information is available, and we incorporate by reference the detailed discussions in those documents rather than repeating the details here. The Estimated Take section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and whether those impacts are reasonably expected to, or reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Summary on Specific Potential Effects of Acoustic Sound Sources

For general information on sound, its interaction with the marine environment, and a description of acoustic terminology, please see, *e.g.,* ANSI (1986, 1995), Au and Hastings (2008); Hastings and Popper (2005); Mitson (1995), NIOSH (1998) Richardson *et al.* (1995); Southall *et al.,* (2007), and Urick (1983). Underwater sound from active acoustic sources can include one or more of the following: Temporary or permanent hearing impairment, behavioral disturbance, masking, stress, and non-auditory physical effects. The degree of effect is intrinsically related to the signal characteristics, received level, distance from the source, and duration of the sound exposure. Marine mammals exposed to high-intensity sound, or to lower-intensity sound for prolonged periods, can experience hearing threshold shift (TS), which is the loss of hearing sensitivity at certain frequency ranges (Finneran, 2015). TS can be permanent (PTS; permanent threshold shift), in which case the loss of hearing sensitivity is not fully recoverable, or temporary (TTS; temporary threshold shift), in which case the animal's hearing threshold would recover over time (Southall *et al.* 2007).

When PTS occurs, there is physical damage to the sound receptors in the ear (*i.e.,* tissue damage), whereas TTS represents primarily tissue fatigue and is reversible (Southall *et al.,* 2007). In addition, other investigators have suggested that TTS is within the normal bounds of physiological variability and tolerance and does not represent physical injury (*e.g.,* Ward, 1997).

Therefore, NMFS does not consider TTS to constitute auditory injury.

Animals in the vicinity of TerraSond's proposed HRG survey activites are unlikely to incur even TTS due to the characteristics of the sound sources, which include a relatively low source level (203 dB re 1 µPa m), and generally very short pulses and potential duration of exposure. These characteristics mean that instantaneous exposure is unlikely to cause TTS because it is unlikely that exposure would occur close enough to the vessel for received levels to exceed peak pressure TTS criteria, and the cumulative duration of exposure would be insufficient to exceed cumulative sound exposure level (SEL) criteria. Even for high-frequency cetacean species (*e.g.,* harbor porpoises), which have the greatest sensitivity to potential TTS, individuals would have to make a very close approach and remain very close to vessels operating these sources in order to receive multiple exposures at relatively high levels necessary to cause TTS. Intermittent exposures—as would occur due to the brief, transient signals produced by these sources—require a higher cumulative SEL to induce TTS than would continuous exposures of the same duration (*i.e.,* intermittent exposure results in lower levels of TTS). Moreover, most marine mammals would more likely avoid a loud sound source rather than swim in such close proximity as to result in TTS. Kremser *et al.* (2005) noted that the probability of a cetacean swimming through the area of exposure when a sub-bottom profiler emits a pulse is small—because if the animal was in the area, it would have to pass the transducer at close range in order to be subjected to sound levels that could cause TTS and would likely exhibit avoidance behavior to the area near the transducer rather than swim through at such a close range.

Behavioral disturbance may include a variety of effects, including subtle changes in behavior (*e.g.,* minor or brief avoidance of an area or changes in vocalizations), more conspicuous changes in similar behavioral activities, and more sustained and/or potentially severe reactions, such as displacement from or abandonment of high-quality habitat. Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.,* species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.,* Richardson *et al.,* 1995; Wartzok *et al.,* 2003; Southall *et al.,* 2007; Weilgart, 2007; Archer *et al.,* 2010; Southall *et al.,* 2021). Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal. If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, the stock, or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.,* Lusseau and Bejder, 2007; Weilgart, 2007; NRC, 2003). As mentioned earlier, the proposed survey area overlaps with a NARW migration BIA and is located adjacent to ESA-designated critical calving habitat and a reproduction BIA. Due to the mobile nature and short duration of the proposed acoustic sources as well as proposed mitigation measures further described in the Proposed Mitigation section, we expect minimal impacts to NARW mother calf pairs.

In addition, sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.,* those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity and may occur whether the sound is natural (*e.g.,* snapping shrimp, wind, waves, precipitation) or anthropogenic (*e.g.,* shipping, sonar, seismic exploration) in origin. Marine mammal communications would not likely be masked appreciably by the acoustic signals given the directionality of the signals for the HRG survey equipment planned for use (Table 2) and the brief period for when an individual mammal would likely be exposed.

An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (*e.g.,* Seyle, 1950; Moberg, 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and ''distress'' is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress will last until the animal replenishes its energetic reserves sufficient to restore normal function. We expect minimal stress responses to result from marine mammals due to the short-term duration of activities and proposed mitigation measures.

Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (*e.g.,* crustaceans, cephalopods, fish, and zooplankton) (*i.e.,* effects to marine mammal habitat). Prey species exposed to sound might move away from the sound source, experience TTS, experience masking of biologically relevant sounds, or show no obvious direct effects. The most likely impacts (if any) for most prey species in a given area would be temporary avoidance of the area. Surveys using active acoustic sound sources move through an area relatively quickly, limiting exposure to multiple pulses. In all cases, sound levels would return to ambient once a survey ends and the noise source is shut down and, when exposure to sound ends, behavioral and/or physiological responses are expected to end relatively quickly. Finally, the HRG survey equipment will not have significant impacts to the seafloor and does not represent a source of pollution.

Vessel Strike

Vessel collisions with marine mammals, or ship strikes, can result in death or serious injury of the animal. These interactions are typically associated with large whales, which are less maneuverable than are smaller cetaceans or pinnipeds in relation to large vessels. Ship strikes generally involve commercial shipping vessels, which are normally larger and of which there is much more traffic in the ocean than geophysical survey vessels. Jensen and Silber (2004) summarized ship strikes of large whales worldwide from 1975–2003 and found that most collisions occurred in the open ocean and involved large vessels (*e.g.,*

commercial shipping). For vessels used in geophysical survey activities, vessel speed while towing gear is typically only 4–5 knots. At these speeds, both the possibility of striking a marine mammal and the possibility of a strike resulting in serious injury or mortality are so low as to be discountable. At average transit speed for geophysical survey vessels, the probability of serious injury or mortality resulting from a strike is less than 50 percent. However, the likelihood of a strike actually happening is again low given the smaller size of these vessels and generally slower speeds. Notably in the Jensen and Silber study, no strike incidents were reported for geophysical survey vessels during that time period.

The potential effects of TerraSond's specified survey activity are expected to be limited to Level B behavioral harassment. No permanent or temporary auditory effects, or significant impacts to marine mammal habitat, including prey, are expected.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization through this IHA, which will inform both NMFS' consideration of ''small numbers,'' and the negligible impact determinations.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would be by Level B harassment only, in the form of disruption of behavioral patterns for individual marine mammals resulting from exposure to sound produced by the sparker. Based primarily on the characteristics of the signals produced by the acoustic source planned for use, Level A harassment is neither anticipated (even absent mitigation), nor proposed to be authorized. As described previously, no serious injury or mortality is anticipated or proposed to be authorized for this activity. Below we describe how the proposed take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimates.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.,* frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (*e.g.,* bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (*e.g.,* Southall *et al.,* 2007, 2021; Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 160 dB re 1 µPa for impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources. Generally speaking, Level B harassment take estimates based on these behavioral harassment thresholds are expected to include any likely takes by TTS as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

TerraSond's proposed activity includes the use of impulsive (*i.e.,* sparkers) sources, and therefore, the RMS SPL thresholds of 160 dB re 1 µPa is applicable.

Level A harassment—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive).

The references, analysis, and methodology used in the development of the thresholds are described in NMFS' 2018 Technical Guidance, which may be accessed at: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TerraSond's proposed activity includes the use of impulsive (*i.e.,* sparkers) sources. However, as discussed above, NMFS has concluded that Level A harassment is not a reasonably likely outcome for marine mammals exposed to noise through use of the sources proposed for use here, and the potential for Level A harassment is not evaluated further in this document. Please see TerraSond's application (Section 6.3.1 Level A) for details of a quantitative exposure analysis exercise, *i.e.,* calculated Level A harassment isopleths and estimated Level A harassment exposures. TerraSond did not request authorization of take by Level A harassment, and no take by Level A harassment is proposed for authorization by NMFS.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

NMFS has developed a user-friendly methodology for estimating the extent of the Level B harassment isopleths associated with relevant HRG survey equipment (NMFS, 2020). This methodology incorporates frequency

and directionality (when relevant) to refine estimated ensonified zones. The sparkers proposed for use by TerraSond are omnidirectional and, therefore, beamwidth does not factor into the calculations.

NMFS considers the data provided by Crocker and Fratantonio (2016) to represent the best available information on source levels associated with HRG survey equipment and, therefore, recommends that source levels provided by Crocker and Fratantonio (2016) be incorporated in the method described above to estimate distances to harassment isopleths. In cases where the source level for a specific type of HRG equipment is not provided in Crocker and Fratantonio (2016), NMFS recommends either the source levels provided by the manufacturer be used, or, in instances where source levels provided by the manufacturer are unavailable or unreliable, a proxy from Crocker and Fratantonio (2016) be used instead. TerraSond plans to use the Applied Acoustics Dura-spark sparker UHRS 400 + 400. For all source configurations (Table 1), the maximum power expected to be discharged from the sparker source is 800 J. However, Crocker and Fratantonio (2016) did not measure the Applied Acoustics Dura-spark with an energy near 800 J and the manufacturer does not provide these specifications. A similar alternative system, the SIG ELC 820 sparker, was measured by Crocker and Fratantonio (2016) with an input voltage of 750 J, and these measurements were used as a proxy for the Applied Acoustics Dura-spark sparker. Table 2 shows the source parameters associated with this proxy. Using the measured source level of 203 dB RMS of the proxy, SIG ELC 820 sparker with an input voltage of 750 J, modeling results of modeling indicated that the Applied Acoustics Dura-spark UHRS 400 + 400 would produce a distance of 141 m to the Level B harassment isopleth.

Daily ensonified area for each of the three survey phases (Table 1) was calculated by using the following equation: Daily survey distance (km) × 2 × (Level B isopleth (km) + separation distance between sparkers (km)) + area of a circle with a radius of Level B isopleth (km). For each phase, the daily survey distance is estimated to be approximately 100 km (Table 6). Phases 2 and 3 would include multiple sparker sources in their tow configurations (Table 1). Table 5 shows the daily ensonified area for each survey phase. In order to calculate the monthly ensonified area for each phase, the daily ensonified area was multiplied by the number of estimated survey days per month for each phase. Monthly ensonified area for each phase is shown in Table 5.

TABLE 5—ENSONIFIED AREA FOR EACH SURVEY PHASE

Phase	Total survey distance (km)	Average daily survey distance (km)	Survey days per month	Number of sparker sources	Daily ensonified area (km^2)	Monthly ensonified area (km^2)
1	4,054	100	3.4	1	28.3	95.5
2	1,300	100	1.2	[1] 3	58.5	68.2
3	12,488	100	10.4	[2] 2	31.3	325.5

[1] 150 m horizontal separation distance between sparkers.
[2] 30 m horizontal separation distance between sparkers.

Marine Mammal Occurrence

In this section we provide information about the occurrence of marine mammals, including density or other relevant information that will inform the take calculations.

Habitat-based density models produced by the Duke University Marine Geospatial Ecology Laboratory (Roberts *et al.,* 2016; Roberts and Halpin, 2022) represent the best available information regarding marine mammal densities in the proposed survey area. The density data presented by Roberts and Halpin (2022) incorporates aerial and shipboard line-transect survey data from NMFS and other organizations and incorporates data from 8 physiographic and 16 dynamic oceanographic and biological covariates, and controls for the influence of sea state, group size, availability bias, and perception bias on the probability of making a sighting. These density models were originally developed for all cetacean taxa in the U.S. Atlantic (Roberts *et al.,* 2016). In subsequent years, certain models have been updated based on additional data as well as certain methodological improvements. More information is available online at *https://seamap.env.duke.edu/models/Duke/EC/.*

The Roberts and Halpin (2022) density-based habitat models provided density estimates for species or species guilds within 5 km × 5 km grids cells on a monthly or annual basis, depending upon the species. TerraSond selected a representative sample of grid cells in and near the proposed survey area by creating a 5 km wide perimeter around the survey area using GIS (ESRI, 2017), and intersecting the perimeter with the density grid cells to select those nearest to the proposed survey area. The average density of each species per month was then calculated from the selected grid cells. Density estimates for each species derived from this method are shown in Table 10 of TerraSond's application. After careful review of this methodology, NMFS agrees with this approach.

Seal species were represented as a single guild by the Roberts density-based habitat models (Roberts *et al.,* 2016; Roberts and Halpin, 2022). In order to determine seal density by species, the proportion of abundance for each seal species was calculated using the stock abundance estimate from the most recent NMFS stock assessment report (Hayes *et al.,* 2022). For example, the stock abundance estimate for harbor seals (61,336) was divided by the sum of the stock abundance estimates for harbor seals (61,336) and gray seals (27,300). This proportion was calculated for harbor seals and gray seals. The proportion was then multiplied by the density estimate for seals as a guild to determine a density-based estimate for each seal species. NMFS has reviewed this methodology for deriving density-based estimates for each seal species from a seal guild estimate, and agrees with this approach.

Take Estimation

Here we describe how the information provided above is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and proposed for authorization. In order to estimate the number of marine mammals predicted to be exposed to sound levels that would result in Level B harassment, estimated take was first calculated by month for each phase. The monthly density for each species in the proposed survey area (Table 10 of the

application) was multiplied by the respective monthly ensonified area for each phase (Table 5) according to the following equation: Estimated monthly take = average monthly density (individuals/km^2) × monthly ensonified area (km^2). Estimated monthly take for each phase was summed across twelve months and is shown for each phase by species in Table 6. Density-based take estimates for each phase were added together for each species to receive a total requested take estimate (Table 6). The percent of each stock abundance requested for take was calculated using the most updated abundance estimates from the NMFS stock assessment report (Hayes *et al.,* 2022) (Table 6).

As the Roberts density-based habitat models (Roberts *et al.,* 2016; Roberts and Halpin, 2022) did not distinguish between short-finned and long-finned pilot whales, the requested take estimate in Table 6 represents both species of pilot whale. NMFS calculated the percent of stock abundance requested assuming all take was from the stock of short-finned pilot whales. NMFS also calculated the percent of stock abundance requested assuming all take was from the stock of long-finned pilot whales. NMFS then compared these calculations to determine which percentage was greater, and found that the calculation assuming all take was from the stock of short-finned pilot whales represented a larger percentage. The percent of take that represents the greatest impact (short-finned pilot whale) is displayed in Table 6. A similar approach was used when calculating percent of take requested for bottlenose dolphins, as two stocks (southern migratory coastal stock and offshore Western North Atlantic stock) may occur within the proposed study area. The percent of take that represents the greatest impact (southern migratory coastal stock) is shown in Table 6.

When determining requested take numbers, TerraSond also considered mean group size estimates for each species based upon available sighting data collected through recent aerial/vessel-based surveys in the southwest Atlantic region (Kraus *et al.,* 2016; Palka *et al.,* 2017). Mean group size estimates were compared to density-based estimates. If the mean group size was greater than the density-based estimate, the requested estimated take was increased to the mean group size value. Requested take was adjusted for mean group size for the following species, as shown in Table 6: Fin whale, humpback whale, NARW, sperm whale, common dolphin, Cuvier's beaked whale, pilot whales, Mesoplodont whales, rough-toothed dolphin, harbor porpoise, harbor seal, and gray seal.

The estimated density-based exposure value was calculated to be and/or rounded to zero for the fin whale, humpback whale, sperm whale, Cuvier's beaked whale, harbor porpoise, Mesoplodont beaked whales, gray seal, and harbor seal. Therefore, TerraSond has requested a small amount of take for these species in the event that they do occur during project activities. The North Carolina coast is part of a migratory pathway for humpback whales moving seasonally between winter foraging grounds and summer breeding grounds (Hayes *et al.,* 2022). Juvenile humpback whales are typically sighted off the Virginia and North Carolina coasts during the winter months (Swingle *et al.,* 1993), and therefore, may potentially occur within the proposed study area. Fin and sperm whale sightings have occurred off of Cape Hatteras, North Carolina, just north of the proposed study area. Fin whales may use the Central Atlantic coast as a calving area, while sperm whales likely calve near Cape Hatteras, NC (Hayes *et al.,* 2022). In addition, Cuvier's beaked whale and harbor porpoise sightings have occurred off of Cape Hatteras, NC (Hayes *et al.,* 2022). Due to the relatively close proximity of Cape Hatteras to the proposed study area, it is possible these species may occur off Carolina Long Bay as well. Based upon documented stranding records, Mesoplodont whale strandings may occur within the proposed study area as well. Mesoplodont strandings have been documented as far south as Florida, and True's, Gervais', and Sowerby's beaked whales are considered temperature species. Over time, harbor seals and gray seals have expanded their range further south along the U.S. Atlantic coast with harbor seal sightings occurring off North Carolina during the fall and spring (Hayes *et al.,* 2022). Harbor seals may also occasionally haul out in northern North Carolina during the winter. Due to documented sighting and stranding records, it is also possible that harbor and gray seals may occur with the proposed study area as well. NMFS has carefully reviewed TerraSond's methodology for calculating estimated requested take and adjusting estimated take based upon mean group size estimates. NMFS agrees with this approach and proposes to authorize the requested take numbers.

TABLE 6—ESTIMATED TAKE NUMBERS AND TOTAL TAKE PROPOSED FOR AUTHORIZATION

Species	Density-based take estimates			Total proposed take	Percent stock abundance proposed for take
	Phase 1	Phase 2	Phase 3		
Fin whale	0	0	0	*2	0.03
Humpback whale	0	0	0	*2	0.14
North Atlantic right whale	0.1	0	0	*3	0.82
Sperm whale	0	0	0	*1	0.02
Pilot whale [1]	0.1	0.1	0	*26	0.09
Cuvier's beaked whale	0	0	0	*3	0.05
Mesoplodont whales	0	0	0	*3	0.09
Bottlenose dolphin [2]	130.6	93.3	445	669	17.8
Atlantic spotted dolphin	122.4	87.5	417	628	1.57
Common dolphin	0.8	0.6	3	*49	0.03
Rough-toothed dolphin	1.5	1	5	*19	14
Harbor porpoise	0	0	0	*3	0.003
Harbor seal	0	0	0	*2	0.003
Gray seal	0	0	0	*2	0.007

*Adjusted for group size.

[1] Represents short-finned and long-finned pilot whales.

[2] Represents offshore and southern migratory coastal stocks of bottlenose dolphins.

Proposed Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which may consider such things as cost and impact on operations.

NMFS proposes the following mitigation measures be implemented during TerraSond's proposed HRG surveys. Pursuant to section 7 of the ESA, TerraSond would also be required to adhere to relevant Project Design Criteria (PDC) of the NMFS' Greater Atlantic Regional Fisheries Office (GARFO) programmatic consultation (specifically PDCs 4, 5, and 7) regarding geophysical surveys along the U.S. Atlantic coast (*https://www.fisheries.noaa.gov/new-england-mid-atlantic/consultations/section-7-take-reporting-programmatics-greater-atlantic#offshore-wind-site-assessment-and-site-characterization-activities-programmatic-consultation*).

Visual Monitoring and Shutdown Zones

TerraSond must employ independent, dedicated, trained PSOs, meaning that the PSOs must (1) be employed by a third-party observer provider, (2) have no tasks other than to conduct observational effort, collect data, and communicate with and instruct relevant vessel crew with regard to the presence of marine mammals and mitigation requirements (including brief alerts regarding maritime hazards), and (3) have successfully completed an approved PSO training course appropriate for geophysical surveys. Visual monitoring must be performed by qualified, NMFS-approved PSOs. PSO resumes must be provided to NMFS for review and approval prior to the start of survey activities.

During survey operations (*e.g.,* any day on which use of the sparker source is planned to occur, and whenever the sparker source is in the water, whether activated or not), a minimum of one visual marine mammal observer (PSO) must be on duty on each source vessel and conducting visual observations at all times during daylight hours (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset). A minimum of two PSOs must be on duty on each source vessel during nighttime hours. Visual monitoring must begin no less than 30 minutes prior to ramp-up (described below) and must continue until one hour after use of sparker source ceases.

Visual PSOs shall coordinate to ensure 360° visual coverage around the vessel from the most appropriate observation posts and shall conduct visual observations using binoculars and the naked eye while free from distractions in a consistent, systematic, and diligent manner. PSOs shall establish and monitor application shutdown zones (see below). These zones shall be based upon the radial distance from the sparker source (rather than being based around the vessel itself).

Two shutdown zones are defined, depending on the species and context. Here, an extended shutdown zone encompassing the area at and below the sea surface out to a radius of 500 meters from the sparker source (0–500 m) is defined for NARWs. For all other marine mammals, the shutdown zone encompasses a standard distance of 100 meters (0–100 m). Any observations of marine mammals by crew members aboard any vessel associated with the survey shall be relayed to the PSO team.

Visual PSOs may be on watch for a maximum of four consecutive hours followed by a break of at least one hour between watches and may conduct a maximum of 12 hours of observation per 24-hour period

Pre-Start Clearance and Ramp-Up

A ramp-up procedure, involving a gradual increase in source level output, is required at all times as part of the activation of the sparker source when technically feasible. Operators should ramp up sparkers to half power for 5 minutes and then proceed to full power. A 30-minute pre-start clearance observation period must occur prior to the start of ramp-up. The intent of the 30-minute pre-start clearance observation period is to ensure no marine mammals are within the shutdown zones prior to the beginning of ramp-up. The intent of ramp-up is to warn marine mammals of pending operations and to allow sufficient time for those animals to leave the immediate vicinity. All operators must adhere to the following pre-start clearance and ramp-up requirements:

- The operator must notify a designated PSO of the planned start of ramp-up as agreed upon with the lead PSO; the notification time should not be less than 60 minutes prior to the planned ramp-up in order to allow the PSOs time to monitor the shutdown zones for 30 minutes prior to the initiation of ramp-up (pre-start clearance). During this 30-minute pre-start clearance period, the entire shutdown zone must be visible, except as indicated below.
- Ramp-ups shall be scheduled so as to minimize the time spent with the source activated.
- A visual PSO conducting pre-start clearance observations must be notified again immediately prior to initiating ramp-up procedures and the operator must receive confirmation from the PSO to proceed.
- Any PSO on duty has the authority to delay the start of survey operations if a marine mammal is detected within the applicable pre-start clearance zone.
- The operator must establish and maintain clear lines of communication directly between PSOs on duty and crew controlling the acoustic source to ensure that mitigation commands are conveyed swiftly while allowing PSOs to maintain watch.
- The pre-start clearance requirement is waived for small delphinids and pinnipeds. Detection of a small delphinid (individuals belonging to the following genera of the Family Delphinidae: *Steno, Delphinus, Lagenorhynchus, Stenella,* and *Tursiops*) or pinniped within the shutdown zone does not preclude beginning of ramp-up, unless the PSO

confirms the individual to be of a genus other than those listed, in which case normal pre-clearance requirements apply.

- If there is uncertainty regarding identification of a marine mammal species (*i.e.,* whether the observed marine mammal(s) belongs to one of the delphinid genera for which the pre-clearance requirement is waived), PSOs may use the best professional judgment in making the decision to call for a shutdown.
- Ramp-up may not be initiated if any marine mammal to which the pre-start clearance requirement applies is within the shutdown zone. If a marine mammal is observed within the shutdown zone during the 30-minute pre-start clearance period, ramp up may not begin until the animal(s) has been observed exiting the zones or until an additional time period has elapsed with no further sightings (30 minutes for all baleen whale species and sperm whales and 15 minutes for all other species).
- PSOs must monitor the shutdown zones 30 minutes before and during ramp-up, and ramp-up must cease and the source must be shut down upon observation of a marine mammal within the applicable shutdown zone.
- Ramp-up may occur at times of poor visibility, including nighttime, if appropriate visual monitoring has occurred with no detections of marine mammals in the 30 minutes prior to beginning ramp-up. Sparker activation may only occur at night where operational planning cannot reasonably avoid such circumstances.
- If the acoustic source is shut down for brief periods (*i.e.,* less than 30 minutes) for reasons other than implementation of prescribed mitigation (*e.g.,* mechanical difficulty), it may be activated again without ramp-up if PSOs have maintained constant visual observation and no detections of marine mammals have occurred within the applicable shutdown zone. For any longer shutdown, pre-start clearance observation and ramp-up are required.

Shutdown Procedures

All operators must adhere to the following shutdown requirements:

- Any PSO on duty has the authority to call for shutdown of the sparker source if a marine mammal is detected within the applicable shutdown zone.
- The operator must establish and maintain clear lines of communication directly between PSOs on duty and crew controlling the source to ensure that shutdown commands are conveyed swiftly while allowing PSOs to maintain watch.
- When the sparker source is active and a marine mammal appears within or enters the applicable shutdown zone, the source must be shut down. When shutdown is instructed by a PSO, the source must be immediately deactivated and any dispute resolved only following deactivation.
- The shutdown requirement is waived for small delphinids and pinnipeds. If a small delphinid (individual belonging to the following genera of the Family Delphinidae: *Steno, Delphinus, Lagenorhynchus, Stenella,* and *Tursiops*) or pinniped is visually detected within the shutdown zone, no shutdown is required unless the PSO confirms the individual to be of a genus other than those listed, in which case a shutdown is required
- If there is uncertainty regarding identification of a marine mammal species (*i.e.,* whether the observed marine mammal(s) belongs to one of the delphinid genera for which shutdown is waived or one of the species with a larger shutdown zone), PSOs may use best professional judgment in making the decision to call for a shutdown.
- Upon implementation of shutdown, the source may be reactivated after the marine mammal has been observed exiting the applicable shutdown zone or following a clearance period (30 minutes for all baleen whale species and sperm whales and 15 minutes for all other species) with no further detection of the marine mammal.

If a species for which authorization has not been granted, or a species for which authorization has been granted but the authorized number of takes have been met, approaches or is observed within the Level B harassment zone, shutdown must occur.

Vessel Strike Avoidance

Crew and supply vessel personnel should use an appropriate reference guide that includes identifying information on all marine mammals that may be encountered. Vessel operators must comply with the below measures except under extraordinary circumstances when the safety of the vessel or crew is in doubt or the safety of life at sea is in question. These requirements do not apply in any case where compliance would create an imminent and serious threat to a person or vessel or to the extent that a vessel is restricted in its ability to maneuver and, because of the restriction, cannot comply.

- Vessel operators and crews must maintain a vigilant watch for all marine mammals and slow down, stop their vessel(s), or alter course, as appropriate and regardless of vessel size, to avoid striking any marine mammals. A visual observer aboard the vessel must monitor a vessel strike avoidance zone based on the appropriate separation distance around the vessel (distances stated below). Visual observers monitoring the vessel strike avoidance zone may be third-party observers (*i.e.,* PSOs) or crew members, but crew members responsible for these duties must be provided sufficient training to (1) distinguish protected species from other phenomena and (2) broadly to identify a marine mammal as a NARW, other whale (defined in this context as sperm whales or baleen whales other than NARW), or other marine mammal.
- All survey vessels, regardless of size, must observe a 10-knot speed restriction in specific areas designated by NMFS for the protection of NARWs from vessel strikes. These include all Seasonal Management Areas (SMA) under 50 CFR 224.105 (when in effect), any dynamic management areas (DMA) (when in effect), and Slow Zones. See *www.fisheries.noaa.gov/national/endangered-species-conservation/reducing-ship-strikes-north-atlantic-right-whales* for specific detail regarding these areas.
- All vessels must reduce their speed to 10 knots or less when mother/calf pairs, pods, or large assemblages of cetaceans are observed near a vessel;
- All vessels must maintain a minimum separation distance of 500 m from NARWs. If a NARW is sighted within the relevant separation distance, the vessel must steer a course away at 10 knots or less until the 500-m separation distance has been established. If a whale is observed but cannot be confirmed as a species other than a right whale, the vessel operator must assume that it is a right whale and take appropriate action.
- All vessels must maintain a minimum separation distance of 100 m from sperm whales and all other baleen whales.
- All vessels must, to the maximum extent practicable, attempt to maintain a minimum separation distance of 50 m from all other marine mammals, with an understanding that at times this may not be possible (*e.g.,* for animals that approach the vessel).
- When marine mammals are sighted while a vessel is underway, the vessel must take action as necessary to avoid violating the relevant separation distance (*e.g.,* attempt to remain parallel to the animal's course, avoid excessive speed or abrupt changes in direction until the animal has left the area, reduce speed and shift the engine to neutral). This does not apply to any vessel

towing gear or any vessel that is navigationally constrained.

Members of the monitoring team would consult NMFS NARW reporting system and Whale Alert, daily and as able, for the presence of NARWs throughout survey operations, and for the establishment of DMAs and/or Slow Zones. It is TerraSond's responsibility to maintain awareness of the establishment and location of any such areas and to abide by these requirements accordingly.

Based on our evaluation of TerraSond's proposed measures, as well as other measures considered by NMFS, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and,
- Mitigation and monitoring effectiveness.

TerraSond must submit PSO resumes for NMFS review and approval prior to commencement of the survey. Resumes should include dates of training and any prior NMFS approval, as well as dates and description of last experience, and must be accompanied by information documenting successful completion of an acceptable training course. For prospective PSOs not previously approved, or for PSOs whose approval is not current, NMFS must review and approve PSO qualifications. Resumes must be accompanied by relevant documentation of successful completion of necessary training.

NMFS may approve PSOs as conditional or unconditional. A conditionally-approved PSO may be one who is trained but has not yet attained the requisite experience. An unconditionally-approved PSO is one who has attained the necessary experience. For unconditional approval, the PSO must have a minimum of 90 days at sea performing the role during a geophysical survey, with the conclusion of the most recent relevant experience not more than 18 months previous.

At least one of the visual PSOs aboard the vessel must be unconditionally-approved. One unconditionally-approved visual PSO shall be designated as the lead for the entire PSO team. This lead should typically be the PSO with the most experience, who would coordinate duty schedules and roles for the PSO team and serve as primary point of contact for the vessel operator. To the maximum extent practicable, the duty schedule shall be planned such that unconditionally-approved PSOs are on duty with conditionally-approved PSOs.

At least one PSO aboard each acoustic source vessel must have a minimum of 90 days at-sea experience working in the role, with no more than eighteen months elapsed since the conclusion of the at-sea experience. One PSO with such experience must be designated as the lead for the entire PSO team and serve as the primary point of contact for the vessel operator. (Note that the responsibility of coordinating duty schedules and roles may instead be assigned to a shore-based, third-party monitoring coordinator.) To the maximum extent practicable, the lead PSO must devise the duty schedule such that experienced PSOs are on duty with those PSOs with appropriate training but who have not yet gained relevant experience.

PSOs must successfully complete relevant training, including completion of all required coursework and passing (80 percent or greater) a written and/or oral examination developed for the training program.

PSOs must have successfully attained a bachelor's degree from an accredited college or university with a major in one of the natural sciences, a minimum of 30 semester hours or equivalent in the biological sciences, and at least one undergraduate course in math or statistics. The educational requirements may be waived if the PSO has acquired the relevant skills through alternate experience. Requests for such a waiver shall be submitted to NMFS and must include written justification. Alternate experience that may be considered includes, but is not limited to (1) secondary education and/or experience comparable to PSO duties; (2) previous work experience conducting academic, commercial, or government-sponsored marine mammal surveys; and (3) previous work experience as a PSO (PSO must be in good standing and demonstrate good performance of PSO duties).

TerraSond must work with the selected third-party PSO provider to ensure PSOs have all equipment (including backup equipment) needed to adequately perform necessary tasks, including accurate determination of distance and bearing to observed marine mammals, and to ensure that PSOs are capable of calibrating equipment as necessary for accurate distance estimates and species identification. Such equipment, at a minimum, shall include:

- At least one thermal (infrared) imagine device suited for the marine environment;
- Reticle binoculars (*e.g.,* 7 x 50) of appropriate quality (at least one per PSO, plus backups);
- Global Positioning Units (GPS) (at least one plus backups);
- Digital cameras with a telephoto lens that is at least 300-mm or equivalent on a full-frame single lens reflex (SLR) (at least one plus backups). The camera or lens should also have an image stabilization system;

- Compass (at least one plus backups);
- Means of communication among vessel crew and PSOs; and
- Any other tools deemed necessary to adequately and effectively perform PSO tasks.

The equipment specified above may be provided by an individual PSO, the third-party PSO provider, or the operator, but TerraSond is responsible for ensuring PSOs have the proper equipment required to perform the duties specified in the IHA.

The PSOs will be responsible for monitoring the waters surrounding the survey vessel to the farthest extent permitted by sighting conditions, including shutdown zones, during all HRG survey operations. PSOs will visually monitor and identify marine mammals, including those approaching or entering the established shutdown zones during survey activities. It will be the responsibility of the PSO(s) on duty to communicate the presence of marine mammals as well as to communicate the action(s) that are necessary to ensure mitigation and monitoring requirements are implemented as appropriate.

PSOs must be equipped with binoculars and have the ability to estimate distance and bearing to detect marine mammals, particularly in proximity to shutdown zones. Reticulated binoculars must also be available to PSOs for use as appropriate based on conditions and visibility to support the sighting and monitoring of marine mammals. During nighttime operations, night-vision goggles with thermal clip-ons and infrared technology must be available for use. Position data would be recorded using hand-held or vessel GPS units for each sighting.

During good conditions (*e.g.,* daylight hours; Beaufort sea state (BSS) 3 or less), to the maximum extent practicable, PSOs must also conduct observations when the acoustic source is not operating for comparison of sighting rates and behavior with and without use of the active acoustic sources and between acquisition periods. Any observations of marine mammals by crew members aboard the vessel associated with the survey would be relayed to the PSO team. Data on all PSO observations would be recorded based on standard PSO collection requirements (see *Proposed Reporting Measures*). This would include dates, times, and locations of survey operations; dates and times of observations, location and weather; details of marine mammal sightings (*e.g.,* species, numbers, behavior); and details of any observed marine mammal behavior that occurs (*e.g.,* noted behavioral disturbances). Members of the PSO team shall consult the NMFS NARW reporting system and Whale Alert, daily and as able, for the presence of NARWs throughout survey operations.

Proposed Reporting Measures

TerraSond shall submit a draft summary report to NMFS on all activities and monitoring results within 90 days of the completion of survey activities or expiration of the IHA, whichever comes sooner. The report must describe all activities conducted and sightings of marine mammals, must provide full documentation of methods, results, and interpretation pertaining to all monitoring, and must summarize the dates and locations of survey operations and all marine mammals sightings (dates, times, locations, activities, associated survey activities). The draft report shall also include geo-referenced, time-stamped vessel tracklines for all time periods during which acoustic sources were operating. Tracklines should include points recording any change in acoustic source status (*e.g.,* when the sources began operating, when they were turned off, or when they changed operational status such as from full array to single gun or vice versa). GIS files shall be provided in ESRI shapefile format and include the UTC date and time, latitude in decimal degrees, and longitude in decimal degrees. All coordinates shall be referenced to the WGS84 geographic coordinate system. In addition to the report, all raw observational data shall be made available. The report must summarize the information. A final report must be submitted within 30 days following resolution of any comments on the draft report. All draft and final marine mammal monitoring reports must be submitted to *PR.ITP.MonitoringReports@noaa.gov* and *nmfs.gar.incidental-take@noaa.gov.*

PSOs must use standardized electronic data forms to record data. PSOs shall record detailed information about any implementation of mitigation requirements, including the distance of marine mammal to the acoustic source and description of specific actions that ensued, the behavior of the animal(s), any observed changes in behavior before and after implementation of mitigation, and if shutdown was implemented, the length of time before any subsequent ramp-up of the acoustic source. If required mitigation was not implemented, PSOs should record a description of the circumstances. At a minimum, the following information must be recorded:

1. Vessel name (source vessel), vessel size and type, maximum speed capability of vessel;
2. PSO names and affiliations;
3. Dates of departures and returns to port with port name;
4. Date and participants of PSO briefings;
5. Visual monitoring equipment used;
6. PSO location on vessel and height of observation location above water surface;
7. Dates and times (Greenwich Mean Time) of survey on/off effort and times corresponding with PSO on/off effort;
8. Vessel location (latitude/longitude) when survey effort begins and ends, and vessel location at beginning and end of visual PSO duty shifts;
9. Vessel location at 30-second intervals if obtainable from data collection software, otherwise at practical regular interval;
10. Vessel heading and speed at beginning and end of visual PSO duty shifts and upon any line change;
11. Water depth (if obtainable from data collection software);
12. Environmental conditions while on visual survey (at beginning and end of PSO shift and whenever conditions change significantly), including wind speed and direction, Beaufort sea state, Beaufort wind force, swell height, weather conditions, cloud cover, sun glare, and overall visibility to the horizon;
13. Factors that may be contributing to impaired observations during each PSO shift change or as needed as environmental conditions change (*e.g.,* vessel traffic, equipment malfunctions); and
14. Survey activity information (and changes thereof), such as acoustic source power output while in operation, number and volume of airguns operating in an array, tow depth of an acoustic source, and any other notes of significance (*i.e.,* pre-start clearance, ramp-up, shutdown, testing, shooting, ramp-up completion, end of operations, streamers, etc.).

Upon visual observation of any marine mammal, the following information must be recorded:

1. Watch status (sighting made by PSO on/off effort, opportunistic, crew, alternate vessel/platform);
2. Vessel/survey activity at time of sighting (*e.g.,* deploying, recovering, testing, shooting, data acquisition, other);
3. PSO who sighted the animal;
4. Time of sighting;
5. Initial detection method;
6. Sightings cue;
7. Vessel location at time of sighting (decimal degrees);

8. Direction of vessel's travel (compass direction);

9. Speed of the vessel(s) from which the observation was made;

10. Identification of the animal (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified); also note the composition of the group if there is a mix of species;

11. Species reliability (an indicator of confidence in identification);

12. Estimated distance to the animal and method of estimating distance;

13. Estimated number of animals (high/low/best);

14. Estimated number of animals by cohort (adults, yearlings, juveniles, calves, group composition, etc.);

15. Description (as many distinguishing features as possible of each individual seen, including length, shape, color, pattern, scars or markings, shape and size of dorsal fin, shape of head, and blow characteristics);

16. Detailed behavior observations (*e.g.,* number of blows, number of surfaces, breaching, spyhopping, diving, feeding, traveling; as explicit and detailed as possible; note any observed changes in behavior before and after point of closest approach);

17. Mitigation actions; description of any actions implemented in response to the sighting (*e.g.,* delays, shutdowns, ramp-up, speed or course alteration, etc.) and time and location of the action;

18. Equipment operating during sighting;

19. Animal's closes point of approach and/or closest distance from the center point of the acoustic source; and

20. Description of any actions implemented in response to the sighting (*e.g.,* delays, shutdown, ramp-up) and time and location of the action.

If a NARW is observed at any time by PSOs or personnel on any project vessels, during surveys or during vessel transit, TerraSond must report sighting information to the NMFS North Atlantic Right Whale Sighting Advisory System (866–755–6622) within two hours of occurrence, when practicable, or no later than 24 hours after occurrence. NARW sightings in any location may also be reported to the U.S. Coast Guard via channel 16 and through the Whale Alert app (*www.whalealert.org*).

In the event that personnel involved in the survey activities discover an injured or dead marine mammal, the incident must be reported to NMFS as soon as feasible by phone (877–942–5343) and by email (*nmfs.gar.stranding@noaa.gov* and *PR.ITP.monitoringreports@noaa.gov*). The report must include the following information:

1. Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);

2. Species identification (if known) or description of the animal(s) involved;

3. Condition of the animal(s) (including carcass condition if the animal is dead);

4. Observed behaviors of the animal(s), if alive;

5. If available, photographs or video footage of the animal(s); and

6. General circumstances under which the animal was discovered.

In the event of a ship strike of a marine mammal by any vessel involved in the activities covered by the IHA, TerraSond must report the incident to the NMFS by phone (877–942–5343) and by email (*nmfs.gar.stranding@noaa.gov* and *PR.ITP.monitoringreports@noaa.gov*) as soon as feasible. The report would include the following information:

1. Time, date, and location (latitude/longitude) of the incident;

2. Species identification (if known) or description of the animal(s) involved;

3. Vessel's speed during and leading up to the incident;

4. Vessel's course/heading and what operations were being conducted (if applicable);

5. Status of all sound sources in use;

6. Description of avoidance measures/requirements that were in place at the time of the strike and what additional measures were taken, if any, to avoid strike;

7. Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, visibility) immediately preceding the strike;

8. Estimated size and length of animal that was struck;

9. Description of the behavior of the marine mammal immediately preceding and following the strike;

10. If available, description of the presence and behavior of any other marine mammals immediately preceding the strike;

11. Estimated fate of the animal (*e.g.,* dead, injured but alive, injured and moving, blood or tissue observed in the water, status unknown, disappeared); and

12. To the extent practicable, photographs or video footage of the animal(s).

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.,* intensity, duration), the context of any impacts or responses (*e.g.,* critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the majority of our analysis applies to all the species listed in Table 3, given that many of the anticipated effects of this activity on different marine mammal stocks are expected to be relatively similar in nature. Where there are meaningful differences between species or stocks, as in the case of the NARW, they are included as separate sub-sections below. NMFS does not anticipate that serious injury or mortality would occur as a result from HRG surveys, even in the absence of mitigation, and no serious injury or mortality is proposed to be authorized. As discussed in the Potential Effects of Specified Activities on Marine Mammals and Their Habitat section, non-auditory physical effects, auditory physical effects, and vessel strike are not expected to occur. NMFS expects that all potential Level B harassment takes would be in the form of temporary avoidance of the area or decreased foraging (if such activity was occurring), reactions that are considered to be of low severity and with no lasting biological consequences (*e.g.,* Southall *et al.,* 2007; Ellison *et al.,* 2012). Even repeated Level B harassment of some small subset of an overall stock is unlikely to result in any significant

realized decrease in viability for the affected individuals, and thus would not result in any adverse impact to the stock as a whole. As described above, Level A harassment is not expected to occur, even absent mitigation, given the nature of the operations and the estimated size of the Level A harassment zones. In addition to being temporary, the ensonified area surrounding the acoustic source is relatively small, with a behavioral harassment zone radius of 141 m associated with the sparker, as compared to the overall distribution of the animals in the area and their use of the habitat.

North Atlantic Right Whales

The status of the NARW population is of heightened concern and, therefore, merits additional analysis. As noted previously, elevated NARW mortalities began in June 2017 and there is currently an active UME. Overall, preliminary findings support human interactions, specifically vessel strikes and entanglements, as the cause of death for the majority of NARWs.

As mentioned earlier, the proposed survey area is within the NARW migratory BIA (November 1–April 30), which extends from Massachusetts to Florida, from the coast to beyond the shelf break. (LaBrecque *et al.,* 2015). This BIA is extensive and sufficiently large (approximately 269,448 km^2), and the acoustic footprint of the proposed survey is sufficiently small (445.4 km^2) that NARW migration would not be impacted by the proposed survey. If NARWs are temporarily displaced, they are expected to be able to resume their migration activities after moving away from areas with disturbing levels of noise. Required vessel strike avoidance measures in addition to the slow survey speed of the vessel (approximately 1.8 m/s or 3.5 knots) would also decrease risk of ship strike during migration such that no ship strike is expected to occur during TerraSond's proposed activities. Additionally, TerraSond would be required to adhere to a 10-knot speed restriction in an active SMA, and any DMA(s), should NMFS establish one (or more) in the proposed survey area.

A small portion of the northwest corner of the proposed survey area overlaps with the NARW reproduction BIA and the Wilmington, NC to Brunswick, GA SMA (November 1 through April). The reproductive BIA is large in size (43,783 km^2) in comparison to the acoustic footprint of the proposed survey (454.4 km^2), thus reproductive opportunities would not be reduced appreciably. In addition, TerraSond would adhere to the 10-knot speed restriction within the boundaries of the SMA. Due to the temporary nature of the disturbance and the availability of similar habitat and resources in the surrounding area, the impacts to NARWs are not expected to cause significant or long-term consequences for individuals of the population. Furthermore, the 500-m shutdown zone for NARWs is conservative (considering the distance to the Level B harassment isopleth for the acoustic source is estimated to be 141 m), and thereby minimizes the potential for behavioral harassment of this species.

Again, Level A harassment is not expected due to the small PTS zones associated with HRG equipment type proposed for use. The proposed behavioral harassment takes of NARW are not expected to exacerbate or compound upon the ongoing UME. The limited NARW behavioral harassment takes proposed for authorization are expected to be of a short duration, and given the number of estimated takes, repeated exposures of the same individual are not expected. As stated previously, it is unlikely that NARW migration or reproduction would be adversely affected given the relatively small size of the ensonified area during TerraSond's proposed survey activities as well as the small degree of overlap between the proposed survey area and NARW reproduction BIA. Accordingly, NMFS does not anticipate potential take of NARWs that would result from TerraSond's proposed activities would impact annual rates of recruitment or survival nor result in population level impacts.

Other Marine Mammal Species With Active UMEs

As noted above, there are several active UMEs occurring in the vicinity of TerraSond's proposed survey area. Elevated humpback whale mortalities have occurred along the Atlantic coast from Maine through Florida since January 2016. Of the cases examined, approximately half had evidence of human interaction (ship strike or entanglement). The UME does not yet provide cause for concern regarding population-level impacts. Despite the UME, the relevant population of humpback whales (the West Indies breeding population, or DPS) remains stable at approximately 12,000 individuals (Hayes *et al.,* 2022).

As mentioned earlier, a UME has been declared for Northeast pinnipeds (including harbor seals and gray seals). However, we do not expect takes that may be authorized to exacerbate the ongoing UME. No injury, serious injury, or mortality is expected or will be authorized, and Level B harassment of humpback whales, harbor seals, and gray seals will be reduced through the incorporation of the required mitigation measures. For the Western North Atlantic stock of harbor seals, the estimated abundance is 61,336 individuals, and the annual M/SI (339) for harbor seals is well below PBR (1,729) (Hayes *et al.,* 2022). The estimated stock abundance for the U.S. portion of the Western North Atlantic gray seal stock is 27,300 animals, and the abundance of gray seals is likely increasing in both the U.S. Atlantic as well as in Canada (Hayes *et al.,* 2022). Given that only two takes by Level B harassment may be authorized for each of these stocks, we do not expect these proposed takes to compound upon the ongoing UME.

The required mitigation measures are expected to reduce the number and/or severity of proposed takes for all species listed in Table 3, including those with active UMEs, to the level of least practicable adverse impact. In particular, ramp-up procedures would provide animals in the vicinity of the survey vessel the opportunity to move away from the sound source before HRG survey equipment reaches full energy, thus preventing them from being exposed to sound levels that have the potential to cause injury (Level A harassment) or more severe type of Level B harassment. As discussed previously, take by Level A harassment (injury) is considered unlikely, even absent mitigation, based on the characteristics of the signals produced by the acoustic source planned for use. Implementation of the required mitigation would further reduce this potential. Therefore, NMFS is not proposing any Level A harassment for authorization.

NMFS expects that takes would be in the form of short-term behavioral harassment by way of temporary vacating of the area, or decreased foraging (if such activity was occurring)—reactions that (at the scale and intensity anticipated here) are considered to be of low severity, with no lasting biological consequences. Since both the sources and marine mammals are mobile, animals would only be exposed briefly to a small ensonified area that might result in take. Additionally, required mitigation measures would further reduce exposure to sound that could result in more severe behavioral harassment.

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect any of

the species or stocks through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated or authorized;
- No Level A harassment (PTS) is anticipated, even in the absence of mitigation measures, or proposed for authorization;
- Any displacement or avoidance of the survey area is expected to be short-term and unlikely to cause significant impacts to any populations;
- Impacts on marine mammal habitat are expected to be minimal, and alternate areas of similar habitat value are readily available;
- Take is anticipated to be by Level B harassment only, consisting of brief startling reactions and/or temporary avoidance of the survey area;
- Survey activities would occur in such a comparatively small portion of the BIA for the NARW migration, including a small portion of the reproduction BIA and SMA, that any avoidance of the area due to survey activities would not affect migration or reproduction. In addition, the mitigation measure to shut down at 500 m to minimize potential for Level B harassment would limit both the number and severity of take of the species.
- Proposed mitigation measures, including visual monitoring and shutdowns, are expected to minimize the intensity of potential impacts to marine mammals.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted previously, only take of small numbers of marine mammals may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

NMFS proposes to authorize incidental take (by Level B harassment only) of 18 marine mammal species (with 19 managed stocks). The total amount of takes proposed for authorization relative to the best available population abundance is less than 20 percent for all stocks, less than 15 percent for 18 stocks, and less than 2 percent for 17 stocks. Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals would be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

NMFS Office of Protected Resources is proposing to authorize take of four species of marine mammals which are listed under the ESA, including the NARW, humpback whale, fin whale, and sperm whale, and has determined that this activity falls within the scope of activities analyzed in NMFS GARFO's programmatic consultation regarding geophysical surveys along the U.S. Atlantic coast in the three Atlantic Renewable Energy Regions (completed June 29, 2021; revised September 2021).

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to TerraSond for conducting marine site characterization surveys in federal waters offshore of North Carolina and South Carolina in the BOEM Lease Areas OCS–A 0545 and 0546 from February 1, 2023 to January 31, 2024, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable.*

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this notice of the proposed IHA. We also request comment on the potential renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent renewal IHA.

On a case-by-case basis, NMFS may issue a one-time, one-year renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical or nearly identical activities as described in the Description of Proposed Activities section of this notice is planned or (2) the activities as described in the Description of Proposed Activities section of this notice would not be completed by the time the IHA expires and a renewal would allow for completion of the activities beyond that described in the *Dates and Duration* section of this notice, provided all of the following conditions are met:

- A request for renewal is received no later than 60 days prior to the needed renewal IHA effective date (recognizing that the renewal IHA expiration date cannot extend beyond one year from expiration of the initial IHA); and
- The request for renewal must include the following:

(1) An explanation that the activities to be conducted under the requested renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take); and

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation

showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

Dated: December 16, 2022.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–27722 Filed 12–20–22; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC528]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to National Oceanic and Atmospheric Administration Office of Marine and Aviation Operations Research Vessel Relocation at Naval Station Newport, Rhode Island

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

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to NOAA Office of Marine Aviation Operations (OMAO) to incidentally harass, by Level A and Level B harassment, marine mammals during construction activities associated with vessel relocation at Naval Station Newport (NAVSTA) in Newport, Rhode Island.

DATES: This authorization is effective from February 1, 2024 to January 31, 2025.

FOR FURTHER INFORMATION CONTACT: Jessica Taylor, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed incidental harassment authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

Summary of Request

On May 6, 2022, NMFS received a request from the U.S. Navy on behalf of OMAO for an IHA to take marine mammals incidental to construction activities associated with the relocation of NOAA research vessels to the Naval Station Newport in Rhode Island. NMFS reviewed the Navy's application and the Navy provided a revised application on July 14, 2022. The application was deemed adequate and complete on October 5, 2022. OMAO's request is for take of 7 species of marine mammals, by Level B harassment and, for a subset of these species, Level A harassment. Neither OMAO nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate. OMAO plans to commence in-water construction activities on February 1, 2024 yet has requested the IHA in advance due to OMAO's NEPA requirements.

Description of Activity

OMAO plans to establish adequate pier, shore side, and support facilities for four NOAA research vessels in Coddington Cove at Naval Station (NAVSTA) Newport in Newport, Rhode Island. As part of the activity, a new pier, trestle, small boat floating dock, and bulkhead will be constructed in Coddington Cove in order to meet NOAA docking/berthing requirements for these four vessels. These construction activities will involve the use of impact and vibratory pile driving, vibratory pile extraction, rotary drilling, and down-the-hole (DTH) mono-hammer excavation events, which have the potential to take marine mammals, by Level A and Level B harassment. The project will also include shore side administrative, warehouse, and other support facilities.

Construction activities will last for approximately one year from February 1, 2024 to January 31, 2025 of which in-water work will take place over 343 non-consecutive days. OMAO anticipates that all work will be limited to daylight hours. Specific construction activities may occur concurrently over a period of approximately 138 days. A detailed description of the planned construction project is provided in the **Federal Register** notice for the proposed IHA (87 FR 66133, November 2, 2022). Since that time, no changes have been made to the planned activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specific activity. Mitigation, monitoring, and reporting measures are described in detail later in this document (please see Mitigation and Monitoring and Reporting).

Comments and Responses

A notice of NMFS' proposal to issue an IHA to OMAO was published in the **Federal Register** on November 2, 2022 (87 FR 66133). That notice described, in detail, OMAO's activity, the marine mammal species that may be affected by the activity, and the anticipated effects on marine mammals. During the 30-day public comment period, no public comments were received.

Changes From the Proposed to Final IHA

Two changes were made between publication of the proposed IHA and this final IHA. The Level B harassment

zone for the vibratory extraction of 12″ timber guide piles while demolishing the floating dock was changed from 3,500 m to 1,359 m. The original calculated distance of 3,500 m was an error. However, PSOs will monitor as far as they can see.

In addition, the final IHA requires OMAO to wait 15 minutes before commencing pile driving activity after a shutdown, rather than 30 minutes as stated in the proposed IHA. This change is consistent with monitoring methods for prior projects consisting of similar construction activities at NAVSTA Newport, RI (86 FR 71162, December 15, 2021) and other locations (87 FR 7128, February 2, 2022; 87 FR 19886, April 6, 2022).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, referenced here, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS' website (*https://www.fisheries.noaa.gov/find-species*.)

Table 1 lists all species or stocks for which take is authorized for these activities, and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no serious injury or mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' U.S. Atlantic and Gulf of Mexico SARs (*e.g.,* Hayes *et al.,* 2022). All values presented in Table 1 are the most recent available at the time of publication (available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports*).

TABLE 1—MARINE MAMMAL SPECIES [1] LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) [2]	Stock abundance (CV, N_{min}, most recent abundance survey) [3]	PBR	Annual M/SI [4]
Order Artiodactyla—Infraorder Cetacea—Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae:						
Atlantic white-sided dolphins.	*Lagenorhynchus acutus*	Western North Atlantic	-, -, N	93,233 (0.71, 54,443, 2016)	544	27
Common dolphins	*Delphinus delphis*	Western North Atlantic	-, -, N	172,974 (0.21, 145,216, 2016)	1,452	390
Family Phocoenidae (porpoises):						
Harbor Porpoise	*Phocoena phocoena*	Gulf of Maine/Bay of Fundy	-, -, N	95,543 (0.31, 74,034, 2016)	851	164
Order Carnivora—Pinnipedia						
Family Phocidae (earless seals):						
Harbor Seal	*Phoca vitulina*	Western North Atlantic	-, -, N	61,336 (0.08, 57,637, 2018)	1,729	339
Gray Seal	*Halichoerus grypus*	Western North Atlantic	-, -, N	27,300 (0.22, 22,785, 2016)	1,389	4,453
Harp Seal	*Pagophilus groenlandicus*	Western North Atlantic	-, -, N	7.6 M (UNK, 7.1, 2019)	426,000	178,573
Hooded Seal	*Cystophora cristata*	Western North Atlantic	-, -, N	593,500 (UNK, UNK, 2005)	UNK	1,680

[1] Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (*https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies/;* Committee on Taxonomy (2022)).

[2] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[3] NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments/.* CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance.

[4] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

As indicated above, all seven species (with seven managed stocks) in Table 2 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur. While several species of whales have been documented seasonally in New England waters, the spatial occurrence of these species is such that take is not expected to occur, and they are not discussed further beyond the explanation provided here. The humpback (*Megaptera novaeangliae*), fin (*Balaenoptera physalus*), sei (*Balaenoptera borealis*), sperm (*Physeter macrocephalus*) and North Atlantic right whales (*Eubaleana glacialis*) occur seasonally in the Atlantic Ocean, offshore of Rhode Island. However, due to the depths of Narragansett Bay and near shore location of the project area, these marine mammals are unlikely to occur in the project area. Therefore,

OMAO did not request, and NMFS is not authorizing takes of these species.

A detailed description of the species to be affected by OMAO's construction activities, including brief introductions to the species and relevant stocks as well as available information regarding population trends and threats, and information regarding local occurrence, were provided in the **Federal Register** notice for the proposed IHA (87 FR 66133, November 2, 2022); since that time, we are not aware of any changes in the status of these species and stocks; therefore, detailed descriptions are not provided here. Please refer to that **Federal Register** notice for these descriptions. Please also refer to the NMFS' website (*https://www.fisheries.noaa.gov/find-species*) for generalized species accounts.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, etc.). Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 2.

TABLE 2—MARINE MAMMAL HEARING GROUPS

[NMFS, 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, Cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.,* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

The effects of underwater noise from OMAO's activities have the potential to result in Level A and Level B harassment of marine mammals in the action area. The notice of the proposed IHA (87 FR 66133, November 2, 2022) included a discussion of the effects of anthropogenic noise on marine mammals and the potential effects of underwater noise from OMAO's construction activities on marine mammals and their habitat. That information and analysis is referenced in this final IHA determination and is not repeated here; please refer to the notice of the proposed IHA (87 FR 66133, November 2, 2022).

Estimated Take

This section provides an estimate of the number of incidental takes authorized through this IHA, which will inform both NMFS' consideration of ''small numbers'' and the negligible impact determinations.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes will primarily be by Level B harassment, as use of the acoustic sources (*i.e.,* pile driving and removal, DTH, and rotary drilling) has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (Level A harassment) to result, primarily for high frequency species and phocids because predicted auditory injury zones are larger than for mid-frequency species. Auditory injury is unlikely to occur for mid-frequency species. The mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable.

As described previously, no serious injury or mortality is authorized for this activity. Below we describe how the authorized take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential

takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the authorized take estimates.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment). Thresholds have also been developed identifying the received level of in-air sound above which exposed pinnipeds would likely be behaviorally harassed.

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.,* frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (*e.g.,* bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (*e.g.,* Southall *et al.,* 2007, 2021, Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 120 dB (referenced to 1 micropascal (re 1 μPa)) for continuous (*e.g.,* vibratory pile-driving, drilling) and above RMS SPL 160 dB re 1 μPa for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources. Generally speaking, Level B harassment take estimates based on these behavioral harassment thresholds are expected to include any likely takes by TTS as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

OMAO's activities includes the use of continuous (vibratory hammer/rotary drill/DTH mono-hammer) and impulsive (impact hammer/DTH mono-hammer) sources, and therefore the RMS SPL thresholds of 120 and 160 dB re 1 μPa are applicable.

Level A harassment—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). OMAO's activity includes the use of impulsive (impact hammer/DTH mono-hammer) and non-impulsive (vibratory hammer/rotary drill/DTH mono-hammer) sources.

These thresholds are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS' 2018 Technical Guidance, which may be accessed at: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 3—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing group	PTS onset thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{p,0\text{-}pk,flat}$: 219 dB; $L_{E,p,\ LF,24h}$: 183 dB	*Cell 2:* $L_{E,p,\ LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	*Cell 3:* $L_{p,0\text{-}pk,flat}$: 230 dB; $L_{E,p,\ MF,24h}$: 185 dB	*Cell 4:* $L_{E,p,\ MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	*Cell 5:* $L_{p,0\text{-}pk,flat}$: 202 dB; $L_{E,p,\ HF,24h}$: 155 dB	*Cell 6:* $L_{E,p,\ HF,24h}$: 173 dB.
Phocid Pinnipeds (PW)(Underwater)	*Cell 7:* $L_{p,0\text{-}pk.flat}$: 218 dB; $L_{E,p,\ PW,24h}$: 185 dB	*Cell 8:* $L_{E,p,\ PW,24h}$: 201 dB.
Otariid Pinnipeds (OW)(Underwater)	*Cell 9:* $L_{p,0\text{-}pk,flat}$: 232 dB; $L_{E,p,\ OW,24h}$: 203 dB.	*Cell 10:* $L_{E,p,\ OW,24h}$: 219 dB.

* Dual metric thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds are recommended for consideration.

Note: Peak sound pressure level ($L_{p,0\text{-}pk}$) has a reference value of 1 μPa, and weighted cumulative sound exposure level ($L_{E,p}$) has a reference value of 1μPa^2s. In this Table, thresholds are abbreviated to be more reflective of International Organization for Standardization standards (ISO 2017). The subscript "flat" is being included to indicate peak sound pressure are flat weighted or unweighted within the generalized hearing range of marine mammals (*i.e.,* 7 Hz to 160 kHz). The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The weighted cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional construction noise from the project. Marine mammals are expected to be affected via sound generated by the primary components of the project (*i.e.,* impact pile driving, vibratory pile driving, vibratory pile removal, rotary drilling, and DTH).

The intensity of underwater sound is greatly influenced by factors, such as the size and type of piles, type of driver or drill, and the physical environment in which the activity takes place. In order to calculate distances to the Level A harassment and Level B harassment thresholds for the methods and piles being used in this project, NMFS used representative source levels (Table 4)

from acoustic monitoring at other locations.

TABLE 4—SOURCE LEVELS FOR CONSTRUCTION ACTIVITIES

Method	Pile type	Pile diameter	Peak (dB re 1 μPa)	RMS (dB re 1 μPa)	SEL (dB re 1 μPa 2-sec sec)	Reference
Vibratory Extraction	Steel pipe [1]	12″	171	155	155	Caltrans 2020, Table 1.2–1d.
	Timber	12″	NA	152	NA	NMFS 2021a, Table 4.
Vibratory Installation	Steel pipe	18″	NA	[2] 162	162	NAVFAC Mid-Atlantic 2019, Table 6–4.
	Sheet pile	Z26–700 [3]	NA	156	NA	Navy 2015.
	Steel pipe	30″	NA	167	167	Navy 2015, p.14.
	Casing/shaft for steel pipe	36″	NA	175	175	NAVFAC Mid-Atlantic 2019, Table 6–4.
DTH Mono-hammer	Steel pipe	18″	172	167	146	Egger, 2021; Guan and Miner 2020; Heyvaert and Reyff, 2021.
	Casing/shaft for steel pipe	36″ [4]	194	167	164	Reyff and Heyvaert 2019; Reyff 2020; and Denes *et al.* 2019.
Rotary Drilling	Steel pipe	18″ and 30″	NA	154	NA	Dazey *et al.* 2012.
Impact Install	Steel pipe [5]	18″	208	187	176	Caltrans 2020, Table 1.2–1a.
	Steel pipe	30″	211	196	181	NAVFAC Southwest 2020, p.A–4.
Vibratory Installation/Extraction.	Steel pipe	16″	NA	162	162	NAVFAC Mid-Atlantic 2019, Table 6–4.

[1] 13-inch steel pipe used as proxy because data were not available for vibratory install/extract of 12-inch steel pipe.
[2] Although conservative, this 162 dB RMS is consistent with source level value used for 18-inch steel pipe in for Dry Dock 1 at Portsmouth Naval Shipyard (84 FR 13252, April 4, 2019).
[3] 30-inch steel pipe pile used as the proxy source for vibratory driving of steel sheet piles because data were not available for Z26–700 (Navy 2015 [p. 14]).
[4] Guidance from NMFS states: For each metric, select the highest SL provided among these listed references (Reyff and Heyvaert, 2019); (Reyff J., 2020); (Denes *et al.,* 2019).
[5] Impact install of 20-inch steel pipe used as proxy because data were not available for 18-inch.
Notes: All SPLs are unattenuated; dB = decibels; NA = Not applicable/Not available; RMS = root mean square; SEL = sound exposure level; Caltrans = California Department of Transportation; NAVFAC = Naval Facilities Engineering Systems Command; dB re 1 μPa = dB referenced to a pressure of 1 microPascal, measures underwater SPL. dB re 1 μPa2-sec = dB referenced to a pressure of 1 microPascal squared per second, measures underwater SEL. Single strike SEL are the proxy source levels presented for impact pile driving and were used to calculate distances to PTS. All data referenced at 10 meters.

NMFS recommends treating DTH systems as both impulsive and continuous, non-impulsive sound source types simultaneously. Thus, impulsive thresholds are used to evaluate Level A harassment, and continuous thresholds are used to evaluate Level B harassment. With regards to DTH mono-hammers, NMFS recommends proxy levels for Level A harassment based on available data regarding DTH systems of similar sized piles and holes (Denes *et al.,* 2019; Guan and Miner, 2020; Reyff and Heyvaert, 2019; Reyff, 2020; Heyvaert and Reyff, 2021) (Table 1 in the **Federal Register** notice for the proposed IHA (87 FR 66133, November 2, 2022) includes number of piles and duration; Table 4 includes sound pressure levels for each pile type). At the time of the Navy's application submission, NMFS recommended a proxy RMS sound pressure level at 10 m of 167 dB when evaluating Level B harassment (Heyvaert and Reyff, 2021) for all DTH pile/hole sizes. However, since that time, NMFS has received additional clarifying information regarding DTH data presented in Reyff and Heyvaert (2019) and Reyff (2020) that allows NMFS to recommend different RMS sound pressure levels at 10 m for piles/holes of varying diameters. Therefore, NMFS proposes to use the following proxy RMS sound pressure levels at 10 m to evaluate Level B harassment from this sound source in this analysis (Table 5): 167 dB RMS for the 18 inch steel pipe piles (Heyvaert and Reyff, 2021) and 174 dB RMS for the 36 inch steel shafts (Reyff and Heyvaert, 2019; Reyff, 2020).

Level B Harassment Zones

Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater TL is:

$$TL = B * \log_{10} (R_1/R_2),$$

Where
TL = transmission loss in dB
B = transmission loss coefficient; for practical spreading equals 15
R_1 = the distance of the modeled SPL from the driven pile, and
R_2 = the distance from the driven pile of the initial measurement.

The recommended TL coefficient for most nearshore environments is the practical spreading value of 15. This value results in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions, known as practical spreading. As is common practice in coastal waters, here we assume practical spreading (4.5 dB reduction in sound level for each doubling of distance). Practical spreading was used to determine sound propagation for this project.

The TL model described above was used to calculate the expected noise propagation from vibratory pile driving/extracting, impact pile driving, rotary drilling, and DTH mono-hammer excavation using representative source levels to estimate the harassment zones or area exceeding the noise criteria. Utilizing the described practical spreading model, NMFS calculated the Level B isopleths shown in Tables 5 and 6. The largest calculated Level B isopleth, with the exception of concurrent activities, discussed below, is 46,416 m for the vibratory installation of the 36″ steel casing/shaft guide piles with rock socket to build the small boat floating dock; however, this distance is truncated by shoreline in all directions, so sound will not reach the full distance of the calculated Level B harassment isopleth. This activity will generate a maximum ensonified area of 3.31 km^2 (Table 6). The maximum ensonified area of 8.53 km^2 is generated by the vibratory installation of the 16″ steel pipe pile, 18″ steel pipe pile, and 30″ steel pipe

pile as well as the vibratory installation/extraction of the 16″ steel pipe template piles. This area represents the maximum area after which distances are truncated.

Level A Harassment Zones

The ensonified area associated with Level A harassment is technically more challenging to predict due to the need to account for a duration component. Therefore, NMFS developed an optional User Spreadsheet tool to accompany the Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal density or occurrence to help predict potential takes. We note that because of some of the assumptions included in the methods underlying this optional tool, we anticipate that the resulting isopleth estimates are typically going to be overestimates of some degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources such as pile driving, the optional User Spreadsheet tool predicts the distance at which, if a marine mammal remained at that distance for the duration of the activity, it would be expected to incur PTS. Inputs used in the optional User Spreadsheet tool are reported in Table 1 of the **Federal Register** notice announcing the proposed IHA (87 FR 66133, November 2, 2022) (number piles/day and duration to drive a single pile) and Table 4 (source levels/distance to source levels). The resulting estimated isopleths are reported below in Tables 5 and 6. The largest Level A isopleth will be generated by the impact driving of the 30″ steel pipe pile at the pier for high-frequency cetaceans (3,500.3 m; Table 5). This activity will have a maximum ensonified area of 6.49 km^2 (Table 5).

TABLE 5—MAXIMUM DISTANCES TO LEVEL A HARASSMENT AND LEVEL B HARASSMENT THRESHOLDS FOR IMPULSIVE SOUND

[Impact hammer and DTH mono-hammer]

Structure	Pile size and type	Activity	Level A (PTS onset) harassment			Level B harassment
			Maximum distance to 185 dB SELcum threshold(m)/ area of harassment zone (km^2)	Maximum distance to 155 dB SELcum threshold(m)/ area of harassment zone (km^2)	Maximum distance to 185 dB SELcum threshold(m)/ area of harassment zone (km^2)	Maximum distance 160 dB RMS SPL (120 dB DTH) threshold (m)/ area of harassment zone (km^2)
			MF cetacean	HF cetacean	Phocid	All marine mammals
Bulkhead construction (Combination Pipe/Z-pile).	18″ steel pipe	Impact Install	48.5/0.0037	1,624.7/0.66	729.9/0.21	631/0.16
		DTH Mono-Hammer	4.6/0.000033	154.2/0.028	69.3/0.0075	13,594/3.31
Trestle (Bents 1–18)	18″ steel pipe	Impact Install	25.2/0.0020	844.9/1.21	379.6/0.38	631/0.82
Trestle (Bent 19)	30″ steel pipe	Impact Install	65.8/0.014	2,205.0/3.72	990.7/1.47	2,512/4.44
Pier	30″ steel pipe	Impact Install	104.5/0.034	3,500.3/6.49	1,572.6/2.50	2,512/4.44
Gangway support piles (small boat floating dock).	18″ steel pipe	Impact Install	19.3/0.00058	644.8/0.17	289.7/0.049	631/0.16
Small Boat Floating Dock	36″ Steel Casing/Shaft with Rock Socket (Guide Pile).	Impact Install	35.5/0.002	1,189.5/0.45	534.4/0.12	3,415/2.14
		DTH Mono-Hammer	73/0.0084	2,444.5/1.21	1,098.2/0.42	13,594/3.31

Notes: dB = decibel; DTH = down-the-hole; dB RMS SPL = decibel root mean square sound pressure level; dB SELcum = cumulative sound exposure level; m = meter; PTS = Permanent Threshold Shift; km^2 = square kilometer.

TABLE 6—MAXIMUM DISTANCES TO LEVEL A HARASSMENT AND LEVEL B HARASSMENT THRESHOLDS FOR CONTINUOUS

[Vibratory hammer/rotary drill]

Structure	Pile size and type	Activity	Level A (PTS onset) harassment			Level B harassment
			Maximum distance to 198 dB SELcum threshold(m)/ area of harassment zone (km^2)	Maximum distance to 173 dB SELcum threshold(m)/ area of harassment zone (km^2)	Maximum distance to 201 dB SELcum threshold(m)/ area of harassment zone (km^2)	Maximum distance 120 dB RMS SPL threshold(m)/ area of harassment zone (km^2)
			MF cetacean	HF cetacean	Phocid	All marine mammals
Abandoned guide piles along bulkhead.	12″ steel pipe	Vibratory Extract	0.3/0	5.3/0.000044	2.2/0.000008	2,514/1.26
Floating dock demolition (Timber Guide Piles).	12″ timber	Vibratory Extract	0.2/0	4/0.000025	1.7/0.000005	1,359/0.53
Bulkhead construction (Combination Pipe/Z-pile).	18″ steel pipe	Vibratory Install	1.8/0.000005	29.7/0.0014	12.2/0.00023	6,310/3.31
	Steel sheet Z26–700	Vibratory Install	0.7/0.000001	11.8/0.00022	4.9/0.000038	2,512/1.26
	16″ steel pipe template piles.	Vibratory Install/Extract	1.1/0.000002	18.7/0.00055	7.7/0.000093	6,310/3.31
Trestle (Bents 1–18)	18″ steel pipe	Vibratory Install	0.7/0.000002	11.8/0.00044	4.8/0.000072	6,310/8.53
	18″ steel pipe hole	Rotary Drill	0.0/0	0.6/0.000001	0.4/0.000001	1,848/2.98
	16″ steel pipe template piles.	Vibratory Install/Extract	1.1/0.000004	18.7/0.0011	7.7/0.00019	6,310/8.53
Trestle (Bent 19)	30″ steel pipe	Vibratory Install	2.0/0.000013	33.2/0.0034	13.7/0.00059	13,594/8.53

TABLE 6—MAXIMUM DISTANCES TO LEVEL A HARASSMENT AND LEVEL B HARASSMENT THRESHOLDS FOR CONTINUOUS—Continued

[Vibratory hammer/rotary drill]

Structure	Pile size and type	Activity	Level A (PTS onset) harassment			Level B harassment
			Maximum distance to 198 dB SELcum threshold(m)/ area of harassment zone (km^2)	Maximum distance to 173 dB SELcum threshold(m)/ area of harassment zone (km^2)	Maximum distance to 201 dB SELcum threshold(m)/ area of harassment zone (km^2)	Maximum distance 120 dB RMS SPL threshold(m)/ area of harassment zone (km^2)
			MF cetacean	HF cetacean	Phocid	All marine mammals
	16″ steel pipe template piles.	Vibratory Install/Extract	1.1/0.000004	18.7/0.0011	7.7/0.00019	6,310/8.53
Pier	30″ steel pipe	Vibratory Install	3.2/0.000032	52.8/0.0087	21.7/0.0015	13,594/8.53
	30″ hole	Rotary Drill	0.0/0	0.6/0.000001	0.4/0.000001	1,848/2.98
	16″ steel pipe template piles.	Vibratory Install/Extract	1.1/0.000004	18.7/0.0011	7.7/0.00019	6,310/8.53
Fender Piles	16″ steel pipe	Vibratory Install	0.9/0.000003	14.3/0.00064	5.9/0.00011	6,310/8.53
	16″ steel pipe template piles.	Vibratory Install/Extract	1.1/0.000004	18.7/0.0011	7.7/0.00019	6,310/8.53
Gangway support piles (small boat floating dock).	18″ steel pipe	Vibratory Install	0.7/0.000001	11.8/0.00022	4.8/0.000036	6,310/3.31
Small Boat Floating Dock	36″ Steel Casing/Shaft Guide Piles with Rock Socket.	Vibratory Install	5.2/0.000042	86.6/0.012	35.6/0.002	46,416/3.31
	16″ steel pipe template piles.	Vibratory Install/Extract	1.1/0.000002	18.7/0.00055	7.7/0.000093	6,310/3.31

Notes: dB = decibel; dB RMS SPL = decibel root mean square sound pressure level; dB SELcum = cumulative sound exposure level; m = meter; PTS = Permanent Threshold Shift; km^2 = square kilometer.

Concurrent Activities

Simultaneous use of two or three impact, vibratory, or DTH hammers, or rotary drills, could occur (potential combinations described in Table 1 of the **Federal Register** notice announcing the proposed IHA; 87 FR 66133, November 2, 2022) and may result in increased sound source levels and harassment zone sizes, given the proximity of the structure sites and the rules of decibel addition (Table 7).

NMFS (2018b) handles overlapping sound fields created by the use of more than one hammer differently for impulsive (impact hammer and Level A harassment zones for drilling with a DTH hammer) and continuous sound sources (vibratory hammer, rotary drill, and Level B harassment zones for drilling with a DTH hammer (Table 7) and differently for impulsive sources with rapid impulse rates of multiple strikes per second (DTH) and slow impulse rates (impact hammering) (NMFS, 2021c). It is unlikely that the two impact hammers will strike at the same instant, and therefore, the SPLs will not be adjusted regardless of the distance between impact hammers. In this case, each impact hammer will be considered to have its own independent Level A harassment and Level B harassment zones.

When two DTH hammers operate simultaneously their continuous sound components overlap completely in time. When the Level B isopleth of one DTH sound source encompasses the isopleth of another DTH sound source, the sources are considered additive and combined using the rules for combining sound source levels generated during pile installation, described in Table 7.

TABLE 7—RULES FOR COMBINING SOUND SOURCE LEVELS GENERATED DURING PILE INSTALLATION

Hammer types	Difference in SSL	Level A zones	Level B zones
Vibratory, Impact	Any	Use impact zones	Use largest zone.
Impact, Impact	Any	Use zones for each pile size and number of strikes.	Use zone for each pile size.
Vibratory, Vibratory Rotary drill, or DTH, DTH.	0 or 1 dB	Add 3 dB to the higher source level	Add 3 dB to the higher source level.
	2 or 3 dB	Add 2 dB to the higher source level	Add 2 dB to the higher source level.
	4 to 9 dB	Add 1 dB to the higher source level	Add 1 dB to the higher source level.
	10 dB or more	Add 0 dB to the higher source level	Add 0 dB to the higher source level.

Note: The method is based on a method created by Washington State Department of Transportation (WSDOT 2020) and has been updated and modified by NMFS.

When two continuous noise sources have overlapping sound fields, there is potential for higher sound levels than for non-overlapping sources. When two or more continuous noise sources are used simultaneously, and the isopleth of one sound source encompasses the isopleth of another sound source, the sources are considered additive and source levels are combined using the rules of decibel addition (Table 8; NMFS, 2021c).

For simultaneous use of three or more continuous sound sources, NMFS first identifies the three overlapping sources with the highest sound source level. Then, using the rules for combining sound source levels generated during

pile installation (Table 8), NMFS determines the difference between the lower two source levels, and adds the appropriate number of decibels to the higher source level of the two. Then, NMFS calculates the difference between the newly calculated source level and the highest source level of the three identified in the first step, and again, adds the appropriate number of decibels to the highest source level of the three.

For example, with overlapping isopleths from 24″, 36″, and 42″ diameter steel pipe piles with sound source levels of 161, 167, and 168 dB RMS respectively, NMFS would first calculate the difference between the 24″ and 36″ source levels (167 dB − 161 dB = 6 dB). Then, given that the difference is 6 dB, as described in Table 8, NMFS would then add 1 dB to the highest of the two sound source levels (167 dB), for a combined noise level of 168 dB. Next, NMFS calculates the difference between the newly calculated 168 dB and the sound source level of the 42″ steel pile (168 dB). Since 168 dB − 168 dB = 0 dB, 3 dB is added to the highest value (168 dB + 3 dB = 171 dB). Therefore, for the combination of 24″, 36″, and 42″ steel pipe piles, zones would be calculated using a combined sound source level of 171 dB.

If an impact hammer and a vibratory hammer are used concurrently, the largest Level B harassment zone generated by either hammer would apply, and the Level A harassment zone generated by the impact hammer would apply. Simultaneous use of two or more impact hammers does not require source level additions as it is unlikely that two hammers would strike at the same exact instant. Thus, sound source levels are not adjusted regardless of distance, and the zones for each individual activity apply.

For activity combinations that do require sound source level adjustment, Table 9 shows the revised proxy source levels for concurrent activities based upon the rules for combining sound source levels generated during pile installation, described in Table 7. Resulting Level A harassment and Level B harassment zones for concurrent activities are summarized in Table 9. The maximum Level A harassment isopleth will be 2,444.5 m for high-frequency cetaceans generated by concurrent use of two vibratory pile drivers and DTH mono-hammer during installation of 36″ shafts for the small boat floating dock (Table 9). The maximum Level B harassment isopleth will be 54,117 m for the concurrent use of DTH mono-hammer and two vibratory pile drivers for installation of 36″ shafts for the small boat floating dock (Table 9).

TABLE 8—PROXY VALUES FOR SIMULTANEOUS USE OF NON-IMPULSIVE SOURCES

Structure	Activity and proxy	New proxy
Bulkhead	Vibratory Install 16-inch steel pipe piles—162 dB RMS Vibratory Install 18-inch steel pipe piles—162 dB RMS. Vibratory Install 18-inch steel pipe piles—162 dB DTH Install 18-inch steel pipe piles—167 dB.	165 dB RMS. 168 dB RMS.
Bulkhead and Trestle	Vibratory Install/extract 16-inch steel pipe piles—162 dB RMS Vibratory Install Z26–700 sheet piles—156 dB RMS. Vibratory Install 18-inch steel pipe piles—162 dB RMS. Vibratory Install/extract 16-inch steel pipe piles—162 dB RMS Vibratory Install Z26–700 sheet piles—156 dB RMS. Rotary Drill 18-inch steel pipe piles—154 dB RMS.	166 dB RMS. 163 dB RMS.
Pier	Vibratory Install/extract 16-inch steel pipe piles—162 dB RMS Vibratory Install 30-inch steel pipe piles—167 dB RMS. Vibratory Install/extract 16-inch steel pipe piles—162 dB RMS Rotary Drill 30-inch steel pipe piles—154 dB RMS.	168 dB RMS. 163 dB RMS.
Pier Fender Piles and Small Boat Floating Dock	Vibratory Install/extract 16-inch steel pipe piles—162 dB RMS Vibratory Install 18-inch steel pipe piles—162 dB RMS. Vibratory Install/extract 16-inch steel pipe piles—162 dB RMS Vibratory Install 36-inch steel pipe piles—175 dB RMS. Vibratory Install 36-inch steel casing—175 dB DTH Install 36-inch steel casing—167 dB.	165 dB RMS. 175 dB RMs. 176 dB.

TABLE 9—MAXIMUM DISTANCES TO LEVEL A AND LEVEL B HARASSMENT THRESHOLDS FOR CONCURRENT ACTIVITIES

Structure	Pile sizes and type	Activity	Total production days	Level A (PTS onset) harassment			Level B harassment
				Maximum distance to continuous 198 dB SEL_{cum}; DTH 185 dB SEL_{cum} thresholds (m)/area of harassment zone (km^2)	Maximum distance to continuous 173 dB SEL_{cum}; DTH 155 dB SEL_{cum} thresholds (m)/area of harassment zone (km^2)	Maximum distance to continuous 201 dB SEL_{cum}; DTH 185 dB SEL_{cum} thresholds (m)/area of harassment zone (km^2)	Maximum distance 120 dB RMS SPL threshold (m)/area of harassment zone (km^2) (continuous and DTH)
				MF cetacean	HF cetacean	Phocid	
Bulkhead	Install of 16-inch and 18-inch steel pipe piles.	Install/Extract using two Vibratory Pile Drivers.	15	3.7/0.000021	61.6/0.0060 ..	25.3/0.001	10,000/3.31

TABLE 9—MAXIMUM DISTANCES TO LEVEL A AND LEVEL B HARASSMENT THRESHOLDS FOR CONCURRENT ACTIVITIES—Continued

Structure	Pile sizes and type	Activity	Total production days	Level A (PTS onset) harassment			Level B harassment
				Maximum distance to continuous 198 dB SEL_{cum}; DTH 185 dB SEL_{cum} thresholds (m)/area of harassment zone (km^2)	Maximum distance to continuous 173 dB SEL_{cum}; DTH 155 dB SEL_{cum} thresholds (m)/area of harassment zone (km^2)	Maximum distance to continuous 201 dB SEL_{cum}; DTH 185 dB SEL_{cum} thresholds (m)/area of harassment zone (km^2)	Maximum distance 120 dB RMS SPL threshold (m)/area of harassment zone (km^2) (continuous and DTH)
				MF cetacean	HF cetacean	Phocid	
	Install of 18-inch steel pile	Install using two Vibratory Pile Drivers and DTH mono-hammer.	12	Vibratory: 1.8/ 0.000005 DTH: 4.6/ 0.000033.	Vibratory: 29.7/ 0.0014 DTH: 154.2/ 0.028.	Vibratory: 12.2/ 0.00023 DTH: 69.3/ 0.0075.	15,848.93/3.31
Bulkhead and Trestle	Install of 16-inch and 18-inch steel pipe and Z26–700 steel sheet piles.	Install/Extract using three Vibratory Pile Drivers.	15	4.1/0.000026	68.3/0.0073 ..	28.1/0.0012 ..	10,000/3.31
		Install/Extract using two Vibratory Pile Drivers and a Rotary Drill.	14	2.9/0.000013	47.8/0.0036 ..	19.7/0.00061	7,356/3.31
Pier	Install of 16- and 30-inch steel pipe.	Install/Extract using two Vibratory Pile Drivers.	30	5.9/0.00011 ..	97.6/0.030	40.1/0.0050 ..	15,849/8.53
		Install/Extract using a vibratory pile driver and rotary drill.	27	2.0/0.0031	33.1/0.0034 ..	13.6/0.00058	7,356/8.53
Pier Fender Piles and Gangway Support for Small Boat Floating Dock.	Install of 16- and 18-inch steel pipe.	Install/Extract using two Vibratory Pile Drivers.	17	2.3/0.000017	38.8/0.0047 ..	16.0/0.0008 ..	10,000/8.53
		Install using two Vibratory Pile Drivers.	20	9.6/0.00029 ..	159.5/0.080 ..	65.6/0.013	46,416/8.53
	Install of 16-inch steel pipe and 36-inch shafts.						
	Install of 36-inch shafts	Install using two Vibratory Pile Drivers and DTH mono-hammer.	2	Vibratory: 5.2/ 0.000042 DTH: 73/ 0.0084.	Vibratory: 86.6/0.012 DTH: 2,444.5/ 1.21.	Vibratory: 35.6/0.002 DTH: 1,098.2/ 0.42.	DTH: 54,117/ 8.53

dB RMS SPL = decibel root mean square sound pressure level; dB SEL_{cum} = cumulative sound exposure level; m = meter; PTS = Permanent Threshold Shift; km^2 = square kilometer.

The Level B harassment zones in Table 9 were calculated based upon the adjusted source levels for simultaneous construction activities (Table 8). OMAO has not planned any scenarios for concurrent work in which the Level A harassment isopleths would need to be adjusted from that calculated for single sources. Regarding implications for Level A harassment zones when multiple vibratory hammers, or vibratory hammers and rotary drills, are operating concurrently, given the small size of the estimated Level A harassment isopleths for all hearing groups during vibratory pile driving, the zones of any two hammers or hammer and drill are not expected to overlap. Therefore, compounding effects of multiple vibratory hammers operating concurrently are not anticipated, and NMFS has treated each source independently.

Regarding implications for Level A harassment zones when vibratory hammers are operating concurrently with a DTH hammer, combining isopleths for these sources is difficult for a variety of reasons. First, vibratory pile driving relies upon non-impulsive PTS thresholds, while DTH hammers use impulsive thresholds. Second, vibratory pile driving accounts for the duration to drive a pile, while DTH account for strikes per pile. Thus, it is difficult to measure sound on the same scale and combine isopleths from these impulsive and non-impulsive, continuous sources. Therefore, NMFS has treated each source independently at this time.

Regarding implications for impact hammers used in combination with a vibratory hammer or DTH hammer, the likelihood of these multiple sources' isopleths completely overlapping in time is slim primarily because impact pile driving is intermittent. Furthermore, non-impulsive, continuous sources rely upon non-impulsive TTS/PTS thresholds, while impact pile driving uses impulsive thresholds, making it difficult to calculate isopleths that may overlap from impact driving and the simultaneous action of a non-impulsive continuous source or one with multiple strikes per second. Thus, with such slim potential for multiple different sources' isopleths to overlap in space and time, specifications should be entered as ''normal'' into the User Spreadsheet for each individual source separately.

Marine Mammal Occurrence

In this section we provide information about the occurrence of marine mammals, including density or other relevant information that will inform the take calculations. Potential exposures to construction noise for each acoustic threshold were estimated using marine mammal density estimates (N) from the Navy Marine Species Density Database (NMSDD) (Navy, 2017a).

OMAO evaluated data reflecting monthly densities of each species to determine minimum, maximum, and average annual densities within Narragansett Bay. Table 10 summarizes the average annual densities of species that may be impacted by the construction activities, with the exception of harbor seals as the density value for this species in the table represents the maximum density value for seals.

TABLE 10—AVERAGE DENSITIES BY SPECIES USED IN EXPOSURE ANALYSIS

Species	Average density in project area (species per km^2)
Atlantic White-sided Dolphin	0.003
Common Dolphin	0.011
Harbor Porpoise	0.012
Harbor Seal	0.623
Gray Seal	0.131
Harp Seal	0.05
Hooded Seal	0.001

The NMSDD models reflect densities for seals as a guild due to difficulty in distinguishing these species at sea. Harbor seal is expected to be the most common pinniped in Narragansett Bay with year-round occurrence (Kenney and Vigness-Raposa, 2010). Therefore, OMAO used the maximum density for the seal guild for harbor seal. Gray seals are the second most common seal to be observed in Rhode Island waters and, based on stranding records, are commonly observed during the spring to early summer and occasionally observed during other months of the year (Kenney, 2020). Therefore, the average density for the seal guild was used for gray seal occurrence in Narragansett Bay. Minimum densities for the seal guild were used for harp seal and hooded seals as they are considered occasional visitors in Narragansett Bay but are rare in comparison to harbor and gray seals (Kenney, 2015). NMFS has carefully reviewed and concurs with the use of these densities used by OMAO.

Take Estimation

Here we describe how the information provided above is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and authorized.

For each species, OMAO multiplied the average annual density by the largest ensonified area (Tables 5, 6, 9) and the maximum days of activity (Tables 5, 6, 9) (take estimate = N × ensonified area × days of pile driving) in order to calculate estimated take by Level A harassment and Level B harassment. OMAO used the pile type, size, and construction method that produce the largest isopleth to estimate exposure of marine mammals to noise impacts. The exposure estimate was rounded to the nearest whole number at the end of the calculation. Table 11 shows the total estimated number of takes for each species by Level A harassment and Level B harassment for individual and concurrent activities as well as estimated take as a percent of stock abundance. Estimated take by activity type for individual and concurrent equipment use for each species is shown in Tables 6–12 through 6–17 in the application. OMAO requested take by Level A harassment of four species (harbor porpoise, harbor seal, gray seal, and harp seal) incidental to construction activities using one equipment type. In addition, OMAO requested one take of harbor seals by Level A harassment during concurrent use of a DTH mono-hammer and two vibratory hammers for installation of 36″ shafts for the small boat floating dock.

To account for group size, OMAO conservatively increased the estimated take by Level B harassment from 9 to 16 Atlantic white-sided dolphins, as the calculated take was less than the documented average group size (NUWC, 2017). NMFS agrees with this approach, and is authorizing 16 takes by Level B harassment of Atlantic white-sided dolphins. The species density for the hooded seal was too low to result in any calculated estimated takes. In order to be conservative, OMAO requested, and NMFS authorized, one take by Level B harassment of hooded seals for each month of construction activity when this species may occur in the project area. Hooded seals may occur in the project area from January through May, which is a total of 5 months. Therefore, OMAO requested, and NMFS authorized, five takes by Level B harassment of hooded seals for individual construction activities and five takes by Level B harassment of hooded seals for concurrent construction activities for a total of 10 takes by Level B harassment of hooded seals.

TABLE 11—TOTAL AUTHORIZED TAKE BY LEVEL A HARASSMENT AND LEVEL B HARASSMENT FOR INDIVIDUAL AND CONCURRENT ACTIVITIES

Species	Individual activities		Concurrent activities		Total authorized take	% of stock
	Level A harassment	Level B harassment	Level A harassment	Level B harassment		
Atlantic white-sided dolphin	0	6	0	3	[1] 16	0.2
Short-beaked common dolphin	0	26	0	13	39	0.2
Harbor Porpoise	2	27	0	13	42	0.044
Harbor Seal	55	1,478	1	589	2,123	3.46
Gray Seal	11	312	0	125	448	1.64
Harp Seal	4	117	0	47	168	0.002
Hooded Seal	0	[2] 5	0	[2] 5	10	0.002

[1] Authorized take has been increased to mean group size (NUWC, 2017). Mean group size was not used for those take estimates that exceeded the mean group size.

[2] OMAO conservatively requested 1 take by Level B harassment of hooded seal per month of construction when this species may occur in the project area (January through May).

Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of

conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which may consider such things as cost and impact on operations.

Shutdown Zones

OMAO will establish shutdown zones for all pile driving activities. The purpose of a shutdown zone is generally to define an area within which shutdown of the activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). Shutdown zones will be based upon the Level A harassment zone for each pile size/type and driving method, as shown in Table 12. If the Level A harassment zone is too large to monitor, the shutdown zone will be limited to a radial distance of 200 m from the acoustic source (86 FR 71162, December 15, 2021; 87 FR 19886, April 6, 2022). For example, the largest Level A harassment zone for high-frequency cetaceans extends approximately 2,444.5 m from the source during DTH mono-hammer excavation while installing the 36 in steel shafts for the small boat floating dock (Table 5). OMAO plans to maintain maximum shutdown zone of 200 m for that activity, consistent with prior projects in the area (87 FR 11860, March 2, 2022).

A minimum shutdown zone of 10 m will be applied for all in-water construction activities if the Level A harassment zone is less than 10 m (*i.e.,* vibratory pile driving, drilling). The 10 m shutdown zone will also serve to protect marine mammals from collisions with project vessels during pile driving and other construction activities, such as barge positioning or drilling. If an activity is delayed or halted due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily exited and been visually confirmed beyond the shutdown zone indicated in Table 12 or 15 minutes have passed without re-detection of the animal. Construction activities must be halted upon observation of a species for which incidental take is not authorized or a species for which incidental take has been authorized but the authorized number of takes has been met entering or within the harassment zone.

If a marine mammal enters the Level B harassment zone, in-water work will proceed and PSOs will document the marine mammal's presence and behavior.

TABLE 12—SHUTDOWN ZONES AND LEVEL B HARASSMENT ZONES BY ACTIVITY

Pile type/size	Driving method	Shutdown zone (m)		Level B harassment zone (m)
		Cetaceans	Pinnipeds	All marine mammals
12″ steel pipe	Vibratory extraction	10	10	2,600.
12″ timber	Vibratory extraction	15	10	1,359.
16″ steel pipe	Vibratory install/extract	20	10	6,400.
18″ steel pipe	Impact install	[1] 200	[1] 200	640.
	Vibratory install	30	15	6,400.
	DTH Mono-hammer	[1] 200	[1] 200	Maximum harassment zone.[2]
	Rotary drilling 18″ holes	10	10	1,900.
Z26–700 steel sheets	Vibratory install	15	10	2,600.
30″ steel pipe	Impact install	[1] 200	[1] 200	2,600.
	Vibratory install	55	25	Maximum harassment zone.[2]
30″ steel pipe	Rotary drilling	10	10	1,900.
36″ steel pipe	Impact install	[1] 200	[1] 200	3,400.
	Vibratory install	90	40	Maximum harassment zone.[2]
36″ shafts	DTH Mono-hammer	[1] 200	[1] 200	Maximum harassment zone.[2]

[1] Distance to shutdown zone distances implemented for other similar projects in the region (NAVFAC, 2019).
[2] Harassment zone will be truncated due to the presence of intersecting land masses and will encompass a maximum area of 3.31 km^2.

Protected Species Observers

The placement of protected species observers (PSOs) during all construction activities (described in the Monitoring and Reporting section) will ensure that the entire shutdown zone is visible. Should environmental conditions deteriorate such that the entire shutdown zone will not be visible (*e.g.,* fog, heavy rain), pile driving will be delayed until the PSO is confident marine mammals within the shutdown zone could be detected.

Monitoring for Level A Harassment and Level B Harassment

PSOs will monitor the full shutdown zones and the remaining Level A harassment and Level B harassment zones to the extent practicable. Monitoring zones provide utility for observing by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring zones enable observers to be aware of and communicate the presence of marine mammals in the project areas outside the shutdown zones and thus prepare for a potential cessation of activity should the animal enter the shutdown zone.

Pre-Activity Monitoring

Prior to the start of daily in-water construction activity, or whenever a break in pile driving of 30 minutes or longer occurs, PSOs will observe the

shutdown, Level A harassment, and Level B harassment for a period of 30 minutes. Pile driving may commence following 30 minutes of observation when the determination is made that the shutdown zones are clear of marine mammals. If a marine mammal is observed within the shutdown zones listed in Table 13, construction activity will be delayed until the animal has voluntarily exited and been visually confirmed beyond the shutdown zone indicated in Table 13 or has not been observed for 15 minutes. When a marine mammal for which Level B harassment take is authorized is present in the Level B harassment zone, activities will begin and Level B harassment take will be recorded. A determination that the shutdown zone is clear must be made during a period of good visibility (*i.e.,* the entire shutdown zone and surrounding waters are visible). If the shutdown zone is obscured by fog or poor lighting conditions, in-water construction activity will not be initiated until the entire shutdown zone is visible.

Soft-Start

Soft-start procedures are used to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. For impact pile driving, contractors will be required to provide an initial set of three strikes from the hammer at reduced energy, followed by a 30-second waiting period, then two subsequent reduced-energy strike sets. Soft start will be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer.

Based on our evaluation of OMAO's measures, NMFS has determined that the mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and,
- Mitigation and monitoring effectiveness.

Visual Monitoring

Marine mammal monitoring during in-water construction activities will be conducted by PSOs meeting NMFS' standards and in a manner consistent with the following:

- Independent PSOs (*i.e.,* employees of the entity conducting construction activities may not serve as PSOs) who have no other assigned tasks during monitoring periods will be used;
- At least one PSO will have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization;
- Other PSOs may substitute education (degree in biological science or related field) or training for experience; and
- Where a team of three or more PSOs is required, a lead observer or monitoring coordinator will be designated. The lead observer will be required to have prior experience working as a marine mammal observer during construction.

PSOs will have the following additional qualifications:

- Ability to conduct field observations and collect data according to assigned protocols;
- Experience or training in the field identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including, but not limited to, the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

Visual monitoring will be conducted by a minimum of two trained PSOs positioned at suitable vantage points. Any activity for which the Level B harassment isopleth will exceed 1,900 meters will require a minimum of three PSOs to effectively monitor the entire Level B harassment zone. PSOs will likely be located on Gould Island South, Gould Island Pier, Coddington Point, Bishop Rock, Breakwater, or Taylor Point as shown in Figure 11–1 in the application. All PSOs will have access to high-quality binoculars, range finders to monitor distances, and a compass to record bearing to animals as well as radios or cells phones for maintaining contact with work crews.

Monitoring will be conducted 30 minutes before, during, and 30 minutes after all in water construction activities. In addition, PSOs will record all incidents of marine mammal occurrence, regardless of distance from activity, and will document any behavioral reactions in concert with distance from piles being driven or removed. Pile driving activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes.

OMAO and the Navy shall conduct briefings between construction

supervisors and crews, PSOs, OMAO and Navy staff prior to the start of all pile driving activities and when new personnel join the work. These briefings will explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures.

Hydro-Acoustic Monitoring

OMAO will implement in situ acoustic monitoring efforts to measure SPLs from in-water construction activities by collecting and evaluating acoustic sound recording levels during activities. Stationary hydrophones will be placed 33 ft (10 m) from the noise source, in accordance with NMFS' most recent guidance for the collection of source levels. If there is the potential for Level A harassment, a second monitoring location will be set up at an intermediate distance between cetacean/phocid shutdown zones and Level A harassment zones. Hydrophones will be deployed with a static line from a stationary vessel. Locations of hydro-acoustic recordings will be collected via GPS. A depth sounder and/or weighted tape measure will be used to determine the depth of the water. The hydrophone will be attached to a weighted nylon cord or chain to maintain a constant depth and distance from the pile area. The nylon cord or chain will be attached to a float or tied to a static line.

Each hydrophone will be calibrated at the start of each action and will be checked frequently to the applicable standards of the hydrophone manufacturer. Environmental data will be collected, including but not limited to, the following: wind speed and direction, air temperature, humidity, surface water temperature, water depth, wave height, weather conditions, and other factors that could contribute to influencing the airborne and underwater sound levels (*e.g.,* aircraft, boats, *etc.*). The chief inspector will supply the acoustics specialist with the substrate composition, hammer or drill model and size, hammer or drill energy settings and any changes to those settings during the piles being monitored, depth of the pile being driven or shaft excavated, and blows per foot for the piles monitored. For acoustically monitored piles and shafts, data from the monitoring locations will be post-processed to obtain the following sound measures:

- Maximum peak pressure level recorded for all the strikes associated with each pile or shaft, expressed in dB re 1 µPa. For pile driving and DTH mono-hammer excavation, this maximum value will originate from the phase of pile driving/drilling during which hammer/drill energy was also at maximum (referred to as Level 4).
- From all the strikes associated with each pile occurring during the Level 4 phase these additional measures will be made:

(1) mean, median, minimum, and maximum RMS pressure level in [dB re 1 µPa];

(2) mean duration of a pile strike (based on the 90 percent energy criterion);

(3) number of hammer strikes;

(4) mean, median, minimum, and maximum single strike SEL in [dB re µPa2 s];

- Cumulative SEL as defined by the mean single strike SEL + 10*log10 (number of hammer strikes) in [dB re µPa2 s];
- Median integration time used to calculate SPL RMS;
- A frequency spectrum (pressure spectral density) in [dB re µPa2 per Hertz {Hz}] based on the average of up to eight successive strikes with similar sound. Spectral resolution will be 1 Hz, and the spectrum will cover nominal range from 7 Hz to 20 kHz;
- Finally, the cumulative SEL will be computed from all the strikes associated with each pile occurring during all phases, *i.e.,* soft-start, Level 1 to Level 4. This measure is defined as the sum of all single strike SEL values. The sum is taken of the antilog, with log10 taken of result to express in [dB re µPa2 s].

Hydro-acoustic monitoring will be conducted for at least 10 percent and up to 10 of each different pile type for each method of installation as shown in Table 13–1 in the application. All acoustic data will be analyzed after the project period for pile driving, rotary drilling, and DTH mono-hammer excavation events to confirm SPLs and rate of transmission loss for each construction activity.

Reporting

OMAO will submit a draft marine mammal monitoring report to NMFS within 90 days after the completion of pile driving activities, or 60 days prior to a requested date of issuance of any future IHAs for the project, or other projects at the same location, whichever comes first. The marine mammal monitoring report will include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets. Specifically, the report will include:

- Dates and times (begin and end) of all marine mammal monitoring;
- Construction activities occurring during each daily observation period, including:

(1) The number and type of piles that were driven and the method (*e.g.,* impact, vibratory, down-the-hole, *etc.*);

(2) Total duration of time for each pile (vibratory driving) number of strikes for each pile (impact driving); and

(3) For down-the-hole drilling, duration of operation for both impulsive and non-pulse components.

- PSO locations during marine mammal monitoring; and
- Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort sea state and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance.

For each observation of a marine mammal, the following will be reported:

- Name of PSO who sighted the animal(s) and PSO location and activity at time of sighting;
- Time of sighting;
- Identification of the animal(s) (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species;
- Distance and location of each observed marine mammal relative to the pile being driven or hole being drilled for each sighting;
- Estimated number of animals (min/max/best estimate);
- Estimated number of animals by cohort (adults, juveniles, neonates, group composition, etc.);
- Animal's closest point of approach and amount of time spent in harassment zone;
- Description of any marine mammal behavioral observations (*e.g.,* observed behaviors such as feeding or traveling), including an assessment of behavioral responses thought to have resulted from the activity (*e.g.,* no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);
- Number of marine mammals detected within the harassment zones, by species; and
- Detailed information about implementation of any mitigation (*e.g.,* shutdowns and delays), a description of specified actions that ensued, and resulting changes in behavior of the animal(s), if any.

If no comments are received from NMFS within 30 days, the draft report will constitute the final report. If comments are received, a final report addressing NMFS' comments will be required to be submitted within 30 days after receipt of comments. All PSO

datasheets and/or raw sighting data will be submitted with the draft marine mammal report.

In the event that personnel involved in the construction activities discover an injured or dead marine mammal, OMAO will report the incident to the Office of Protected Resources (OPR) (*PR.ITP.MonitoringReports@noaa.gov*), NMFS and to the Northeast Region (GARFO) regional stranding coordinator as soon as feasible. If the death or injury was clearly caused by the specified activity, OMAO will immediately cease the specified activities until NMFS is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the terms of the IHAs. OMAO will not resume their activities until notified by NMFS.

The report will include the following information:

1. Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);

2. Species identification (if known) or description of the animal(s) involved;

3. Condition of the animal(s) (including carcass condition if the animal is dead);

4. Observed behaviors of the animal(s), if alive;

5. If available, photographs or video footage of the animal(s); and

6. General circumstances under which the animal was discovered.

OMAO will also provide a hydro-acoustic monitoring report based upon hydro-acoustic monitoring conducted during construction activities. The hydro-acoustic monitoring report will include:

- Hydrophone equipment and methods: recording device, sampling rate, distance (meter) from the pile where recordings were made; depth of water and recording device(s);
- Type and size of pile being driven, substrate type, method of driving during recordings (*e.g.,* hammer model and energy), and total pile driving duration;
- Whether a sound attenuation device is used and, if so, a detailed description of the device used and the duration of its use per pile;
- For impact pile driving and/or DTH mono-hammer excavation (per pile): Number of strikes and strike rate; depth of substrate to penetrate; pulse duration and mean, median, and maximum sound levels (dB re: 1 μPa): root mean square sound pressure level (SPL_{rms}); cumulative sound exposure level (SEL_{cum}), peak sound pressure level (SPL_{peak}), and single-strike sound exposure level (SEL_{s-s});
- For vibratory driving/removal and/or DTH mono-hammer excavation (per pile): Duration of driving per pile; mean, median, and maximum sound levels (dB re: 1 μPa): root mean square sound pressure level (SPL_{rms}), cumulative sound exposure level (SEL_{cum}) (and timeframe over which the sound is averaged);
- One-third octave band spectrum and power spectral density plot; and
- General daily site conditions, including date and time of activities, water conditions (*e.g.,* sea state, tidal state), and weather conditions (*e.g.,* percent cover, visibility.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.,* intensity, duration), the context of any impacts or responses (*e.g.,* critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the majority of our analysis applies to all the species listed in Table 1, given that many of the anticipated effects of this project on different marine mammal stocks are expected to be relatively similar in nature. Where there are meaningful differences between species or stocks, or groups of species, in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, they are described independently in the analysis below.

Pile driving activities associated with the OMAO vessel relocation project have the potential to disturb or displace marine mammals. Specifically, the project activities may result in take, in the form of Level B harassment, and for harbor porpoise, harbor seal, gray seal, and harp seal, Level A harassment, from underwater sounds generated from pile driving and removal, DTH, and rotary drilling. Potential takes could occur if individuals are present in zones ensonified above the thresholds for Level B harassment, identified above, when these activities are underway.

No serious injury or mortality is expected, even in the absence of required mitigation measures, given the nature of the activities. Further, no take by Level A harassment is anticipated for Atlantic white-sided dolphins, short-beaked common dolphins, and harp seals due to the application of planned mitigation measures, such as shutdown zones that encompass the Level A harassment zones for these species. The potential for harassment will be minimized through the construction method and the implementation of the planned mitigation measures (see Mitigation section).

Take by Level A harassment is authorized for four species (harbor porpoise, harbor seal, gray seal, and harp seal) as the Level A harassment zones exceed the size of the shutdown zones for specific construction scenarios. Therefore, there is the possibility that an animal could enter a Level A harassment zone without being detected, and remain within that zone for a duration long enough to incur PTS. Any take by Level A harassment is expected to arise from, at most, a small degree of PTS (*i.e.,* minor degradation of hearing capabilities within regions of hearing that align most completely with the energy produced by impact pile driving such as the low-frequency region below 2 kHz), not severe hearing impairment or impairment within the ranges of greatest hearing sensitivity. Animals would need to be exposed to higher levels and/or longer duration than are expected to occur here in order to incur any more than a small degree of PTS.

Further, the amount of take authorized by Level A harassment is very low for all marine mammal stocks and species. For three species, Atlantic white-sided dolphin, short-beaked common dolphin, and harp seal, NMFS

neither anticipates nor authorized Level A harassment take over the duration of OMAO's planned activities; for the other four stocks, NMFS authorized no more than 56 takes by Level A harassment for any stock. If hearing impairment occurs, it is most likely that the affected animal would lose only a few decibels in its hearing sensitivity. Due to the small degree anticipated, any PTS potential incurred would not be expected to affect the reproductive success or survival of any individuals, much less result in adverse impacts on the species or stock.

Additionally, some subset of the individuals that are behaviorally harassed could also simultaneously incur some small degree of TTS for a short duration of time. However, since the hearing sensitivity of individuals that incur TTS is expected to recover completely within minutes to hours, it is unlikely that the brief hearing impairment would affect the individual's long-term ability to forage and communicate with conspecifics, and will therefore not likely impact reproduction or survival of any individual marine mammal, let alone adversely affect rates of recruitment or survival of the species or stock.

As described above, NMFS expects that marine mammals will likely move away from an aversive stimulus, especially at levels that would be expected to result in PTS, given sufficient notice through use of soft start. OMAO will also shut down pile driving activities if marine mammals enter the shutdown zones (see Table 12) further minimizing the likelihood and degree of PTS that would be incurred.

Effects on individuals that are taken by Level B harassment in the form of behavioral disruption, on the basis of reports in the literature as well as monitoring from other similar activities, will likely be limited to reactions such as avoidance, increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring) (*e.g.,* Thorson and Reyff, 2006). Most likely, individuals will simply move away from the sound source and temporarily avoid the area where pile driving is occurring. If sound produced by project activities is sufficiently disturbing, animals are likely to simply avoid the area while the activities are occurring. We expect that any avoidance of the project areas by marine mammals will be temporary in nature and that any marine mammals that avoid the project areas during construction will not be permanently displaced. Short-term avoidance of the project areas and energetic impacts of interrupted foraging or other important behaviors is unlikely to affect the reproduction or survival of individual marine mammals, and the effects of behavioral disturbance on individuals is not likely to accrue in a manner that will affect the rates of recruitment or survival of any affected stock.

Since June 2022, an Unusual Mortality Event (UME) has been declared for Northeast pinnipeds in which elevated numbers of sick and dead harbor seals and gray seals have been documented along the southern and central coast of Maine (NOAA Fisheries, 2022). Currently, 25 gray seals and 258 harbor seals have stranded. However, we do not expect the takes authorized by this IHA to exacerbate or compound upon this ongoing UME. As noted previously, no non-auditory injury, serious injury, or mortality is expected or authorized, and takes of harbor seal and gray seal will be reduced to the level of least practicable adverse impact through the incorporation of the required mitigation measures. For the WNA stock of gray seal, the estimated U.S. stock abundance is 27,300 animals (estimated 424,300 animals in the Canadian portion of the stock). Given that only 448 takes are authorized for this stock, we do not expect this authorization to exacerbate or compound upon the ongoing UME. For the WNA stock of harbor seals, the estimated abundance is 61,336 individuals. The estimated M/SI for this stock (339) is well below the PBR (1,729) (Hayes *et al.,* 2020). As such, the authorized takes of harbor seal are not expected to exacerbate or compound upon the ongoing UME.

The project is also not expected to have significant adverse effects on affected marine mammals' habitats. No ESA-designated critical habitat or biologically important areas (BIAs) are located within the project area. The project activities will not modify existing marine mammal habitat for a significant amount of time. The activities may cause a low level of turbidity in the water column and some fish may leave the area of disturbance, thus temporarily impacting marine mammals' foraging opportunities in a limited portion of the foraging range; but, because of the short duration of the activities and the relatively small area of the habitat that may be affected (with no known particular importance to marine mammals), the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences. Seasonal nearshore marine mammal surveys were conducted at NAVSTA Newport from May 2016 to February 2017, and several harbor seal haul outs were identified in Narragansett Bay, but no pupping was observed.

For all species and stocks, take will occur within a limited, relatively confined area (Coddington Cove) of the stock's range. Given the availability of suitable habitat nearby, any displacement of marine mammals from the project areas is not expected to affect marine mammals' fitness, survival, and reproduction due to the limited geographic area that will be affected in comparison to the much larger habitat for marine mammals within Narragansett Bay and outside the bay along the Rhode Island coasts. Level A harassment and Level B harassment will be reduced to the level of least practicable adverse impact to the marine mammal species or stocks and their habitat through use of mitigation measures described herein.

Some individual marine mammals in the project area, such as harbor seals, may be present and be subject to repeated exposure to sound from pile driving activities on multiple days. However, pile driving and extraction is not expected to occur on every day, and these individuals will likely return to normal behavior during gaps in pile driving activity within each day of construction and in between workdays. As discussed above, there is similar transit and haul out habitat available for marine mammals within and outside of the Narragansett Bay along the Rhode Island coast, outside of the project area, where individuals could temporarily relocate during construction activities to reduce exposure to elevated sound levels from the project. Therefore, any behavioral effects of repeated or long duration exposures are not expected to negatively affect survival or reproductive success of any individuals. Thus, even repeated Level B harassment of some small subset of an overall stock is unlikely to result in any effects on rates of reproduction and survival of the stock.

In summary and as described above, the following factors primarily support our determination that the impacts resulting from this activity are not expected to adversely affect any of the species or stocks through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated or authorized;
- No Level A harassment of Atlantic white-sided dolphins, short-beaked common dolphins, or harp seals is authorized;
- The small Level A harassment takes of harbor porpoises, harbor seals, gray seals, and hooded seals authorized are expected to be of a small degree;

• The intensity of anticipated takes by Level B harassment is relatively low for all stocks. Level B harassment will be primarily in the form of behavioral disturbance, resulting in avoidance of the project areas around where impact or vibratory pile driving is occurring, with some low-level TTS that may limit the detection of acoustic cues for relatively brief amounts of time in relatively confined footprints of the activities;

• Nearby areas of similar habitat value (*e.g.,* transit and haul out habitats) within and outside of Narragansett Bay are available for marine mammals that may temporarily vacate the project area during construction activities;

• The specified activity and associated ensonified areas do not include habitat areas known to be of special significance (BIAs or ESA-designated critical habitat);

• Effects on species that serve as prey for marine mammals from the activities are expected to be short-term and, therefore, any associated impacts on marine mammal feeding are not expected to result in significant or long-term consequences for individuals, or to accrue to adverse impacts on their populations;

• The ensonified areas are very small relative to the overall habitat ranges of all species and stocks, and will not adversely affect ESA-designated critical habitat for any species or any areas of known biological importance;

• The lack of anticipated significant or long-term negative effects to marine mammal habitat; and

• The efficacy of the mitigation measures in reducing the effects of the specified activities on all species and stocks.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS finds that the total marine mammal take from the planned activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The instances of take NMFS proposes to authorize is below one-third of the estimated stock abundance for all impacted stocks (Table 12). (In fact, take of individuals is less than 4 percent of the abundance for all affected stocks.) The number of animals that we are authorizing to be taken is considered small relative to the relevant stocks or populations, even if each estimated take occurred to a new individual. Furthermore, these takes are likely to only occur within a small portion of the each stock's range and the likelihood that each take will occur to a new individual is low.

Based on the analysis contained herein of the planned activity (including the mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks will not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

No incidental take of ESA-listed species is authorized or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of the IHA qualifies to be categorically excluded from further NEPA review.

Authorization

NMFS has issued an IHA to OMAO for the potential harassment of small numbers of seven marine mammal species incidental to construction activities at Naval Station Newport, in Newport, RI, provided the previously mentioned mitigation, monitoring, and reporting requirements are followed.

Dated: December 15, 2022.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–27727 Filed 12–20–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XV189]

Space Weather Advisory Group Meeting

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Space Weather Advisory Group (SWAG) will meet for 2 and a half-days on January 18–20, 2023.

DATES: The meeting is scheduled as follows: January 18–19, 2023 from 9 a.m.–5 p.m. Eastern Standard Time (EST) and January 20, 2023 from 9 a.m.–12 p.m. EST.

ADDRESSES: The public meeting will be a hybrid event with the SWAG and invited guests convening ''in person'' at

the Herbert C. Hoover Building, 1401 Constitution Avenue NW, Washington, DC, and any public participants attending virtually via Webinar. For details on how to connect to the webinar or to submit comments, please visit *www.weather.gov/swag* or contact Jennifer Meehan, National Weather Service; telephone: 301–427–9798; email: *jennifer.meehan@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer Meehan, National Weather Service, NOAA, 1325 East West Highway, Silver Spring, Maryland, 20910; 301–427–9798 or *jennifer.meehan@noaa.gov;* or visit the SWAG website: *https://www.weather.gov/swag.*

SUPPLEMENTARY INFORMATION: Pursuant to the Promoting Research and Observations of Space Weather to Improve the Forecasting of Tomorrow (PROSWIFT) Act, 51 U.S.C. 60601 *et seq.,* the Administrator of NOAA and the National Science and Technology Council's Space Weather Operations, Research, and Mitigation (SWORM) Subcommittee established the Space Weather Advisory Group (SWAG) on April 21, 2021. The SWAG is the only Federal Advisory SWAG that advises and informs the interest and work of the SWORM. The SWAG is to receive advice from the academic community, the commercial space weather sector, and nongovernmental space weather end users to carry out the responsibilities of the SWAG set forth in the PROSWIFT Act, 51 U.S.C. 60601 *et seq.*

The SWAG is directed to advise the SWORM on the following: facilitating advances in the space weather enterprise of the United States; improving the ability of the United States to prepare for, mitigate, respond to, and recover from space weather phenomena; enabling the coordination and facilitation of research to operations and operations to research, as described in section 60604(d) of title 51, United States Code; and developing and implementing the integrated strategy under 51 U.S.C. 60601(c), including subsequent updates and reevaluations. The SWAG shall also conduct a comprehensive survey of the needs of users of space weather products to identify the space weather research, observations, forecasting, prediction, and modeling advances required to improve space weather products, as required by 51 U.S.C. 60601(d)(3).

Matters To Be Considered

The meeting will be open to the public. During the meeting, the SWAG will discuss the PROSWIFT Act, 51 U.S.C. 60601 *et seq.,* directed duties of the SWAG including the required 51 U.S.C. 60601(d)(3) user survey, and the update to the 2019 National Space Weather Strategy and Action Plan (*https://tinyurl.com/NSWSAP2019*) Implementation Plan. The full agenda and meeting materials will be published on the SWAG website: *https://www.weather.gov/swag.*

Additional Information and Public Comments

The meeting will be held over two and a half-days and will be conducted in a hybrid manner (for meeting details see **ADDRESSES**). Please register for the meeting through the website: *https://www.weather.gov/swag.*

This event is accessible to individuals with disabilities. For all other special accommodation requests, please contact *Jennifer.meehan@noaa.gov.* This webinar is a NOAA public meeting and will be recorded and transcribed. If you have a public comment, you acknowledge you will be recorded and are aware you can opt out of the meeting. Participation in the meeting constitutes consent to the recording. Both the meeting minutes and presentations will be posted to the SWAG website (*https://www.weather.gov/swag*). The agenda, speakers and times are subject to change. For updates, please check the SWAG website (*https://www.weather.gov/swag*).

Public comments directed to the SWAG members and SWAG related topics are encouraged. In particular, the SWAG would like to hear from all interested parties on what the SWAG should consider advising the SWORM on in regard to the 2019 National Space Weather Strategy and Action Plan (*https://tinyurl.com/NSWSAP2019*) Implementation Plan update. For example, the SWAG seeks input from the public on the following:

1. In priority order, how, where, and why should the Federal Government invest limited resources to enhance research, technology, and innovation to improve observations and understanding of space weather events?

2. In priority order, what activities should the Federal Government undertake to enhance national capabilities to prepare for, recover from, adapt to, or otherwise mitigate the effects of space weather events?

3. What innovative tools, platforms, or technologies are needed by the Federal Government and space weather research and development communities to advance the transition of research to operations for models and observations of space weather phenomena? Please include any barriers to implement the identified tools, platforms, or technologies.

4. In priority order, what opportunities exist to enhance U.S. operational space weather predictions, alerts, and services, for Earth, near-Earth, and deep space applications? Please include any barriers for implementation and utilization of these capabilities.

5. Beyond regulation and grant programs, what can the Federal government do to enable and advance the private sector role for capabilities, forecasting, modeling, mitigation, research, development, and observation in the space weather domain?

6. What opportunities exist for the United States to marshal the collective resources of like-minded nations and organizations to address the global hazard of space weather?

7. Is there any additional information related to enhancing national capabilities to address space weather events, not listed above, that you believe the SWAG should consider?

The public input provided will inform the work of the SWAG as it works with the SWORM to develop the updated National Space Weather Strategy and Action Plan Implementation Plan. Individuals or groups who would like to submit recommendations to the SWAG will be given two minutes to present one slide. Please email the request to speak and the slide to *jennifer.meehan@noaa.gov* by January 13, 2023 to provide sufficient time for SWAG review.

For other written public comments, please email *jennifer.meehan@noaa.gov* by January 13, 2023. Written comments received after this date will be distributed to the SWAG but may not be reviewed prior to the meeting date. As time allows, public comments will be read into the public record during the meeting. Advance comments will be collated and posted to the meeting website.

Dated: December 16, 2022.

Michael Farrar,

Director, National Centers for Environmental Prediction, National Weather Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2022–27733 Filed 12–20–22; 8:45 am]

BILLING CODE 3510–KE–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Law School Clinic Certification Program

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

ACTION: Notice of information collection; request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651–0081 Law School Clinic Certification Program. The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

DATES: To ensure consideration, comments regarding this information collection must be received on or before February 21, 2023.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Justin Isaac, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Dahlia George, Office of Enrollment and Discipline, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–4097; or by email at *Dahlia.George@uspto.gov* with ''0651–0081 comment'' in the subject line. Additional information about this information collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

Public Law 113–227 (Dec. 16, 2014) requires the United States Patent and Trademark Office to establish regulations and procedures for application to, and participation in, the USPTO Law School Clinic Certification Program. The Program allows students enrolled in a participating law school's clinic to practice patent or trademark law before the USPTO under the direct supervision of an approved faculty clinic supervisor. Each clinic provides legal services on a pro bono basis for clients who qualify for assistance from the law school's clinic. By drafting, filing, and prosecuting patent and trademark applications, students gain valuable experience that would otherwise be unavailable to them while in law school. The program also facilitates the provision of pro bono services to patent and trademark applicants who lack the financial resources necessary for traditional legal representation. Currently, 61 law schools participate in the program.

This information collection covers the applications from law schools that wish to enter the program, faculty advisors who seek to become a faculty clinic supervisor, and students who seek to participate in this program. The collection also includes the required semiannual reports from participating law school clinics and biennial renewals required by the program as well as the request to make special under the Law School Clinic Certification Program, which allows a limited number of applications per semester to be advanced out of turn (accorded special status) for examination if the applicant makes the appropriate showing, to provide law students with practical experience as they will be more likely to receive substantive examination of applications within the school year that the application is filed.

II. Method of Collection

By mail, facsimile, hand delivery, or electronically via email to the USPTO.

III. Data

OMB Control Number: 0651–0081.

Forms: (LS = Law School; SB = Specimen Book).

- PTO–158LS, (Application for Limited Recognition in USPTO Law School Program for Law Students to Practice Before the USPTO).
- PTO/SB/419 (Certification and Request to Make Special under the Law School Program).

Type of Review: Extension and revision of a currently approved information collection.

Affected Public: Private sector; individuals or households.

Respondent's Obligation: Required to obtain or retain benefits.

Estimated Number of Annual Respondents: 860 respondents.

Estimated Number of Annual Responses: 920 responses.

Estimated Time per Response: The USPTO estimates that the responses in this information collection will take the public approximately between 30 minutes (0.5 hours) and 40 hours to complete. This includes the time to gather the necessary information, create the document, and submit the completed item to the USPTO.

Estimated Total Annual Respondent Burden Hours: 1,220 hours.

Estimated Total Annual Respondent Hourly Cost Burden: $63,338.

TABLE 1—TOTAL BURDEN HOURS AND HOURLY COSTS TO PRIVATE SECTOR RESPONDENTS

Item No.	Item	Number of respondents (a)	Responses per respondent (b)	Number of responses (a) × (b) = (c)	Estimated response time (hours) (d)	Estimated annual burden hours (c) × (d) = (e)	Rate [1] ($/hr) (f)	Total hourly cost burden (e)×(f) = (g)
1	Application by Law School to Enter the Program.	5	1	5	40	200	$62.89	$12,578
4	Semiannual Report Required of Law School Clinics.	60	2	120	5	600	62.89	37,734
5	Biennial Renewal Application by Law School.	30	1	30	1	30	62.89	1,887
Total		95		155		830		52,199

TABLE 2—TOTAL BURDEN HOURS AND HOURLY COSTS TO INDIVIDUAL AND HOUSEHOLD RESPONDENTS

Item No.	Item	Number of respondents (a)	Responses per respondent (b)	Number of responses (a) × (b) = (c)	Estimated response time (hours) (d)	Estimated annual burden hours (c) × (d) = (e)	Rate [2] ($/hr) (f)	Total hourly cost burden (e) × (f) = (g)
2	Application by Law School Faculty Member to Become a Faculty Clinic Supervisor.	10	1	10	1	10	$62.89	$629
3	Application for Limited Recognition for Law Students.	750	1	750	0.5	375	27.19	10,196
6	Certification and Request to Make Special under the Law School Program.	5	1	5	1	5	62.89	314
Total		765		765		390		11,139

Estimated Total Annual Respondent Non-hourly Cost Burden: $46.

There are no maintenance costs, capital start-up costs, or recordkeeping costs associated with this information collection. However, the USPTO estimates that the total annual (non-hour) cost burden for this information collection, in the form of postage is $46.

Postage

The USPTO does not presently use automated or other technological information collection techniques for the items in this collection of information, but submissions are accepted electronically through email. Submissions are also accepted via postal mail and hand delivery. The USPTO expects that only five (5) submissions will be submitted through the U.S. Postal Service. The remaining items will be submitted electronically. The average USPS postage cost for a mailed submission, using a Priority Mail flat rate legal envelope is $9.25. Therefore, the USPTO estimates that the total postage costs for the mailed submissions in this information collection will total $46.

[1] The USPTO expects that university faculty members will complete most of the items in this information collection at an estimated rate of $62.89 per hour. The faculty rate is found in the Occupational Employment and Wage Statistics (25–1112 Law Teachers, Postsecondary (*https://www.bls.gov/oes/current/oes251112.htm*)). While no exact number is listed as a mean hourly wage, USPTO reached the estimated rate by taking the mean annual wage ($130,820) and dividing it by 2,080, which is the number of annual work hours based on a 40-hour work week. Faculty members serving as Clinic Supervisors must be practicing attorneys (and registered with the Patent Bar for those schools handling patent matters before the USPTO on behalf of applicants).

The cost for law students applying to participate in the program is estimated to be at the 50% hourly rate for legal occupations (BLS 23–0000 Legal Occupations) which is $27.29 per hour (*https://www.bls.gov/oes/current/oes230000.htm*). This accounts for law students' possible employment in various entry level legal positions.

[2] Ibid.

IV. Request for Comments

The USPTO is soliciting public comments to:

(a) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(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.

All comments submitted in response to this notice are a matter of public record. USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personally identifiable information (PII) in a comment, be aware that the entire comment—including PII—may be made publicly available at any time. While you may ask in your comment to withhold PII from public view, USPTO cannot guarantee that it will be able to do so.

Justin Isaac,

Information Collections Officer, Office of the Chief Adminstrative Officer, United States Patent and Trademark Office.

[FR Doc. 2022–27677 Filed 12–20–22; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

LIBRARY OF CONGRESS

Copyright Office

[Docket No. PTO–C–2022–0035]

Study on Non-Fungible Tokens and Related Intellectual Property Law Issues

AGENCY: United States Patent and Trademark Office, Department of Commerce; United States Copyright Office, Library of Congress.

ACTION: Notice of inquiry; extension of written comment period and date change for public roundtables.

SUMMARY: The United States Patent and Trademark Office (USPTO) and United States Copyright Office (USCO) (collectively, the Offices) published a request for comments in the **Federal Register** on November 23, 2022, seeking comments from the public on various intellectual property (IP) law and policy issues associated with non-fungible tokens (NFTs). Through this notice, the Offices are extending the period for written public comment until February 3, 2023. In addition, the Offices are changing the dates of the public roundtables in this study.

DATES:

Written comments: Written comments must be received by 11:59 p.m. Eastern Time on February 3, 2023.

Public roundtables: The roundtable on *Trademarks and NFTs* will now be held on Tuesday, January 24, 2023; the roundtable on *Patents and NFTs* will now be held on Thursday, January 26, 2023; and the roundtable on *Copyrights and NFTs* will now be held on Tuesday, January 31, 2023. The deadline for requests to participate as a panelist in one or more of the roundtables is unchanged. Such requests must be

received by 11:59 p.m. Eastern Time on December 21, 2022.

ADDRESSES:

Submission of written comments: For reasons of Government efficiency, comments must be submitted through the Federal eRulemaking Portal at *www.regulations.gov.* To submit comments via the portal, enter docket number PTO–C–2022–0035 on the homepage and click ''Search.'' The site will provide a search results page listing all documents associated with this docket. Find a reference to this request for information and click on the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in ADOBE® portable document format (PDF) or MICROSOFT WORD® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included. Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic submission of comments is not feasible due to a lack of access to a computer and/or the internet, please contact the Offices using the contact information below for special instructions on how to submit comments by other means.

Submission of business confidential information: Any submissions containing business confidential information must be marked ''confidential treatment requested'' and submitted through the Federal eRulemaking Portal. Submitters should provide an index listing the document(s) or information they would like the Offices to withhold. The index should identify the confidential document(s) by document number(s) and document title(s) and should identify the confidential information by description(s) and relevant page number(s) and/or section number(s) within a document. Submitters should provide a statement explaining their grounds for requesting non-disclosure of the information to the public as well. The Offices also request that submitters of business confidential information include a non-confidential version (either redacted or summarized) that will be posted on *www.regulations.gov* and available for public viewing. In the event that the submitter cannot provide a non-confidential version of their submission, the Offices request that the submitter post a notice in the docket stating that they have provided the Offices with business confidential information. Should a submitter fail either to docket a non-confidential version of their submission or to post a notice that they have provided business confidential information, the Offices will note the receipt of the submission on the docket with the submitter's organization or name (to the degree permitted by law) and the date of submission.

Anonymous submissions: The Offices will accept anonymous submissions. Enter ''N/A'' in the required fields if you wish to remain anonymous.

Public roundtables: The roundtables will be conducted virtually. Requests to participate as a panelist at one or more of these roundtables must be submitted via email to *NFTStudySpeakingRequests@uspto.gov* and must be received by 11:59 p.m. Eastern Time on December 21, 2022. Requests to participate as a panelist at a roundtable made in any other form, including as part of comments submitted via the Federal eRulemaking Portal, will not be considered. If email submission of requests to participate as a panelist is not feasible, please contact the Offices using the contact information below for special instructions. The submission of written comments in response to this notice is not a prerequisite to participation as a panelist in a roundtable. Please note that the Offices will review all requests to participate and will endeavor to invite participants representing diverse viewpoints on the subject matter discussed at each roundtable. The Offices may not be able to accommodate all requests.

FOR FURTHER INFORMATION CONTACT: Kevin R. Amer, Senior Level Attorney, USPTO, *kevin.amer@uspto.gov,* 571-272–9300; Branden Ritchie, Senior Level Attorney, USPTO, *branden.ritchie@uspto.gov,* 571–272–9300; Andrew Foglia, Senior Counsel, USCO, *afoglia@copyright.gov,* 202–707–8350; or Jenée Iyer, Counsel, USCO, *jiyer@copyright.gov,* 202–707–8350.

SUPPLEMENTARY INFORMATION: On November 23, 2022, the Offices published a notice in the **Federal Register** announcing that the Offices are conducting a joint study regarding issues of intellectual property (IP) law and policy associated with non-fungible tokens (NFTs) in response to a June 9, 2022 request from Senators Patrick Leahy and Thom Tillis. *See* Notice of inquiry; notice of public roundtables, 87 FR 71584 (Nov. 23, 2022). In that notice, the Offices indicated that they are seeking public comments on these matters to assist in their work on IP policy related to NFTs and in conducting the study. To assist in gathering public input, the Offices published questions and sought focused written public comments on various (IP) law and policy issues associated with NFTs. The notice requested written public comments be submitted on or before January 9, 2023. In addition, the Offices announced a series of three public roundtables to allow them to gather further input.

Through this notice, the Offices are extending the period for written public comments until February 3, 2023, to give interested members of the public additional time to submit comments. Previously submitted written comments do not need to be resubmitted.

The Offices are also changing the dates of the three public roundtables. The roundtable on *Trademarks and NFTs* will now be held on Tuesday, January 24, 2023; the roundtable on *Patents and NFTs* will now be held on Thursday, January 26, 2023; and the roundtable on *Copyrights and NFTs* will now be held on Tuesday, January 31, 2023. The deadline for requests to participate as a panelist in one or more of the roundtables is unchanged. Such requests must be received by 11:59 p.m. Eastern Time on December 21, 2022.

All other information and instructions to commenters provided in the November 23, 2022, notice remain unchanged.

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

Shira Perlmutter,

Register of Copyrights and Director, United States Copyright Office.

[FR Doc. 2022–27694 Filed 12–20–22; 8:45 am]

BILLING CODE 3510–16–P; 1410–30–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Quarterly Public Meeting

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Notice of public meeting.

Date and Time: January 31, 2023, from 1 p.m. to 4 p.m., ET.

Place: The meeting will be virtual only via Zoom webinar.

FOR FURTHER INFORMATION CONTACT: Angela Phifer, 355 E Street SW, Suite 325, Washington, DC 20024; (703) 798–5873, or *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Committee for Purchase From People Who Are Blind

or Severely Disabled is an independent government agency operating as the U.S. AbilityOne Commission. It oversees the AbilityOne Program, which provides employment opportunities through Federal contracts for people who are blind or have significant disabilities in the manufacture and delivery of products and services to the Federal Government. The Javits-Wagner-O'Day Act (41 U.S.C. Chapter 85) authorizes the contracts.

Registration: Attendees not requesting speaking time must register not later than 11:59 p.m. ET on January 30, 2023. Attendees requesting speaking time should register not later than 11:59 p.m. ET on January 19, 2023, and use the comment fields in the registration form to specify the intended speaking topic/s. The registration link will be posted on the Commission's home page, *www.abilityone.gov,* not later than January 4, 2023.

Commission Statement: This regular quarterly public meeting will include updates from the Commission Chairperson, Executive Director, and Inspector General. A panel of Federal customers will broadly address, from an overall acquisition perspective, what is important to Federal agencies in terms of contractor performance—whether or not those contracts are awarded under the auspices of the AbilityOne Program. Panelist topics may include but are not limited to quality, timely delivery, best value, innovation, and compliance with cybersecurity and other Federal guidance.

Public Participation: The Commission invites public comments and suggestions about the panel topic, including perspectives on contract performance, quality assurance, and measurement of customer satisfaction. During registration, you may choose to submit comments, or you may request speaking time at the meeting. The Commission may invite some attendees who submit advance comments to discuss their comments during the meeting. Comments submitted will be reviewed by staff and the Commission members before the meeting. Comments posted in the chat box during the meeting will be shared with the Commission members after the meeting. The Commission is not subject to the requirements of 5 U.S.C. 552(b); however, the Commission published this notice to encourage the broadest possible participation in its meeting.

Personal Information: Do not include any information that you do not want publicly disclosed.

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2022–27712 Filed 12–20–22; 8:45 am]

BILLING CODE 6353–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 11 a.m. EST, Monday, December 19, 2022.

PLACE: Virtual meeting.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Enforcement matters. In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.cftc.gov/.*

CONTACT PERSON FOR MORE INFORMATION: Christopher Kirkpatrick, 202–418–5964.

Authority: 5 U.S.C. 552b.

Dated: December 19, 2022.

Christopher Kirkpatrick,

Secretary of the Commission.

[FR Doc. 2022–27818 Filed 12–19–22; 4:15 pm]

BILLING CODE 6351–01–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2022–0085]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (Bureau or CFPB) requests the revision of the Office of Management and Budget's (OMB's) approval of an existing information collection titled ''Evaluation of Financial Empowerment Training Program'' approved under OMB Control Number 3170–0067.

DATES: Written comments are encouraged and must be received on or before February 21, 2023 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: PRA_Comments@cfpb.gov.* Include Docket No. CFPB–2022–0085 in the subject line of the email.
- *Mail/Hand Delivery/Courier:* Comment Intake, Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW, Washington, DC 20552. Because paper mail in the Washington, DC area and at the Bureau is subject to delay, commenters are encouraged to submit comments electronically.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Anthony May, PRA Officer, at (202) 435–7278, or email: *CFPB_PRA@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.* Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Evaluation of Financial Empowerment Training Program.

OMB Control Number: 3170–0067.

Type of Review: Revision of a currently approved collection.

Affected Public: Private sector.

Estimated Number of Respondents: 5,300.

Estimated Total Annual Burden Hours: 1,274.

Abstract: The Bureau's Office of Community Affairs (OCA) is responsible for developing strategies to improve the financial capability of low-income and economically vulnerable consumers, such as consumers who are unbanked or underbanked, those with thin or no credit file, and households with limited savings. To address the needs of these consumers, OCA has developed Your Money, Your Goals, a suite of financial empowerment materials with an accompanying training program. These resources equip frontline staff and volunteers in a range of organizations to provide relevant and effective information, tools, and resources designed to improve the financial outcomes and capability of these consumers. The collection focuses on evaluating Your Money, Your Goals virtual and in-person training practices in enhancing the ability of frontline staff

and volunteers to inform low-income consumers about rights and options for managing their finances and how to prevent and address consumer harm.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB's approval. All comments will become a matter of public record.

Anthony May,

Paperwork Reduction Act Officer, Consumer Financial Protection Bureau.

[FR Doc. 2022–27740 Filed 12–20–22; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2022–OS–0140]

Privacy Act of 1974; System of Records

AGENCY: Under Secretary of Defense for Personnel & Readiness (USD(P&R)), Department of Defense (DoD).

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the DoD is modifying and reissuing a current system of records originally titled, ''Military OneSource Case Management System (CMS),'' DPR 45, which is being renamed as ''Military OneSource Business Operations Information System''. This system of records was originally established by the USD(P&R) to collect and maintain records in the Military OneSource Case Management of individuals' eligibility for support as well as processing training registration, enrollment, requests, and self-motivated education/training for its Learning Management System. The Military OneSource is a call center and website providing comprehensive information on available benefits and services to Active Duty Military, Reserve and National Guard, eligible separated members and their family members. These benefits and services include financial counseling, educational assistance and benefits, relocation planning and preparation, quality of life programs, and family and community programs. In addition to formatting administrative changes, this modification changes the categories of individuals, categories of records, the system location, system manager, authorities, record source categories, policy and practices for storage, record access, contesting and notification procedures, as well as the routine uses within the SORN.

DATES: This system of records modification is effective upon publication; however, comments on the Routine Uses will be accepted on or before January 20, 2023. The Routine Uses are effective at the close of the comment period.

ADDRESSES: You may submit comments, identified by docket number and title, by either of the following methods:

* *Federal Rulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *https://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Rahwa Keleta, Defense Privacy and Civil Liberties Division, Directorate for Privacy, Civil Liberties and Freedom of Information, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Department of Defense, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700; *OSD.DPCLTD@mail.mil;* (703) 571–0070.

SUPPLEMENTARY INFORMATION:

I. Background

The Military OneSource system of records provides service members and their families with access to a wide variety of resources and confidential support in order to weather the demands of military life. In an increasingly technological and mobile world, the Military OneSource offers support 24 hours a day, telephonically as well as online. Subject to public comment, the DoD is updating this SORN to add the standard DoD routine uses (routine uses A through J). Additionally, the following sections of this SORN are being modified as follows: system and number to support the integration of the Military OneSource Case Management System (CMS) into the larger Military OneSource Business Operations Information System technological environment; system location in order to expand the operating environments in support of the Military OneSource Business Operations Information System; system manger to support the dual-designation Military OneSource system manager responsibilities in support of the Military OneSource Business Operations Information System; authorities to include the addition of public law citations and National Defense Authorization Act (NDAA) authorities; the purpose to improve clarity; categories of individuals in order to incorporate those who have been determined, by DoD policy, to be eligible for the web-based services and capabilities; categories of records in order to improve clarity; record sources section incorporates formatting edits; policies and practices for storage to account for the use of Government-validated Cloud Computing environments; safeguards in order to describe additional measures that are employed in support of the Military One Source Business Operations Information System; record access procedures in order to improve clarity; contesting procedures to ensure the correct citation is listed for accessing records, contesting content, and appealing initial agency determinations; notification procedures in order to add clarity.

DoD SORNs have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at the Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency (OATSD(PCLT)) website at *https://dpcld.defense.gov/privacy.*

II. Privacy Act

Under the Privacy Act, a ''system of records'' is a group of records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying

particular assigned to the individual. In the Privacy Act, an individual is defined as a U.S. citizen or lawful permanent resident.

In accordance with 5 U.S.C. 552a(r) and Office of Management and Budget (OMB) Circular No. A–108, the DoD has provided a report of this system of records to the OMB and to Congress.

Dated: December 15, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

SYSTEM NAME AND NUMBER:

Military OneSource Business Operations Information System, DPR 45.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Defense Information Systems Agency (DISA), 6910 Cooper Avenue, Fort Meade, MD 20755–7085, Amazon Web Services (AWS) GovCloud Region, and MC&FP IT and Cyber Operations, 4800 Mark Center Drive, Alexandria, VA 22350–2300.

SYSTEM MANAGER(S):

(1) Under Secretary of Defense for Personnel and Readiness (USD/P&R), Office of the Deputy Assistant Secretary of Defense (DASD) for Military Community and Family Policy (MC&FP), Director, Military Community Support Programs (MCSP), 4800 Mark Center Drive, Suite 14E08, Alexandria, VA 22350–2300.

(2) Under Secretary of Defense for Personnel and Readiness (USD/P&R), Office of the Deputy Assistant Secretary of Defense (DASD) for Military Community and Family Policy (MC&FP), Director, Military Community Outreach (MCO) Directorate, 4800 Mark Center Drive, Alexandria, VA 22350–2300, email: *osd.pentagon.ousd-p-r.mbx.mcfp-mcsp@mail.mil.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness; 10 U.S.C. 1788, Additional Family Assistance; 10 U.S.C. Chapter 88, Military Family Programs and Military Child Care, Subchapter I, Military Family Programs; 10 U.S.C. 53, Miscellaneous Rights and Benefits; Directive-type Memorandum (DTM)–17–004, DoD Expeditionary Civilian Workforce; DoD Directive 1322.18, Military Training; DoD Instruction (DoDI) 1342.22, Military Family Readiness; DoDI 6490.06, Counseling Services for DoD Military, Guard and Reserve, Certain Affiliated Personnel, and Their Family Members; and DoDI 1322.26, Distributed Learning (DL).

PURPOSE(S) OF THE SYSTEM:

The Military OneSource Business Operations Information System drives the technological capabilities that deliver the full ecosystem of Military OneSource web-based services that supports Service members and families throughout their military life, which includes one-year post military transition and survivors. The Military OneSource Business Operations Information System, Military OneSource digital enclave, and Military OneSource Content Management System (CMS) allow for documenting an individual's eligibility for these services; identification of the caller's inquiry or issue to provide a warm hand-off, referral and/or requested information; and the development of a final solution and referral information. The system also allows access to tools and resources such as live chat, appointment scheduling, community resource finder, MilTax software, financial calculators, Morale, Welfare, and Recreation (MWR) Digital Library; personalized moving checklists; training registration, enrollment requests, and self-motivated education/training for its Learning Management System (LMS). Records may be used as a management tool for statistical analysis, tracking, reporting, and evaluating program effectiveness and conducting research.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Active Duty Service members; Reserve and National Guard members; members of the Coast Guard activated as part of the Department of the Navy under Title 10 authority; medically discharged Service members participating in one of the Services Wounded Warrior or Seriously Ill and Injured Programs; those with honorable, other than honorable and general (under honorable conditions) discharges; Retired service members until 365 days past end of tour of service, retirement date or discharge date, including service members on the Temporary Disability Retirement List. Discharged service members (if discharged honorably) until 365 days past end of tour of service, retirement date or discharge date. Coast Guard veterans (if discharged honorably) and their immediate family are eligible from their separation date until 365 days past end of tour of service; Reserve Officer Training Course and Service Academy Cadets; DoD Civilians Expeditionary Workforce Personnel; survivors (surviving spouses who have not remarried and children) of active duty, National Guard and Reserve Service members (regardless of activation status or cause of Service member's death); immediate family members of the groups described above; individuals with a legal responsibility to care for service member's children acting for the benefit of the children; survivors of deceased Service members contacting Military OneSource seeking information, referrals, or non-medical counseling; service providers accessing the LMS.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's full name, DoD ID number, date of birth, gender, gender identification, marital status, relationship to Service member, rank/grade, unit, branch of military Service, official duty address, military status and records (role of individual [*e.g.,* Service Member, Survivor, Family Member, Service Provider] and military installation assigned to), current address and mailing address, emergency contact; participant education information, legal status, mother's middle/maiden name, telephone numbers (work/home/cell/DSN) and participant authorization or refusal to allow incoming/outgoing text messages between participant and Military OneSource, email addresses, participant ID and case number (automatically generated internal numbers not provided to the participant), presenting issue/information requested, handoff type to contractor, handoff notes, if interpretation is requested and the language requested, referrals, and feedback from quality assurance follow-up with participants.

Online Learning Platform: User account name, course history (attempted dates/times, grades), member type, agency, installation, unit, and service provider affiliation.

Non-medical counseling information: Non-medical counseling information includes a brief, non-clinical intake to ascertain the scope of support the participant needs (*e.g.,* to effectively communicate with others).

RECORD SOURCE CATEGORIES:

Records and information stored in this system of records are obtained from:

A. Individual,

B. Military OneSource program officials,

C. Transition Assistance Program (TAP) Data Retrieval Web Service (TDRWS), and

D. Authorized contractors providing advice and support to the individual.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C.

552a(b) of the Privacy Act of 1974, as amended, these records may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal Government when necessary to accomplish an agency function related to this system of records.

B. To the appropriate Federal, State, local, territorial, tribal, foreign, or international law enforcement authority or other appropriate entity where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether criminal, civil, or regulatory in nature.

C. To any component of the Department of Justice for the purpose of representing the DoD, or its components, officers, employees, or members in pending or potential litigation to which the record is pertinent.

D. In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body or official, when the DoD or other Agency representing the DoD determines that the records are relevant and necessary to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

E. To the National Archives and Records Administration for the purpose of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

F. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

G. To appropriate agencies, entities, and persons when (1) the DoD suspects or confirms a breach of the system of records; (2) the DoD determines as a result of the suspected or confirmed breach there is a risk of harm to individuals, the DoD (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the DoD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

H. To another Federal agency or Federal entity, when the DoD determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

I. To another Federal, State or local agency for the purpose of comparing to the agency's system of records or to non-Federal records, in coordination with an Office of Inspector General in conducting an audit, investigation, inspection, evaluation, or some other review as authorized by the Inspector General Act of 1978, as amended.

J. To such recipients and under such circumstances and procedures as are mandated by Federal statute or treaty.

K. To the appropriate Federal, State, local, territorial, tribal, foreign, or international law enforcement authority or other appropriate entity when necessary pursuant to a showing of compelling circumstances affecting the health or safety of an individual.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic storage media. The records may be stored on magnetic disc, tape, or digital media; in agency-owned cloud environments; or in vendor Cloud Service Offerings certified under the Federal Risk and Authorization Management Program (FedRAMP).

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by the participant's or Service members name, date of birth, participant ID, case ID, DoD ID number, phone number, email address, or an LMS account username.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Master database files: Cut off after 3 years of continuous inactivity or notification of discharge, retirement or separation of the Service member. Destroy 10 years after cut off.

Non-medical counseling records: Cut off after 3 years of continuous inactivity or notification of discharge, retirement or separation of the Service member. Destroy 15 years after cut off.

Training records: Cut off annually upon completion of training. Destroy 5 years after cut off.

Call center recordings: Cut off after referral to non-medical counseling, employee assistance program support, information and referral. Destroy 90 days after cut off.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The DoD safeguards records in this system of records according to applicable rules, policies, and procedures, including all applicable DoD automated systems security and access policies. DoD policies require the use of controls to minimize the risk of compromise of personally identifiable information (PII) in paper and electronic form and to enforce access by those with a need to know and with appropriate clearances. Additionally, the DoD established security audit and accountability policies and procedures which support the safeguarding of PII and detection of potential PII incidents. The DoD routinely employs safeguards such as the following to information systems and paper recordkeeping systems: records are maintained in a secure building in a controlled area accessible only to authorized personnel. Physical entry is restricted by the use of locks, passwords, and administrative procedures, which are changed periodically. The system is designed with access controls, comprehensive intrusion detection, and virus protection. Access to personally identifiable information in this system is role-based and restricted to those requiring the data in the performance of their official duties and completing annual information assurance and privacy training. Records are encrypted during transmission to protect session information, and while not in use (data at rest).

RECORDS ACCESS PROCEDURES:

Individuals seeking access to information about themselves or their minor legal dependent(s) in this record system should address inquiries in writing to the Office of the Secretary of Defense/Joint Staff Freedom of Information Act Requester Service Center, 1155 Defense Pentagon, Washington, DC 20701–1155. Signed, written requests should include the individual's full name (First, Middle, Last), all other names used, current address, telephone number, email address, date of birth (YYYYMMDD), and the name and number of this system of records notice (SORN). In addition, the requester must provide either a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the appropriate format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the

foregoing is true and correct. Executed on (date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

CONTESTING RECORD PROCEDURES:

The DoD rules for accessing records, contesting contents, and appealing initial Component determinations are contained in 32 CFR part 310, or may be obtained from the system manager.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system of records should follow the instructions for Record Access Procedures above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

January 24, 2017, 82 FR 8182; February 11, 2015, 80 FR 7579; October 15, 2014, 79 FR 61854.

[FR Doc. 2022–27671 Filed 12–20–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2022–SCC–0125]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Annual State Application Under Part B of the Individuals With Disabilities Act as Amended in 2004

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before January 20, 2023.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link *www.reginfo.gov/public/do/PRAMain* to access the site. Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Jennifer Simpson, 202–245–6042.

SUPPLEMENTARY INFORMATION: The Department 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: Annual State Application Under Part B of the Individuals with Disabilities Act as Amended in 2004.

OMB Control Number: 1820–0030.

Type of Review: An extension without change of a currently approved ICR.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 60.

Total Estimated Number of Annual Burden Hours: 2,340.

Abstract: The Individuals with Disabilities Education Act, signed on December 3, 2004, became Public Law 108–446. In accordance with 20 U.S.C. 1412(a) a State is eligible for assistance under Part B for a fiscal year if the State submits a plan that provides assurances to the Secretary that the State has in effect policies and procedures to ensure that the State meets each of the conditions found in 20 U.S.C. 1412. Information Collection 1820–0030 is being extended so that a State can provide assurances that it either has or does not have in effect policies and procedures to meet the eligibility requirements of Part B of the Act as found in Public Law 108–446. Information Collection 1820–0030 corresponds with 34 CFR 300.100–176; 300.199; 300.640–645; 300.646–647 and 300.705. These sections include the requirement that the Secretary and local educational agencies located in the State be notified of any State-imposed rule, regulation, or policy that is not required by this title and Federal regulations.

In addition, Information Collection 1820–0300 is being updated to make a nonsubstantive change to the application template to address a statement that is referenced in two places in the application document. The statement appears under Section II.C. (Certifications), item number two and is also referenced under Section II.D (Statement). This statement pertains to a provision, under the Education Department General Administrative Regulations (EDGAR) at 34 CFR 76.104, relating to State eligibility, authority and approval to submit and carry out the provisions of its State application, and consistency of that application with State law are in place within the State. The purpose of the nonsubstantive change is to remove the statement from under Section II.C. (Certifications) in order to eliminate the duplication of the statement within the application template.

Dated: December 16, 2022.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–27709 Filed 12–20–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

List of Federal Education Assistance for Proprietary Institutions of Higher Education To Include as Federal Revenue

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

SUMMARY: This notice lists the Federal education assistance funds for qualifying students that proprietary institutions of higher education must include as Federal revenue in their non-Federal revenue calculation (known as ''90/10'').

DATES: Institutions must include these Federal education funds in their 90/10 calculations for fiscal years beginning on or after January 1, 2023.

FOR FURTHER INFORMATION CONTACT: Ashley Clark, U.S. Department of Education, 400 Maryland Avenue SW, Room 2C185, Washington, DC 20202. Telephone: (202) 453–7977. Email: *Ashley.Clark@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Background: On October 28, 2022, the Department published final regulations amending 34 CFR 668.28, ''Non-Federal Education Assistance Funds (90/10).'' [1] The final regulations implemented amendments to sections 487(a) and (d) of the Higher Education Act of 1965, as amended (HEA), made by the American Rescue Plan Act of 2021 (ARP).[2] Sections 487(a) and (d) govern how proprietary institutions of higher education (''institutions'') must calculate their non-Federal revenue percentage (*e.g.,* the 90/10 calculation).[3] Per section 487(a) of the HEA, institutions must derive not less than 10 percent of their revenue from sources other than Federal education assistance funds that are disbursed or delivered to or on behalf of a student to attend the institution. The statutory change requires that institutions count all Federal education assistance funds as Federal revenue in their 90/10 calculation for fiscal years beginning on or after January 1, 2023. Regulations at 34 CFR 668.28 identify the types of funds that institutions must treat as Federal and non-Federal revenue. 34 CFR 668.28(a)(1)(i) provides that the Secretary will identify Federal education assistance funds, by agency, to assist proprietary institutions in complying with the 90/10 requirement. The Department is publishing this notice in the **Federal Register** in accordance with § 668.28(a)(1)(i), and we will publish updates to this list for subsequent fiscal years as needed.

List of Federal education assistance funds: The Department surveyed Federal agencies to compile this list of Federal education assistance funds. In accordance with the definition of Federal education assistance funds in § 668.28, this list includes Federal funds that may be disbursed directly to an institution; disbursed to a student for purposes of paying tuition, fees, or other institutional charges; or comingled with non-Federal funds in a disbursement made by a non-Federal public agency, regardless of whether proprietary institutions are currently eligible. Information obtained by the Department indicated that most education assistance funds are disbursed directly to an institution for specific students, and, therefore, the institution should be aware of and able to account for these funds. For the programs that disburse Federal funds directly to students, institutions are expected to determine if any students making payments to the institution are receiving Federal education funds from the listed sources and use that information to accurately calculate the percentage of their revenue derived from non-Federal sources.[4]

The statute requires institutions to include all Federal education assistance funds in their 90/10 calculation. If an institution is aware of Federal education assistance funds not included on this list that were provided either to the institution or directly to a student to cover tuition and fees or other institutional charges, the institution must obtain the necessary information to account for those funds in its 90/10 revenue calculation. If Federal education assistance funds are comingled with other types of aid and the institution cannot determine what portion of the funds are from a Federal entity, the funds should not be included in either the numerator or denominator of the revenue calculation. Institutions should document for their records how they determine whether students are receiving federal education assistance from these programs.

Note that the following list of sources of Federal education funds is in addition to title IV, HEA program funds, which existing regulations already require institutions to include in the 90/10 calculation.

Department of Agriculture:

- National Institute of Food and Agriculture (NIFA): Agriculture and Food Research Initiative Predoctoral Fellowships

Department of Commerce:

- Hollings Scholarship Program
- National Oceanic and Atmospheric Administration (NOAA) Educational Partnership Program with Minority Serving Institutions, Cooperative Science Centers Direct Student Support
- NOAA Educational Partnership Program with Minority Serving Institutions, Graduate Fellowship Program
- NOAA Educational Partnership Program with Minority Serving Institutions, Undergraduate Scholarship Program

Department of Defense:

- Advanced Civil Schooling
- Army/Navy/Air Force Health Professions Scholarship Program
- Civilian Career Program/Civilian Tuition Assistance
- Credentialing Assistance
- Military Spouse Career Advancement Account (MyCAA)
- Military Tuition Assistance
- Navy Advanced Education Voucher Program
- Navy Graduate Education Voucher
- Navy Seaman to Admiral
- Reserve Officers' Training Corps (ROTC) Scholarships

Department of Education:

- Leadership Consortia in Sensory Disabilities and Disabilities Associated with Intensive Service Needs
- Perkins V (including the Native American Career and Technical Education Program and the Native Hawaiian Career and Technical Education Program)
- Personnel Preparation in Special Education, Early Intervention, and Related Services for Personnel Serving Children with Disabilities
- Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel
- Statewide Models for Ensuring That Special Education Students in Inclusive Schools are Served by Highly Qualified Teachers
- Workforce Investment Opportunity Act (WIOA) Title II (Adult Education and Family Literacy Act)

Department of Health and Human Services:

- Addiction Medicine Fellowship Program (AMF)
- Advanced Nursing Education; Nurse Practitioner Residency Integration Program (ANE–NPRIP)
- Advanced Nursing Education; Nurse Practitioner Residency Program (ANE–NPR)
- Advanced Nursing Education Workforce (ANEW)
- Behavioral Health Workforce Education and Training Program for Paraprofessionals (BHWET)
- Behavioral Health Workforce Education and Training Program for Professionals (BHWET)
- Chafee Education and Training Vouchers

[1] 87 FR 65426.

[2] Public Law 117–2.

[3] Public Law 110–315, as amended.

[4] See 87 FR at 65446 (''For purposes of 90/10, we understand that proprietary institutions need a basis to calculate the Federal funds disbursed directly to its students. The Department considers a certification from an agency describing the Federal funds that a student received as a sufficient basis for this calculation. In cases where an agency does not provide this information to an institution, we will evaluate on a case-by-case basis whether the institution made a good-faith effort to obtain this information, including if a student certifies that they received Federal funds and the amount of funds received.''). See also 87 FR at 65451–52 (''Although institutions must exclude funds for which they cannot determine the breakdown, we expect institutions to attempt to determine the Federal and non-Federal breakdown of grant funds. The Department would evaluate whether the institution sufficiently attempted to determine the Federal and non-Federal components of grant funds on a case-by-case basis . . . when the institution is unable to obtain this breakdown.'')

- Children's Hospitals Graduate Medical Education Program (CHGME)
- Dental Faculty Loan Repayment Program (DFLRP)
- Geriatric Workforce Enhancement Program (GWEP)
- Graduate Psychology Education Program (GPE)
- Health Careers Opportunity Program (HCOP)
- Indian Health Professions (IHS) Section 103 Scholarships
- IHS Section 104 Scholarships
- Indian Health Service
- Indians Into Medicine
- Integrated Substance Use Disorder Training Program (ISTP)
- Medical Student Education (MSE)
- Native Hawaiian Health Scholarship Program (NHHSP)
- National Health Service Corps Scholarship Program (NHSC SP)
- Non-National Research Service Award Predoctoral Fellowships
- Nurse Anesthetist Traineeship (NAT)
- Nurse Corps Scholarship Program
- Nurse Education, Practice, Quality and Retention; Registered Nurses in Primary Care (NEPQR–RNPC)
- Nurse Education, Practice, Quality and Retention; Veteran Nurses in Primary Care Training Program (VNPC)
- Nursing Workforce Diversity (NWD)
- Nursing Workforce Diversity; Eldercare Enhancement (NWD–E2)
- Oral Health Training: Predoctoral Training in General, Pediatric and Public Health Dentistry
- Primary Care Training and Enhancement; Physician Assistant Rural Training Program (PCTE–PAT)
- Public Health Training Centers (PHTC)
- Non-National Research Service Award Training Grants
- Opioid-Impacted Family Support Program (OIFSP)
- Preventative Medicine Residency Program (PMR)
- Public Health Scholarship Program (PHSP)
- Scholarships for Disadvantaged Students (SDS)
- Ruth L. Kirschstein National Research Service Award Institutional Research Training Grants
- Ruth L. Kirschstein National Research Service Award Predoctoral Fellowships
- Temporary Assistance to Needy Families

Department of Labor:

- H–1B Skills Training Grants
- Reentry Employment Opportunities
- Strengthening Community Colleges
- Trade Adjustment Assistance
- WIOA Title I (Adult, Dislocated Worker, and Youth)
- YouthBuild

Department of Transportation:

- Federal Highway Administration; Dwight David Eisenhower Transportation Fellowship Program (DDETFP)
- Maritime Administration; Direct Payments State Maritime Academies (SMA)
- Maritime Administration; Student Incentive Program
- Maritime Administration; United States Merchant Marine Academy

Department of Veterans Affairs:

- All-Volunteer Force Educational Assistance (also known as Montgomery GI Bill; Active Duty)
- Marine Gunnery Sergeant John David Fry Scholarship
- Montgomery GI Bill Selected Reserve; Reserve Educational Assistance Program
- National Call to Service Program
- Post-9/11 Veterans Educational Assistance (also known as Post-9/11 GI Bill)
- Post-Vietnam Era Veterans' Educational Assistance Program
- Survivors and Dependents Educational Assistance
- Veteran Employment Through Technology Education Courses (VET TEC)
- Veteran Rapid Retraining Assistance Program
- Veteran Readiness and Employment (formerly Vocational Rehabilitation)

Nuclear Regulatory Commission:

- University Nuclear Leadership Program

Accessible Format: On request to the person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

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 Department documents 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.

Nasser H. Paydar,

Assistant Secretary, Office of Postsecondary Education.

[FR Doc. 2022–27732 Filed 12–20–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG23–30–000.

Applicants: Chesapeake Solar Project, LLC.

Description: Chesapeake Solar Project, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 12/14/22.

Accession Number: 20221214–5204.

Comment Date: 5 p.m. ET 1/4/23.

Docket Numbers: EG23–31–000.

Applicants: East Point Energy Center, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of East Point Energy Center, LLC.

Filed Date: 12/14/22.

Accession Number: 20221214–5209.

Comment Date: 5 p.m. ET 1/4/23.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18–2358–000.

Applicants: GridLiance High Plains LLC, Southwest Power Pool, Inc.

Description: Refund Report: Southwest Power Pool, Inc. submits tariff filing per 35.19a(b): GridLiance—Second Refund Report in Response to Order issued in ER18–2358 to be effective N/A.

Filed Date: 12/15/22.

Accession Number: 20221215–5003.

Comment Date: 5 p.m. ET 1/5/23.

Docket Numbers: ER22–1839–000.

Applicants: Panther Creek Power Operating, LLC.

Description: Refund Report: Refund Report to be effective N/A.

Filed Date: 12/15/22.

Accession Number: 20221215–5015.

Comment Date: 5 p.m. ET 1/5/23.

Docket Numbers: ER22–1850–001.

Applicants: ISO New England Inc., The United Illuminating Company.

Description: Compliance filing: ISO New England Inc. submits tariff filing

per 35: The United Illuminating Company; Docket No. ER22–1850—Rev. to Schedule 21–UI to be effective 1/27/2020.

Filed Date: 12/15/22.

Accession Number: 20221215–5056.

Comment Date: 5 p.m. ET 12/27/22.

Docket Numbers: ER22–2867–001.

Applicants: Bluegrass Solar, LLC.

Description: Tariff Amendment: Response to Deficiency Letter in Docket ER22–2867 to be effective 10/1/2022.

Filed Date: 12/15/22.

Accession Number: 20221215–5028.

Comment Date: 5 p.m. ET 1/5/23.

Docket Numbers: ER23–258–001.

Applicants: Palmer Solar, LLC.

Description: Tariff Amendment: Amendment Filing to be effective 12/28/2022.

Filed Date: 12/15/22.

Accession Number: 20221215–5095.

Comment Date: 5 p.m. ET 1/5/23.

Docket Numbers: ER23–630–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2022–12–14_Attachment Y Process Improvements to be effective 2/13/2023.

Filed Date: 12/14/22.

Accession Number: 20221214–5131.

Comment Date: 5 p.m. ET 1/4/23.

Docket Numbers: ER23–631–000.

Applicants: San Diego Gas & Electric Company.

Description: § 205(d) Rate Filing: 2023 TACBAA Update to be effective 1/1/2023.

Filed Date: 12/14/22.

Accession Number: 20221214–5135.

Comment Date: 5 p.m. ET 1/4/23.

Docket Numbers: ER23–632–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: Compliance filing: Cost Based Rate Tariff to be effective 3/7/2022.

Filed Date: 12/14/22.

Accession Number: 20221214–5153.

Comment Date: 5 p.m. ET 1/4/23.

Docket Numbers: ER23–633–000.

Applicants: Westlands Transmission, LLC.

Description: § 205(d) Rate Filing: Second Amended TSA with Westlands Solar Blue, LLC to be effective 12/15/2022.

Filed Date: 12/14/22.

Accession Number: 20221214–5158.

Comment Date: 5 p.m. ET 1/4/23.

Docket Numbers: ER23–634–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Allow LREs to Use Deliverable Capacity to Meet Winter Season Obligation to be effective 2/14/2023.

Filed Date: 12/15/22.

Accession Number: 20221215–5037.

Comment Date: 5 p.m. ET 1/5/23.

Docket Numbers: ER23–635–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Attachment Y to Update the Transmission Owner Selection Process to be effective 2/14/2023.

Filed Date: 12/15/22.

Accession Number: 20221215–5055.

Comment Date: 5 p.m. ET 1/5/23.

Docket Numbers: ER23–636–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Add a Process to Allow an Exemption of the Deficiency Payment to be effective 2/14/2023.

Filed Date: 12/15/22.

Accession Number: 20221215–5062.

Comment Date: 5 p.m. ET 1/5/23.

Docket Numbers: ER23–637–000.

Applicants: ISO New England Inc., NSTAR Electric Company.

Description: § 205(d) Rate Filing: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii: NSTAR Electric Company; Request for Updated Depreciation Rates in App D to Att F to be effective 1/1/2023.

Filed Date: 12/15/22.

Accession Number: 20221215–5065.

Comment Date: 5 p.m. ET 1/5/23.

Docket Numbers: ER23–638–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3774R1 The Energy Authority and MEAN Meter Agent Agreement to be effective 4/1/2023.

Filed Date: 12/15/22.

Accession Number: 20221215–5085.

Comment Date: 5 p.m. ET 1/5/23.

Docket Numbers: ER23–639–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 4036 Southwestern Power Admin & People's Electric Inter Agr to be effective 1/1/2023.

Filed Date: 12/15/22.

Accession Number: 20221215–5092.

Comment Date: 5 p.m. ET 1/5/23.

Docket Numbers: ER23–640–000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii: City of Troy NITSA Amendment Filing (Update Network Resource) to be effective 11/30/2022.

Filed Date: 12/15/22.

Accession Number: 20221215–5093.

Comment Date: 5 p.m. ET 1/5/23.

Docket Numbers: ER23–641–000.

Applicants: R–WS Antelope Valley Gen-Tie, LLC.

Description: § 205(d) Rate Filing: Assignment and Assumptions of Co-Tenancy Interests in Shared Facilities to be effective 12/16/2022.

Filed Date: 12/15/22.

Accession Number: 20221215–5120.

Comment Date: 5 p.m. ET 1/5/23.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 15, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–27721 Filed 12–20–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC22–23–000]

Commission Information Collection Activities (FERC–516a); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–516A (Standardization of Small Generator Interconnection Agreements and Procedures) which will be submitted to the Office of Management and Budget (OMB) for a review of the information collection requirements.

DATES: Comments on the collection of information are due January 20, 2023.

ADDRESSES: Send written comments on FERC–516A to OMB through *www.reginfo.gov/public/do/PRAMain,* Attention: Federal Energy Regulatory Commission Desk Officer. Please identify the OMB control number (1902–0203) in the subject line. Your comments should be sent within 30 days of publication of this notice in the **Federal Register**.

Please submit copies of your comments (identified by Docket No. IC22–23–000) to the Commission as noted below. Electronic filing through *http://www.ferc.gov* is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery.

○ *Mail via U.S. Postal Service Only:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

○ *Hand (including courier) delivery:* Deliver to: Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: OMB submissions must be formatted and filed in accordance with submission guidelines at *www.reginfo.gov/public/do/PRAMain;* Using the search function under the ''Currently Under Review field,'' select Federal Energy Regulatory Commission; click ''submit'' and select ''comment'' to the right of the subject collection.

FERC submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov* and telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–516A, Standardization of Small Generator Interconnection Agreements and Procedures.

OMB Control No.: 1902–0203.

Type of Request: Three-year extension of the FERC–516A information collection requirements with no changes to the current reporting requirements.[1]

Abstract: Sections 205 and 206 of the Federal Power Act (FPA) (16 U.S.C. 824d and 824e) require the Commission to ensure just and reasonable electric transmission rates and charges, and ensure that jurisdictional providers do not subject any person to any undue prejudice or disadvantage. In order to implement these Commission responsibilities, the regulation at 18 CFR 35.28(f)(1) requires transmission providers to include the following information in their open-access transmission tariffs (OATTs): [2]

- Commission-approved, standard, *pro forma* interconnection procedures (*i.e.,* small generator interconnection procedures or SGIP); and
- A single, uniformly applicable interconnection agreement (*i.e.,* a small generator interconnection agreement or SGIA).

This information helps the Commission ensure that transmission providers consider and process interconnection requests by small generators consistently and in compliance with the FPA.

Type of Respondents: Jurisdictional transmission service providers and interconnection customers.

Estimate of Annual Burden: [3] The Commission estimates the annual public reporting burden for the information collection as follows:

Requirements [4]	Number of respondents annually (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden & cost per response [5] (4)	Total annual burden hours & total annual cost (3) * (4) = (5)	Cost per respondent ($) (5) ÷ (1)
Maintenance of Documents—Transmission Providers.	46	1	46	1 hr.; $87.00	46 hrs.; $4,002	$87.00
Filing of Agreements—Transmission Providers.	95	1	95	25 hrs.; $2,175.00	2,375 hrs.; $206,625	2,175.00
Pre-Application Report—Interconnection Customers [6].	800	1	800	1 hr.; $87.00	800 hrs.; $69,600	87.00
Pre-Application Report—Transmission Providers.	142	6	852	2.5 hrs.; $217.50	2,130 hrs.; $185,310	1,305
Supplemental Review—Interconnection Customers.	500	1	500	0.5 hr.; $43.50	250 hrs.; $21,750	43.50
Supplemental Review—Transmission Providers.	142	3.52	*500	20 hrs.; $1,740.00	10,000 hrs.; $870,000	*6,126.76

[1] This information collection request does not include the revisions in the information collection request involving FERC–516 and FERC–516A in the proposed rule in FERC Docket No. RM22–14–000.

[2] The regulation at 35.28(c)(1) requires an OATT ''of general applicability'' for every public utility that owns, controls, or operates facilities used for the transmission of electric energy in interstate commerce. The OATT must be the *pro forma* tariff promulgated by the Commission, as amended from time to time, or such other tariff as may be approved by the Commission consistent with the principles set forth in Commission rulemaking proceedings promulgating and amending the *pro forma* tariff.

[3] The Commission defines burden as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, see 5 CFR 1320.3.

[4] All requirements for transmission providers are mandatory. All requirements for interconnection customers are voluntary.

[5] Commission staff assumes that the average hourly cost (including wages and benefits) for the industry is comparable to the $87.00 average hourly cost in FY2021 (including wages and benefits) for Commission employees.

[6] We assume each request for a pre-application report corresponds with one Interconnection Customer.

Requirements [4]	Number of respondents annually (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden & cost per response [5] (4)	Total annual burden hours & total annual cost (3) * (4) = (5)	Cost per respondent ($) (5) ÷ (1)
Review of Required Upgrades—Interconnection Customers.	250	1	250	1 hr.; $87.00	250 hrs.; $21,750	87.00
Review of Required Upgrades—Transmission Providers.	142	1.76	250	2 hrs.; $174	500 hrs.; $43,500	*306.34
Totals			3,293		16,351 hrs.; $1,422,537	

* (rounded).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: December 15, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–27719 Filed 12–20–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2165–040]

Alabama Power Company; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Recreation Management Plan Update.

b. *Project No:* 2165–040.

c. *Date Filed:* April 29, 2022.

d. *Applicant:* Alabama Power Company.

e. *Name of Project:* Warrior River Hydroelectric Project.

f. *Location:* The project is located on the Black Warrior River and the Sipsey Fork, a headwater tributary to the Black Warrior River, in Cullman, Walker, Winston, and Tuscaloosa Counties, Alabama. The project occupies federal lands managed by the U.S. Forest Service and the Bureau of Land Management.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* David Anderson, Alabama Power Company, 600 N 18th Street, Birmingham, AL 35203; telephone (205) 257–1398; or email *dkanders@southernco.com.*

i. *FERC Contact:* Mark Ivy, (202) 502–6156, or *mark.ivy@ferc.gov.*

j. *Deadline for filing comments, motions to intervene, and protests:* January 17, 2023.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include the docket number P–2165–040. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The licensee filed a Recreation Management Plan update, which includes a description and of the recreation facilities at each project recreation site, a discussion of the methods used to gather recreation use data; a process for determining recreational needs at the project, criteria for decommissioning required recreation sites, a report of recreation use at each site, and documentation of consultation with stakeholders. The plan also includes a request to modify the requirement to conduct recreation monitoring and to file plan updates from every six years to every ten years over the remaining license term. Additionally, the licensee requests to remove the Exhibit R drawings from the plan, to replace them with the as-built drawings included in Appendix D of the updated plan, and to modify the requirement for any future drawings to use the as-built format.

l. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should

so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: December 15, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–27718 Filed 12–20–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 6898–003]

Shenandoah Hydro Company, The Dam, LLC; Notice of Transfer of Exemption

1. On October 31, 2022, Shenandoah Hydro Company, exemptee for the 300-kilowatt Chapman Dam Hydroelectric Project No. 6898, filed a letter notifying the Commission that the project was transferred from Shenandoah Hydro Company to The Dam, LLC. The exemption from licensing was originally issued on June 9, 1983.[1] The project is located on the North Fork of the Shenandoah River, Shenandoah County, Virginia. The transfer of an exemption does not require Commission approval.

The Dam, LLC is now the exemptee of the Chapman Dam Hydroelectric Project No. 6898. All correspondence must be forwarded to Mr. Benjamin C. and Mrs. Susan F. Freakley, The Dam, LLC, 375 Morning Star Lane, Woodstock, VA 22664.

Dated: December 15, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–27717 Filed 12–20–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP23–285–000

Applicants: Maritimes & Northeast Pipeline, L.L.C.

Description: § 4(d) Rate Filing: Name Change Clean-up Filing to be effective 1/16/2023.

Filed Date: 12/15/22.

Accession Number: 20221215–5014.

Comment Date: 5 p.m. ET 12/27/22.

Docket Numbers: RP23–286–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: AGT Name Change Cleanup to be effective 1/16/2023.

Filed Date: 12/15/22.

Accession Number: 20221215–5024.

Comment Date: 5 p.m. ET 12/27/22.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP21–1187–010.

Applicants: Eastern Gas Transmission and Storage, Inc.

Description: Compliance filing: EGTS—December 15, 2022 Rate Case Compliance Filing to be effective 4/1/2022.

Filed Date: 12/15/22.

Accession Number: 20221215–5012.

Comment Date: 5 p.m. ET 12/27/22.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 15, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–27720 Filed 12–20–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10279–01–R2]

Proposed CERCLA Cost Recovery Settlement for the Jewett White Lead Company Superfund Site, Located on Staten Island, Richmond County, New York

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: In accordance with the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (''CERCLA''), notice is hereby given by the U.S. Environmental Protection Agency (''EPA''), Region 2, of a proposed cost recovery settlement agreement (''Settlement'') pursuant to CERCLA with NL Industries, Inc. (''NL''), Moran Towing Corporation and Moran Shipyard Corporation (jointly referred to as ''Moran''), and Perfetto Realty, Co. Inc. (collectively, the ''Settling Parties'') for the Jewett White Lead Company Superfund Site, located on Staten Island, Richmond County, New York (the ''Site'').

DATES: Comments must be submitted on or before January 20, 2023.

ADDRESSES: Requests for copies of the proposed Settlement and the

[1] *Shenandoah Hydro Company,* 23 FERC ¶ 62,032 (1983).

submission of comments must be via electronic mail. Comments should reference the Jewett White Lead Company Superfund Site, Index No. CERCLA–02–2023–2007. For those unable to communicate via electronic mail, please contact the EPA employee identified below.

FOR FURTHER INFORMATION CONTACT: Henry Guzman, Assistant Regional Counsel, Office of Regional Counsel, U.S. Environmental Protection Agency, 290 Broadway, 17th Floor, New York, NY 10007–1866. Email: *guzman.henry@epa.gov* Telephone: 212–637–3166.

SUPPLEMENTARY INFORMATION: The Settling Parties will pay a total of $1,000,000 to the EPA Hazardous Substance Superfund in reimbursement of EPA's past response costs paid in connection with the Site. Moran shall pay $200,000, NL shall pay $600,000, and Perfetto shall pay $200,000. These payments shall be made within thirty (30) days of the effective date of the Settlement. The Settlement includes a covenant by EPA not to sue or to take administrative action against the Settling Parties pursuant to section 107(a) of CERCLA, 42 U.S.C. 9607(a), to recover EPA's past response costs as provided in the Settlement. For thirty (30) days following the date of publication of this notice, EPA will accept any written comments relating to the Settlement. EPA will consider all comments received and may modify or withdraw its consent to the Settlement if comments received disclose facts or considerations that indicate that the proposed Settlement is inappropriate, improper, or inadequate. EPA's response to any comments received will be available for public inspection at EPA Region 2, 290 Broadway, New York, New York 10007–1866.

Pasquale Evangelista,

Director, Superfund & Emergency Management Division, Environmental Protection Agency, Region 2.

[FR Doc. 2022–27742 Filed 12–20–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2022–0918; FRL–10490–01–OCSPP]

Cumulative Risk Assessment; Science Advisory Committee on Chemicals (SACC); Request for Nominations of ad hoc Expert Reviewers and Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or ''Agency'') is seeking public nominations of scientific and technical experts that EPA can consider for service as *ad hoc* reviewers assisting the Science Advisory Committee on Chemicals (SACC) with the peer review of two draft documents entitled: ''Draft Proposed Principles of Cumulative Risk Assessment Under the Toxic Substances Control Act'' and ''Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer Requested Phthalate Under the Toxic Substance Control Act.'' The two draft documents will be submitted to the SACC and released for public review and comment in late February 2023. EPA is also announcing the scheduling of a 4-day virtual public meeting for the SACC to consider and review the two draft documents.

DATES: The following is a chronological listing of the dates for the specific activities that are described in more detail under **SUPPLEMENTARY INFORMATION**.

January 20, 2023—Deadline for submitting all nominations to EPA.

April 24, 2023—Deadline for submitting a request for special accommodations to allow EPA time to process the request before the meeting.

May 8 to 11, 2023, from 10:00 a.m. to approximately 5:30 p.m. (ET)—The public virtual meeting will be held via a webcast platform such as ''Zoom.gov'' and audio teleconference, and you must register to receive the links.

ADDRESSES:

Nominations: Submit your nominations to the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**.

Special accommodations: For information on meeting access or services for individuals with disabilities, and to request accommodation for a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Contact the DFO, Dr. Alaa Kamel, Mission Support Division, Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency; telephone number: (202) 564–5336 or call the SACC main office at (202) 564–8450; email address: *kamel.alaa@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. What action is the Agency taking?

The Agency is seeking public nominations of scientific and technical experts that EPA can consider for service as *ad hoc* reviewers assisting the Science Advisory Committee on Chemicals (SACC) with the peer review of two draft documents entitled: ''Draft Proposed Principles of Cumulative Risk Assessment Under the Toxic Substances Control Act'' and ''Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer Requested Phthalate Under the Toxic Substance Control Act.'' EPA is also announcing the scheduling of a 4-day virtual public meeting for the SACC to consider and review the two draft documents. EPA will be soliciting comments from the SACC on the two draft documents on issues related to chemical grouping for purposes of CRA, health outcomes related to phthalate syndrome, and possible approaches to developing the cumulative hazard and exposure assessment for High-Priority phthalates and a Manufacturer-Requested phthalate.

This document provides instructions for submitting nominations for *ad hoc* reviewers, requesting special accommodations for the virtual public meeting, and accessing the materials provided to the SACC. EPA will publish a separate document in the **Federal Register** in late February 2023 to announce the availability of and solicit public comment on the two draft documents, and instructions for submitting comments, and registering to provide oral comments.

B. What is the Agency's authority for taking this action?

The SACC was established by EPA in 2016 in accordance with the Toxic Substances Control Act (TSCA) section 26(o), 15 U.S.C. 2625(o), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Public Law 114–182, June 22, 2016, to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of TSCA. The SACC operates in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. appendix 2 *et seq.,* and supports activities under the TSCA, 15 U.S.C. 2601 *et seq.,* the Pollution Prevention Act (PPA), 42 U.S.C. 13101 *et seq.,* and other applicable statutes.

C. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to those involved in the manufacture, processing, distribution, and disposal of chemical substances and mixtures, and/or those interested in the assessment of risks involving chemical substances and mixtures regulated under TSCA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

D. What should I consider as I submit my nominations to EPA?

1. *Submitting CBI.* Do not submit CBI or other sensitive information to EPA through *https://www.regulations.gov* or email. If your nomination contains any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting that information. For inclusion in the public docket, please submit a copy of the nomination that does not contain the information you consider to be CBI or otherwise protected.

2. *Tips for preparing comments.* When preparing and submitting your comments, see Tips for Effective Comments at *https://www.epa.gov/dockets.*

II. Nominations for ad hoc Reviewers

A. What is the purpose of the SACC?

The SACC provides independent scientific advice and recommendations to the EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated under TSCA. The SACC is comprised of experts in toxicology; environmental risk assessment; exposure assessment; and related sciences (*e.g.,* synthetic biology, pharmacology, biotechnology, nanotechnology, biochemistry, biostatistics, physiologically based pharmacokinetic modelling (PBPK), computational toxicology, epidemiology, environmental fate, and environmental engineering and sustainability). The SACC currently consists of 17 members. When needed, the committee will be assisted by *ad hoc* reviewers with specific expertise in the topics under consideration.

B. Why is EPA seeking nominations for ad hoc reviewers?

As part of a broader process for developing a pool of candidates for SACC peer reviews, EPA is asking the public and stakeholder communities for nominations of scientific and technical experts that EPA can consider as prospective candidates for service as *ad hoc* reviewers assisting the SACC with the peer reviews. Any interested person or organization may nominate qualified individuals for consideration as prospective candidates for this review by following the instructions provided in this document. Individuals may also self-nominate.

Those who are selected from the pool of prospective candidates will be invited to attend the public meeting and to participate in the discussion of key issues and assumptions at the meeting. In addition, they will be asked to review and to help finalize the meeting minutes.

C. What expertise is sought for this peer review?

Individuals nominated for this SACC peer review, should have expertise in one or more of the following areas: Chemical mixtures risk assessment (especially with experience using dose additive component-based mixtures approaches, including relative potency factors); mode of action (MOA); phthalate toxicology; male reproductive toxicology; exposure assessment (occupational, consumer, and general population exposure); biomonitoring data; and biostatistics. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments on the scientific issues for this review.

D. How do I make a nomination?

By the deadline indicated under **DATES**, submit your nomination to the DFO listed under **FOR FURTHER INFORMATION CONTACT**. Each nomination should include the following information: Contact information for the person making the nomination; name, affiliation, and contact information for the nominee; and the disciplinary and specific areas of expertise of the nominee.

E. Will ad hoc reviewers be subjected to an ethics review?

SACC members and *ad hoc* reviewers are subject to the provisions of the Standards of Ethical Conduct for Employees of the Executive Branch at 5 CFR part 2635, conflict of interest statutes in title 18 of the United States Code and related regulations. In anticipation of this requirement, prospective candidates for service on the SACC will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidate's employment, stocks and bonds, and where applicable, sources of research support. EPA will evaluate the candidates' financial disclosure forms to assess whether there are financial conflicts of interest, appearance of a loss of impartiality, or any prior involvement with the development of the documents under consideration (including previous scientific peer review) before the candidate is considered further for service on the SACC.

F. How will EPA select the ad hoc reviewers?

The selection of scientists to serve as *ad hoc* reviewers for the SACC is based on the function of the Committee and the expertise needed to address the Agency's charge to the Committee. No interested scientists shall be ineligible to serve by reason of their membership on any other advisory committee to a federal department or agency or their employment by a federal department or agency, except EPA. Other factors considered during the selection process include availability of the prospective candidate to fully participate in the Committee's reviews, absence of any conflicts of interest or appearance of loss of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of loss of impartiality, lack of independence, and bias may result in non-selection, the absence of such concerns does not assure that a candidate will be selected to serve on the SACC.

Numerous qualified candidates are often identified for SACC reviews. Therefore, selection decisions involve carefully weighing a number of factors including the candidates' areas of expertise and professional qualifications and achieving an overall balance of different scientific perspectives across reviewers. The Agency will consider all nominations of prospective candidates for service as *ad hoc* reviewers for the SACC that are received on or before the date listed in the **DATES** section of this document. However, final selection of *ad hoc* reviewers is a discretionary function of the Agency. At this time, EPA anticipates selecting approximately 8–12 *ad hoc* reviewers to assist the SACC in their review of the designated topic.

EPA plans to make a list of candidates under consideration as prospective *ad hoc* reviewers for this review available for public comment by mid to late February 2023. The list will be available in the docket at *http://www.regulations.gov* (docket ID number EPA–HQ–OPPT–2022–0918) and on the

SACC website. You may also subscribe to the following listserv for alerts regarding this and other SACC-related activities: *https://public.govdelivery.com/accounts/USAEPAOPPT/subscriber/new?topic_id=USAEPAOPPT_101.*

III. Virtual Public Meeting of the SACC

A. What is the purpose of this public meeting?

The focus of the 4-day virtual public meeting is the SACC peer review of the following two draft documents:

- Draft Proposed Principles of Cumulative Risk Assessment Under the Toxic Substances Control Act; and
- Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer Requested Phthalate Under the Toxic Substance Control Act.

EPA will be soliciting comments from the SACC on issues related to chemical grouping for purposes of Cumulative Risk Assessment (CRA), health outcomes related to phthalate syndrome, and possible approaches to developing the cumulative hazard and exposure assessment for High-Priority phthalates and a Manufacturer-Requested phthalate. In addition, EPA intends to publish a separate document in the **Federal Register** to announce the availability of and solicit public comment on the two draft documents, at which time EPA will provide instructions for submitting comments and registering to provide oral comments at the meeting. EPA also intends to provide a meeting agenda for each day of the meeting, and, as needed, may provide updated times for each day in the meeting agenda that will be posted in docket and on the SACC website.

B. Why did EPA develop these documents?

Between 2020 and 2022 EPA published final scoping documents for twenty High-Priority and three Manufacturer-Requested chemical substances for risk evaluation under TSCA. During the scoping process, EPA received comments from stakeholders urging the Agency to consider evaluating several chemical substances undergoing risk evaluation for cumulative risk to human health. TSCA does not explicitly require EPA to conduct cumulative risk assessments (CRAs). However, TSCA does require EPA to consider the reasonably available information and to use the best available science and to make decisions based on the weight of scientific evidence [15 U.S.C. 2625(h), (i), (k)]. EPA recognizes that for some chemical substances, the best available science may indicate that the development of a CRA is appropriate to ensure that any risks to human health and the environment are adequately characterized.

1. *Proposed principles of CRAs under TSCA.* EPA's document entitled ''Draft Proposed Principles of Cumulative Risk Assessment Under the Toxic Substances Control Act'' will describe the fundamental principles of CRA of chemical substances and how they may be applied within the regulatory requirements of TSCA to ensure TSCA risk evaluations are based on the best available science and are protective of human health. This draft document is not intended to be a framework nor a guidance document on conducting CRAs of chemical substances under TSCA, and it will not address cumulative impacts.

2. *Proposed approach for a CRA of phthalates under TSCA.* Recognizing that human exposure to phthalates is widespread and that multiple phthalates can disrupt development of the male reproductive system in laboratory animals at potentially human relevant doses, EPA asked the National Research Council (NRC) of the National Academies of Science to review the health effects of phthalates and determine whether a cumulative risk assessment of phthalates should be conducted, and if so, what approaches could be used for the assessment. In 2008, NRC published their findings to EPA in a final report entitled ''Phthalates and Cumulative Risk Assessment: The Task Ahead'' (*https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryId=202508*). In that report, the NRC recommended that a cumulative risk assessment should be conducted for phthalates. EPA's document entitled ''Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer Requested Phthalate Under the Toxic Substance Control Act'' will describe EPA's proposed approach for evaluating a subset of High-Priority and Manufacturer-Requested phthalates for cumulative risk to human health under TSCA based on the principles of CRA described in EPA's draft principles document referenced previously. EPA's draft proposed approach will follow many of the recommendations made by the NRC in 2008. This draft document is not a CRA, and no risk estimates are presented. Instead, this draft document will outline several options EPA is considering for conducting a phthalate CRA under TSCA.

C. How can I access the documents submitted for review to the SACC?

EPA is planning to release the two draft documents mentioned above and all background documents, related supporting materials, and draft charge questions provided to the SACC by late February 2023. At that time, EPA will publish a separate document in the **Federal Register** to announce the availability of and solicit public comment on the two draft documents and provide instructions for submitting comments and registering to provide oral comments. These materials will also be available in the docket through *https://www.regulations.gov* (docket ID number EPA–HQ–OPPT–2022–0918) and the SACC website. In addition, as additional background materials become available and are provided to the SACC, EPA will include those additional background documents (*e.g.,* SACC members and consultants participating in this meeting and the meeting agenda) in the docket and on the SACC website.

D. How can I participate in the virtual public meeting?

The public virtual meeting will be held via a webcast platform such as ''Zoom.gov'' and audio teleconference. You must register online to receive the webcast meeting link and audio teleconference information. Please follow the registration instructions that will be announced on the SACC website in February. You may subscribe to the following listserv for alerts regarding this and other SACC-related activities: *https://public.govdelivery.com/accounts/USAEPAOPPT/subscriber/new?topic_id=USAEPAOPPT_101.*

Authority: 15 U.S.C. 2625(o); 5 U.S.C. appendix 2 *et. seq.*

Dated: December 16, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2022–27707 Filed 12–20–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2022–0337; FRL–10497–01–OCSPP]

Pesticides; Evaluating the Efficacy of Antimicrobial Test Substances on Porous Surfaces in Non-Residential Settings; Interim Guidance and Methods; Notice of Availability and Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting comment on interim guidance and methods for adding efficacy claims to antimicrobial products for use on porous materials, including fabrics, textiles, and upholstered items in non-residential settings. Specifically, EPA is seeking public comment on an interim guidance document that describes efficacy testing for antimicrobial products to support claims for use on surfaces of certain porous materials in clinical and institutional (non-residential) settings and how to prepare an application for registration, an interim quantitative method for evaluating the efficacy of antimicrobial products on porous surfaces against viruses, and an interim quantitative method for evaluating the efficacy of antimicrobial products on porous surfaces against bacteria. The interim guidance does not address residential use sites with surfaces such as upholstered furniture (including backing material/stuffing under the porous surface), carpets, rugs, draperies, etc. In addition to the feedback requested above, EPA is also seeking public comment on proposed carrier materials to represent the surfaces commonly found in residential settings.

DATES: Comments must be received on or before January 20, 2023.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2022–0337, through the Federal eRulemaking Portal at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marc Carpenter, Microbiology Laboratory Branch (7503M), Biological and Economic Analysis Division, Office of Pesticide Programs, Environmental Protection Agency, Environmental Science Center, 701 Mapes Road, Ft. Meade, MD 20755–5350; telephone number: (410) 305–2927; email address: *carpenter.marc@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This document is directed to the public in general; although this action may be of particular interest to those persons who are or may be required to conduct testing of chemical substances under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Background

EPA received requests to develop interim test methods and an associated registration process for antimicrobial products intended to treat bacterial and viral public health pathogens on the surface of porous materials. There is significant interest from stakeholders and the public in the availability of antimicrobial products with these public health claims, particularly in institutional, clinical, and health-care settings. Currently, most EPA-registered liquid-based antimicrobial products are intended to treat hard, non-porous surfaces.

EPA is making available for comment interim quantitative efficacy test methods for both bacteria and viruses on porous surfaces, in addition to interim guidance for companies wishing to add specific claims to antimicrobial products for efficacy against public health pathogens when used on porous materials in clinical and institutional (non-residential) settings. These materials include non-clothing fabrics, textiles, and/or upholstery that may be laundered on an infrequent (non-routine) basis where surface wiping and spot treatment is the primary means of cleaning and or disinfection. Examples of non-residential sites include waiting rooms and offices in clinical settings, hospitals and long-term care facilities, schools, hotels, movie theaters, office buildings, and retail establishments, with a focus on high traffic areas and frequently used surfaces. The guidance does not address claims for porous materials such as clothing, untreated wood, concrete and other hard porous materials, carpet or rugs, and the backing material/stuffing under the porous surface (*e.g.,* beyond what can be visibly observed). The guidance does not address claims for residual antimicrobial product efficacy when used on porous materials.

III. Do guidance documents contain binding requirements?

As guidance, these documents are not binding on the Agency or any outside parties, and the Agency may depart from it where circumstances warrant and without prior notice. While EPA has made every effort to ensure the accuracy of the discussion in the guidance, the obligations of EPA and the regulated community are determined by statutes, regulations, or other legally binding documents. In the event of a conflict between the discussion in the guidance documents and any statute, regulation, or other legally binding document, the guidance documents will not be controlling.

Authority: 7 U.S.C. 136 *et seq.*

Dated: December 15, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2022–27693 Filed 12–20–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10506–01–OW]

Notice of Public Meeting of the Environmental Financial Advisory Board (EFAB) With Webcast

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public EFAB meeting.

SUMMARY: The Environmental Protection Agency (EPA) announces a public meeting with a webcast of the Environmental Financial Advisory Board (EFAB). The meeting will be shared in real-time via webcast and public comments may be provided in writing in advance or virtually via webcast. Please see **SUPPLEMENTARY INFORMATION** for further details. The purpose of the meeting will be for the EFAB to provide updates on the

Greenhouse Gas Reduction Fund charge and previous EFAB deliverables, consider possible future advisory topics, and receive updates on EPA activities. The meeting will be conducted in a hybrid format of in-person and virtual via webcast.

DATES: The meeting will be held:

1. January 24, 2023, from 9 a.m. to 4 p.m. Eastern Time;
2. January 25, 2023, from 9 a.m. to 4 p.m. Eastern Time; and
3. January 26, 2023, from 9 a.m. to 12 p.m. Eastern Time.

ADDRESSES:

In-Person: U.S. Environmental Protection Agency, William Jefferson Clinton East Building, 1201 Constitution Avenue NW, Washington, DC 20004.

Webcast: Information to access the webcast will be provided upon registration in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wants information about the meeting may contact Tara Johnson via telephone/voicemail at (202) 564–6186 or email to *efab@epa.gov.* General information concerning the EFAB is available at *www.epa.gov/waterfinancecenter/efab.*

SUPPLEMENTARY INFORMATION:

Background: The EFAB is an EPA advisory committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, to provide advice and recommendations to EPA on innovative approaches to funding environmental programs, projects, and activities. Administrative support for the EFAB is provided by the Water Infrastructure and Resiliency Finance Center within EPA's Office of Water. Pursuant to FACA and EPA policy, notice is hereby given that the EFAB will hold a public meeting with a webcast for the following purposes:

(1) Provide updates on the Greenhouse Gas Reduction Fund charge and other recent EFAB deliverables;

(2) Discuss potential future EFAB charges; and

(3) Receive briefings on environmental finance topics from invited speakers from EPA.

Registration for the Meeting: To register for the meeting, please visit *www.epa.gov/waterfinancecenter/efab#meeting.* Interested persons who wish to attend the meeting must register by January 10, 2023, to attend in person or by January 17, 2023, to attend via webcast. Pre-registration is strongly encouraged. In person attendees should review EPA's Visitor Guidance at *https://www.epa.gov/aboutepa/visiting-epa-building-access* in advance of the meeting. In the event the in-person component of the meeting cannot be held due to relevant pandemic protocols, the meeting will be conducted fully via webcast.

Availability of Meeting Materials: Meeting materials, including the meeting agenda and briefing materials, will be available on EPA's website at *www.epa.gov/waterfinancecenter/efab.*

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office. Federal advisory committees provide independent advice to EPA. Members of the public may submit comments on matters being considered by the EFAB for consideration as the Board develops its advice and recommendations to EPA.

Oral Statements: In general, individuals or groups requesting an oral presentation at a public meeting will be limited to three minutes each. Persons interested in providing oral statements at the January 2023 meeting should register in advance and provide notification, as noted in the registration confirmation, by January 10, 2023, to be placed on the list of registered speakers.

Written Statements: Written statements should be received by January 17, 2023, so that the information can be made available to the EFAB for its consideration prior to the meeting. Written statements should be sent via email to *efab@epa.gov.* Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the EFAB website. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities or to request accommodations for a disability, please register for the meeting and list any special requirements or accommodations needed on the registration form at least 10 business days prior to the meeting to allow as much time as possible to process your request.

Andrew D. Sawyers,

Director, Office of Wastewater Management, Office of Water.

[FR Doc. 2022–27699 Filed 12–20–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[FR ID 119419]

Open Commission Meeting Wednesday, December 21, 2022

December 15, 2022.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Wednesday, December 21, 2022, which is scheduled to commence at 10:30 a.m. in the Commission Meeting Room of the Federal Communications Commission, 45 L Street NE, Washington, DC. While attendance at the Open Meeting is available to the public, the FCC headquarters building is not open access, and all guests must check in with and be screened by FCC security at the main entrance on L Street. Attendees at the Open Meeting will not be required to have an appointment but must otherwise comply with protocols outlined at: *www.fcc.gov/visit.* Open Meetings are streamed live at: *www.fcc.gov/live* and on the FCC's YouTube channel.

Item No.	Bureau	Subject
1	Wireline Competition	*Title:* Implementing the Infrastructure Investment and Jobs Act: Prevention and Elimination of Digital Discrimination (GN Docket No. 22–69). *Summary:* The Commission will consider a Notice of Proposed Rulemaking that would take the next step in the Commission's efforts to promote equal access to broadband by seeking comment on potential rules to address digital discrimination of access to broadband, consistent with Congress's direction in the Infrastructure Investment and Jobs Act.

Item No.	Bureau	Subject
2	International	*Title:* Expediting Initial Processing of Satellite and Earth Station Applications (IB Docket No. 22–411); Space Innovation (IB Docket No. 22–271). *Summary:* The Commission will consider a Notice of Proposed Rulemaking seeking comment on changes to its rules, policies, or practices to facilitate the acceptance for filing of satellite and earth station applications under Part 25 to help Commission processing stay apace with the number of innovative satellite applications in the new space age.
3	Public Safety & Homeland Security	*Title:* Location-Based Routing for Wireless 911 Calls (PS Docket No. 18–64). *Summary:* The Commission will consider a Notice of Proposed Rulemaking regarding a proposal to require wireless carriers and covered text providers to implement location-based routing on their networks in order to reduce misrouting of wireless 911 calls and texts and improve emergency response times.
4	Consumer & Governmental Affairs	*Title:* Internet Protocol Captioned Telephone Service Compensation (CG Docket No. 22–408); Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities (CG Docket No. 03–123); Misuse of Internet Protocol (IP) Captioned Telephone Service (CG Docket No. 13–24). *Summary:* The Commission will consider a Notice of Proposed Rulemaking and Order on Reconsideration to propose Telecommunications Relay Services (TRS) Fund compensation for Internet Protocol Captioned Telephone Service (IP CTS), propose a technical amendment to the compensation formula for Internet Protocol Relay Service (IP Relay), and resolve petitions for reconsideration of a prior order setting IP CTS compensation.
5	Enforcement	*Title:* Enforcement Bureau Action. *Summary:* The Commission will consider an enforcement action.

* * * * *

The meeting will be webcast at: *www.fcc.gov/live.* Open captioning will be provided as well as a text only version on the FCC website. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted but may be impossible to fill. Send an email to: *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530.

Press Access—Members of the news media are welcome to attend the meeting and will be provided reserved seating on a first-come, first-served basis. Following the meeting, the Chairwoman may hold a news conference in which she will take questions from credentialed members of the press in attendance. Also, senior policy and legal staff will be made available to the press in attendance for questions related to the items on the meeting agenda. Commissioners may also choose to hold press conferences. Press may also direct questions to the Office of Media Relations (OMR): *MediaRelations@fcc.gov.* Questions about credentialing should be directed to OMR.

Additional information concerning this meeting may be obtained from the Office of Media Relations, (202) 418–0500. Audio/Video coverage of the meeting will be broadcast live with open captioning over the internet from the FCC Live web page at *www.fcc.gov/live.*

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2022–27672 Filed 12–20–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

[Docket No. 22–34]

SeaFair USA LLC, Complainant v. Sterling Container Line Limited and Atlantic Forwarding Ltd., Respondents; Notice of Filing of Complaint and Assignment

Served: December 15, 2022.

Notice is given that a complaint has been filed with the Federal Maritime Commission (Commission) by SeaFair USA, LLC., hereinafter ''Complainant,'' against Sterling Container Line Limited and Atlantic Forwarding Ltd., (hereinafter ''Respondents.'') Complainant states that it is a Florida limited liability company with a principal place of business in Florida.

Complainant identifies the Sterling Container Line Limited is a foreign non-vessel-operating common carrier organized under the laws of Hong Kong with a principal place of business in Hong Kong. Complainant identifies Atlantic Forwarding Ltd. is the parent company and agent of Sterling Container Line Limited and an ocean transportation intermediary organized under the laws of Switzerland with a principal place of business in Switzerland.

Complainant alleges that Respondent violated 46 U.S.C. 41102(a), 41102(c), 41104(a)(4)(A), and 41104(a)(2)(A) regarding its practices and the billing and payment of charges on the shipments of cargo, including the provision of services in the liner trade that are not in accordance with the rates, charges, classifications, rules, and practices contained in its tariff. An answer to the complaint is due to be filed with the Commission within twenty-five (25) days after the date of service. The full text of the complaint can be found in the Commission's Electronic Reading Room at *https://www2.fmc.gov/readingroom/proceeding/22-34/.*

This proceeding has been assigned to Office of Administrative Law Judges. The initial decision of the presiding officer in this proceeding shall be issued by December 15, 2023, and the final decision of the Commission shall be issued by July 1, 2024.

William Cody,

Secretary.

[FR Doc. 2022–27638 Filed 12–20–22; 8:45 am]

BILLING CODE 6730–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–855I and CMS–855O]

Agency Information Collection Activities: Submission for OMB Review; 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 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by January 20, 2023.

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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Registration Application; *Use:* Various sections of the Social Security Act (Act), the United States Code (U.S.C.), Internal Revenue Service Code (Code) and the Code of Federal Regulations (CFR) require providers and suppliers to furnish information concerning the amounts due and the identification of individuals or entities that furnish medical services to beneficiaries before allowing payment. The principal function of the CMS–855O is to gather information from a physician or other eligible professional to help CMS determine whether he or she meets certain qualifications to enroll in the Medicare program for the sole purpose of ordering or certifying certain Medicare items or services. The CMS–855O allows a physician or other eligible professional to enroll in Medicare without approval for billing privileges.

The collection and verification of this information protects our beneficiaries from illegitimate providers/suppliers. These procedures also protect the Medicare Trust Funds against fraud. The CMS–855O gathers information that allow Medicare contractors to ensure that the physician or eligible professional is not sanctioned from the Medicare and/or Medicaid program(s), or debarred, or excluded from any other Federal agency or program. Furthermore, the data collected also ensures that the applicant has the necessary credentials to order and certify health care services. This is the sole instrument implemented for this purpose.

Form Number: CMS- 855O (OMB control number 0938–1135); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits), State, Local, or Tribal Governments; *Number of Respondents:* 6,190; *Number of Responses:* 6,190; *Total Annual Hours:* 3,095. (For policy questions regarding this collection contact Frank Whelan at 410–786–1302).

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Enrollment Application for Physician and Non-Physician Practitioners; *Use:* The Social Security Act (Act) requires providers and suppliers to furnish information concerning the amounts due and the identification of individuals or entities that furnish medical services to beneficiaries before allowing payment. The primary function of the CMS–855I Medicare enrollment application for physicians and non-physician practitioners is to gather information from an individual provider or supplier that tells us who he/she is, whether he/she meets certain qualifications to be a Medicare health care provider or supplier, where he/she practices or renders services, and other information necessary to establish correct claims payments.

The collection and verification of this information is the first line defense to defend and protect our beneficiaries from illegitimate physicians, non-physician practitioners, and other eligible professionals and to protect the Medicare Trust Fund against fraud. It gathers information that allow Medicare contractors to ensure only legitimate physicians, non-physician practitioners, and other eligible professionals enroll in the Medicare program, and are not sanctioned from the Medicare and/or Medicaid program(s), or debarred, or excluded from any other Federal agency or program. This is the sole instrument implemented for this purpose. *Form Number:* CMS–855I (OMB control number 0938–1355); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments, Private Sector (not-for-profit institutions); *Number of Respondents:* 472,617; *Number of Responses:* 472,617; *Total Annual Hours:* 961,651. (For policy questions regarding this collection contact Frank Whelan at 410–786–1302).

Dated: December 16, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–27739 Filed 12–20–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Child Care and Development Fund (CCDF) Consumer Education Website and Reports of Serious Injuries and Death

AGENCY: Office of Child Care, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for Public Comments.

SUMMARY: The Office of Child Care (OCC), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting a 3-year extension of the CCDF Consumer Education website and Reports of Serious Incidents and Death (Office of Management and Budget (OMB) #: 0970–0473, expiration date: April 30, 2023). There are no changes requested to the reporting requirements.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The existing Consumer Education website reporting requirement will not be modified and requires states and territories to include information about state or territory policies (related to licensing, monitoring, and background checks) and provider-specific information, including results of monitoring and inspection reports and, if available, information about quality. The existing Reporting of Serious Injuries and Death reporting requirement will not be modified. CCDF Lead Agencies must establish procedures that require child care providers that care for children receiving CCDF subsidies to report to a designated state, territorial, or tribal entity any serious injuries or deaths of children occurring in child care. There are no standard federal forms associated with these reporting requirements.

Respondents: The Consumer Education website information collection requirement applies to the 50 states, the District of Columbia, and 5 territories that receive CCDF grants. Reporting of Serious Injuries and Death is a requirement for child care providers.

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
Consumer Education Website	56	1	300	50,400	16,800
Reporting of Serious Injuries and Death	10,000	1	1	30,000	10,000

Estimated Total Annual Burden Hours: 26,800.

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: Pub. L. 113–186; 42 U.S.C. 9858 *et seq.*

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–27665 Filed 12–20–22; 8:45 am]

BILLING CODE 4184–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–P–1189]

Canned Tuna Deviating From Identity Standard; Amendment of Temporary Marketing Permit

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is amending StarKist Co.'s temporary permit to market test canned tuna. The temporary permit is amended to add one additional manufacturing location. This amendment will allow the applicant to continue to test market and collect data on consumer acceptance of the test product.

FOR FURTHER INFORMATION CONTACT: Marjan Morravej, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 20, 2014 (79 FR 35362), we issued a notice announcing that we had issued a temporary permit to StarKist Co., 225 North Shore Dr., Pittsburgh, PA 15212, to market test products identified as canned tuna products. The permit allowed for the test product to be manufactured at Galapesca S.A., Km. 12.5 Via A Duale, Guayaquil, Ecuador, and StarKist Samoa Co., 368 Atu'u Rd., Pago Pago, American Samoa 96799. We issued the permit to facilitate market testing of products that deviate from the requirements of the standard of identity for canned tuna in 21 CFR 161.190, which was issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

In the **Federal Register** of March 7, 2016 (81 FR 11813), we issued a notice announcing that we were extending the temporary market permit issued to StarKist Co., among other parties. The extension allows the applicants to continue to measure consumer acceptance of the products and assess the commercial feasibility of the products, in support of a petition to

amend the standard of identity for canned tuna. The new expiration date of the permit will be either the effective date of a final rule amending the standard of identity for canned tuna that may result from the petition or 30 days after denial of the petition.

In the **Federal Register** of March 5, 2021 (86 FR 12954), we issued a notice announcing that we were amending the temporary permit issued to StarKist Co. to allow the test product to be manufactured at three additional plants: Tropical Canning (Thailand) Public Co., LTD., 1/1 M.2 T.Thungyai, Hatyai, Songkhla 90110, Thailand; ISA Value Co., Ltd., 44/4 Moo1, Petchkasem Road, Yaicha, Sampran, Nakornpathom 73110, Thailand; and Tri-Marine (Solomon Islands), Soltuna Ltd., 1 Tuna Dr., Noro, Western Province, Solomon Islands, and to increase the amount of test product to 213,500,000 pounds (96,841,971 kilograms).

In the **Federal Register** of December 28, 2021 (86 FR 73789), we issued a notice announcing that we were amending the temporary permit issued to StarKist Co. to increase the amount of test product to be market tested to 217,900,000 pounds (98,837,777 kilograms) in retail cans of various sizes and to allow the test product to be manufactured at one additional plant: Société De Conserverie en Afrique (SCA S.A.), Nouveau Quai de Peche-Mole 10–BP 782, Dakar, Senegal.

Under our regulations at 21 CFR 130.17(f), we are amending the temporary permit issued to StarKist Co. to allow the test product to be manufactured at one additional plant: RD Foods Americas, 48 S Franklin Turnpike, Suite 204, Ramsey, NJ 07446 USA. All other conditions and terms of this permit remain the same.

Dated: December 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27710 Filed 12–20–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1140]

Enforcement Policy Regarding Federal Veterinarian-Client-Patient Relationship Requirements To Facilitate Veterinary Telemedicine During the COVID–19 Outbreak; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of the guidance document entitled ''Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID–19 Outbreak,'' which was issued in March 2020. FDA is withdrawing this guidance document in recognition that the conditions that created the need for the enforcement policy have evolved, such that the policy is no longer needed.

DATES: The withdrawal date is February 21, 2023.

FOR FURTHER INFORMATION CONTACT: William Flynn, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5704, *AskCVM@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

As part of FDA's commitment to providing timely guidance to support continuity and response efforts to the Coronavirus Disease 2019 (COVID–19) [1] pandemic, in March 2020, the Agency published the guidance document GFI #269, ''Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID–19 Outbreak,'' recognizing the vital role veterinarians play in protecting public health. In accordance with the process announced by the Agency in the **Federal Register** on March 25, 2020 (85 FR 16949) for making COVID–19-related guidances available to the public, the notice of availability for the guidance published on May 12, 2020 (85 FR 28010).

When the COVID–19 public health emergency began in January 2020, FDA understood that veterinarians might face challenges affecting their ability to make on-premises examination of their patients. Given that the Federal veterinarian-client-patient relationship (VCPR) definition (21 CFR 530.3(i)) requires animal examination and/or medically appropriate and timely visits to the premises where the animal(s) are kept, the Federal VCPR definition cannot be met solely through telemedicine. To facilitate veterinarians' ability to utilize telemedicine to address animal health needs during the COVID–19 outbreak, FDA published GFI #269, stating that it intended to temporarily suspend enforcement of a portion of the Federal VCPR requirements. Specifically, FDA generally intended not to enforce the animal examination and premises visit VCPR requirements relevant to FDA regulations governing Extralabel Drug Use in Animals (21 CFR part 530) and Veterinary Feed Directive Drugs (21 CFR 558.6).

FDA stated in the guidance that, given the temporary nature of this policy, we planned to reassess it periodically and provide revision or withdrawal of this guidance as necessary. The Agency acknowledges that the public health emergency declared by the Secretary of Health and Human Services for the COVID–19 pandemic continues to exist. However, the conditions that created the need for the temporary enforcement policy outlined in GFI #269 have evolved, such that the policy is no longer needed. After careful review of current industry practices with regard to on-premises animal examination and comments submitted to the public docket associated with the guidance, the Agency has determined the guidance document should be withdrawn.

Therefore, in accordance with 21 CFR 10.115(k), FDA is withdrawing the ''Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID–19 Outbreak'' guidance in its entirety.

II. Withdrawal Date

The withdrawal date for the guidance document discussed in this document is February 21, 2023.

Dated: December 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27673 Filed 12–20–22; 8:45 am]

BILLING CODE 4164–01–P

[1] The virus has been named ''SARS–CoV–2'' and the disease it causes has been named ''Coronavirus Disease 2019'' (COVID–19).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–0614]

Determination That ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, was not withdrawn from sale for reasons of safety or effectiveness. This

determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Michelle Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993–0002, 240–402–0374, *Michelle.Weiner@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but it must be made prior to FDA's approval of an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, is the subject of NDA 020711, held by GlaxoSmithKline LLC, and initially approved on May 14, 1997. ZYBAN is indicated as an aid to smoking cessation treatment.

ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Yichang Humanwell Pharmaceutical Co., Ltd. submitted a citizen petition dated April 18, 2022 (Docket No. FDA–2022–P–0614), under 21 CFR 10.30, requesting that the Agency determine whether ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ZYBAN (Bupropion Hydrochloride) Tablets, Extended Release, 150 Milligrams, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27647 Filed 12–20–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Healthy Start Evaluation and Capacity Building Support, OMB No. 0906–xxxx—New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this Notice has closed.

DATES: Comments on this ICR must be received no later than January 20, 2023.

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 Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the acting HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call 301–594–4394.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Healthy Start Evaluation and Capacity Building Support, OMB No. 0906–xxxx—New.

Abstract: The National Healthy Start Program, authorized by 42 U.S.C. 254c–8 (section 330H of the Public Health Service Act) and funded through HRSA, has the goal of reducing disparities in

maternal and infant health. The program began as a demonstration project with 15 grantees in 1991 and has expanded over the past 3 decades to 101 grantees across 35 states; Washington, DC; and Puerto Rico. Healthy Start grantees operate in communities with rates of infant mortality at least 1.5 times the U.S. national average, or with high rates of other adverse perinatal outcomes (*e.g.,* low birthweight, preterm birth). Grantees may also qualify for the program if their project areas meet other relevant criteria (*e.g.,* high rates of diabetes, obesity, or tobacco use during pregnancy; low utilization of prenatal care in the first trimester; no utilization of prenatal care during pregnancy) that demonstrate disparities in health outcomes for pregnant women in their communities. Healthy Start programs are located in communities that are geographically, racially, ethnically, and linguistically diverse. Healthy Start covers services during the perinatal period (before, during, after pregnancy) and follows the women, infants, and fathers/partners in the program through 18 months after the end of the pregnancy. The Healthy Start program uses a life course approach that includes women's health, family health and wellness, and community/population health.

HRSA seeks to implement a mixed-methods evaluation to assess the effectiveness of the program on individual, organizational, and community-level outcomes. Data collection instruments will include the (1) Healthy Start Program Survey, (2) Healthy Start Network Survey, (3) Healthy Start Participant Survey, and (4) Healthy Start Stakeholder Interview Guide. These instruments have been specifically designed to be non-duplicative. Using previously approved content, the Healthy Start Program Survey is designed to collect information on the experiences of all 101 grantee programs related to program infrastructure, services/activities, participants, community partnerships, new maternal and fatherhood initiatives, and health equity. The information collected in the survey will allow the Healthy Start grantees to better assess risk, identify needed services, provide appropriate follow-up activities to program participants, and improve overall service delivery and quality.

The two other surveys and interview guide will be administered to a subset of 15 grantees, their community partners, and participants. The Healthy Start Network Survey focuses on understanding the participation of members in the Healthy Start Community Action Networks (CANs) [1] and collaborations within the CANs to improve maternal, infant, and family outcomes within the Healthy Start communities. Results from the survey will help the Healthy Start programs and their CANs identify areas of strength and opportunities for further collaborations, understand how well the CAN members are working together to serve women and their families, and whether they are supporting the programs in addressing the participants' greatest needs. The Healthy Start Participant Survey is designed to collect information about the experiences of the Healthy Start participants with the program and assess whether the programs are meeting their needs. The Healthy Start grantees can use this information to identify areas to strengthen the services provided to the participants. The Healthy Start Stakeholder Interview Guide is designed to collect more in-depth information about the Healthy Start services, the new maternal health and fatherhood initiatives, CAN activities, and activities developed to improve the Healthy Start benchmarks and achieve health equity.

A 60-day notice was published in the **Federal Register**, 87 FR 43535 (July 21, 2022). There were no public comments.

Need and Proposed Use of the Information: The purpose of the data collection instruments is to obtain consistent information across all grantees about Healthy Start, its operations and outcomes. The data will be used to (1) conduct ongoing performance monitoring of the program; (2) provide credible and rigorous evidence of program effect on outcomes; (3) meet program needs for accountability, programmatic decision-making, and ongoing quality assurance; and (4) strengthen the evidence base and identify best and promising practices for the program to support sustainability, replication, and dissemination of the program.

Likely Respondents: Respondents will include project directors and staff for the Healthy Start Program Survey, members of the CANs for the Healthy Start Network Survey, program participants for the Healthy Start Participant Survey, and program and administrative staff for the Healthy Start Stakeholder Interview Guide.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information.

The total annual burden hours estimated for this ICR are summarized in the table below. The total number of responses was multiplied by the average burden per response and summed to produce the total annualized burden hours, which is estimated to be 600 hours. A break-down of these hours is detailed in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Healthy Start Program Survey	101	1	101	1.00	101
Healthy Start Network Survey	[1] 600	1	600	0.33	198
Healthy Start Participant Survey	[2] 750	1	750	0.25	188
Healthy Start Stakeholder Interview Guide	[3] 150	1	150	0.75	113
Total	1,601		1,601		600

[1] This is the maximum number of responses for this data collection instrument.

[1] A CAN is an existing, formally organized partnership of organizations and individuals. The CAN represents consumers and appropriate agencies which unite in an effort to collectively apply their resources to the implementation of one or more common strategies to achieve a common goal within that project area.

[2] Ibid.
[3] Ibid.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–27698 Filed 12–20–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Nurse Corps Loan Repayment Program; OMB No. 0915–0140 Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than January 20, 2023.

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 Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the acting HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call 301–594–4394.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Nurse Corps Loan Repayment Program (Nurse Corps LRP), OMB No. 0915–0140—Extension.

Abstract: The Nurse Corps LRP assists in the recruitment and retention of professional Registered Nurses (RNs), including Advanced Practice Registered Nurses (APRNs), by decreasing the financial barriers associated with pursuing a nursing education. RNs in this instance include APRNs (*e.g.,* nurse practitioners, certified registered nurse anesthetists, certified nurse-midwives, and clinical nurse specialists) dedicated to working at eligible health care facilities with a critical shortage of nurses (*i.e.,* a Critical Shortage Facility) or working as nurse faculty in eligible, accredited schools of nursing. The Nurse Corps LRP provides loan repayment assistance to these nurses to repay a portion of their qualifying educational loans in exchange for full-time service at a public or private Critical Shortage Facility or in an eligible, accredited school of nursing.

A 60-day notice published in the **Federal Register** on September 29, 2022, vol. 87, No. 188; pp. 59106–07. There were no public comments.

Need and Proposed Use of the Information: Individuals must submit an application in order to participate in the program. The application asks for personal, professional, educational, and financial information required to determine the applicant's eligibility to participate in the Nurse Corps LRP. This information collection is used by the Nurse Corps program to make award decisions about Nurse Corps LRP applicants and to monitor a participant's compliance with the program's service requirements. The Nurse Corps LRP is requesting an extension and is seeking to use the previously approved forms.

Likely Respondents: Professional RNs or APRNs who are interested in participating in the Nurse Corps LRP, and official representatives at their service sites.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Nurse Corps LRP Application*	7,100	1	7,100	2.00	14,200
Authorization to Release Information Form**	7,100	1	7,100	.10	710
Employment Verification Form**	7,100	1	7,100	.10	710
Disadvantaged Background Form	450	1	450	.20	90
Confirmation of Interest Form	500	1	500	.20	100
Total for Applicants	22,250		22,250		15,810

*The burden hours associated with this instrument account for both new and continuation applications. Additional (uploaded) supporting documentation is included as part of this instrument and reflected in the burden hours.

**The same respondents are completing these instruments.

The estimates of reporting for Participants are as follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Participant Semi-Annual In Service Verification Form	500	2	1,000	.50	500
Nurse Corps Critical Shortage Facility Verification Form	500	1	500	.10	50
Nurse Corps Nurse Faculty Employment Verification Form	450	1	450	.20	90
Total for Participants	1,450		1,950		640
Total for Applicants and Participants	23,700		24,200		16,450

*The 16,450 figure is a combination of burden hours for applicants and participants. This revision adds an additional form (the Disadvantaged Background Form).

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–27696 Filed 12–20–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Instrumentation Program (S10).

Date: January 17, 2023.

Time: 12:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9608, Bethesda, MD 20892–9608, 301–443–4525, *steinerr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: December 15, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–27642 Filed 12–20–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Deafness and Other Communication Disorders Advisory Council.

The is a virtual meeting and will be open to the public as indicated below. The url link to this meeting is *https://www.nidcd.nih.gov/about/advisory-council/upcoming-meetings* or the open session will be videocast and can be accessed from the NIH Videocast website (*http://videocast.nih.gov/*). Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Deafness and Other Communication Disorders Advisory Council.

Date: February 2–3, 2023.

Closed: February 02, 2023, 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Neuroscience Center 6001 Executive Boulevard Rockville, MD 20852 (Virtual Meeting).

Open: February 02, 2023, 1:00 p.m. to 4:00 p.m.

Agenda: Staff reports on divisional, programmatical, and special activities.

Place: National Institutes of Health ,Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Open: February 03, 2023, 11:00 a.m. to 1:00 p.m.

Agenda: Staff reports on divisional, programmatical, and special activities.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Rebecca Wagenaar-Miller, Ph.D., Director Division of Extramural Activities, NIDCD/NIH, 6001 Executive Boulevard, Bethesda, MD 20892 (301) 496–8693, *rebecca.wagenaar-miller@nih.gov*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.nidcd.nih.gov/about/advisory-council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: December 15, 2022.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–27682 Filed 12–20–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to 42 U.S.C. 285g, notice is hereby given of the National Advisory Child Health and Human Development Council Stillbirth Working Group.

The meeting will be open to the public as a virtual meeting. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting website (*http://videocast.nih.gov/*.)

Name of Committee: National Advisory Child Health and Human Development Council Stillbirth Working Group—Public Listening Session.

Dates and Times: January 5, 2023, 3:00 p.m.–5:00 p.m. EST.

Agenda: The NICHD Stillbirth Working Group of Council (Working Group) is charged with providing a report to the National Advisory Child Health and Human Development Council focusing on the current barriers to collecting data on stillbirths throughout the United States, communities at higher risk of stillbirth, the psychological impact and treatment for mothers following stillbirth, and known risk factors for stillbirth.

Registration: Those who would like to attend and participate in the public listening session may register at *https://bit.ly/3F7ftYz.* Please register by 12 noon, January 4, 2023.

- When registering, registrants are to identify whether they will be speaking on behalf of an organization or individually.
- An identified spokesperson should speak on behalf of each organization registered.
- During the meeting, the comment time for each registered speaker will depend upon the number of organizations and individuals registered.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892–7510, (Virtual Meeting).

Contact Person: Dr. Natasha H. Williams, Branch Chief, Office of Legislation and Public Policy, *Eunice Kennedy Shriver*, National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, *natasha.williams2@nih.gov*, Bethesda, MD 20892–7510, (240) 551–4985.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.nichd.nih.gov/about/advisory,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: December 15, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–27681 Filed 12–20–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2022–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below. The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP).

DATES: The date of May 23, 2023 has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *https://msc.fema.gov* by the date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below. (Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

Community	Community map repository address
Brooks County, Georgia and Incorporated Areas Docket No.: FEMA–B–2207	
City of Morven	City Hall, 178 2nd Street, Morven, GA 31638.
City of Quitman	City Hall, 100 West Screven Street, Quitman, GA 31643.
Unincorporated Areas of Brooks County	Brooks County Office Building, 610 South Highland Road, Quitman, GA 31643.
Anderson County, Kentucky and Incorporated Areas Docket No.: FEMA–B–2208	
Unincorporated Areas of Anderson County	Anderson County Zoning Administration Office, 139 South Main Street, Lawrenceburg, Kentucky 40342.
Boyle County, Kentucky and Incorporated Areas Docket No.: FEMA–B–2208	
City of Perryville	City Hall, 314 East 2nd Street, Perryville, KY 40468.
Unincorporated Areas of Boyle County	Boyle County Courthouse, 321 West Main Street, Danville, KY 40422.
Bullitt County, Kentucky and Incorporated Areas Docket No.: FEMA–B–2208	
City of Lebanon Junction	City Hall, 271 Main Street, Lebanon Junction, KY, 40150.
Unincorporated Areas of Bullitt County	Bullitt County, Nina Mooney Courthouse Annex Building, 149 North Walnut Street, 3rd Floor, Shepherdsville, KY 40165.
Casey County, Kentucky and Incorporated Areas Docket No.: FEMA–B–2208	
Unincorporated Areas of Casey County	Casey County Court Clerk Office, 625 Campbellsville Street, Liberty, KY 42539.
Hardin County, Kentucky and Incorporated Areas Docket No.: FEMA–B–2208	
Unincorporated Areas of Hardin County	Hardin County Engineering Department, 150 North Provident Way, Suite 223, Elizabethtown, KY 42701.
LaRue County, Kentucky and Incorporated Areas Docket No.: FEMA–B–2208	
Unincorporated Areas of LaRue County	LaRue County Courthouse, 209 West High Street, Hodgenville, KY 42748.
Marion County, Kentucky and Incorporated Areas Docket No.: FEMA–B–2208	
City of Bradfordsville	City Hall, 202 West Main Street, Bradfordsville, KY 40009.
City of Lebanon	City Hall, 240 West Main Street, Lebanon, KY 40033.
City of Raywick	Marion County, Dave Ross Hourigan Government Center Building, 223 North Spalding Avenue, Suite 201, Lebanon, KY 40033.
Unincorporated Areas of Marion County	Marion County, Dave Ross Hourigan Government Center Building, 223 North Spalding Avenue, Suite 201, Lebanon, KY 40033.
Mercer County, Kentucky and Incorporated Areas Docket No.: FEMA–B–2208	
Unincorporated Areas of Mercer County	The Greater Harrodsburg/Mercer County Planning and Zoning Commission, 109 Short Street, Number 1, Harrodsburg, KY 40330.
Nelson County, Kentucky and Incorporated Areas Docket No.: FEMA–B–2208	
City of Bardstown	Nelson County Old Courthouse, 1 Court Square, Bardstown, KY 40004.
City of New Haven	Nelson County Old Courthouse, 1 Court Square, Bardstown, KY 40004.
Unincorporated Areas of Nelson County	Nelson County Old Courthouse, 1 Court Square, Bardstown, KY 40004.

Community	Community map repository address
Washington County, Kentucky and Incorporated Areas Docket No.: FEMA–B–2208	
City of Springfield	City Hall, 127 West Main Street, Springfield, KY 40069.
Unincorporated Areas of Washington County	Washington County Judicial Center, 109 North Cross Main Street, Springfield, KY 40069.
Caroline County, Virginia and Incorporated Areas Docket No.: FEMA–B–2189	
Town of Bowling Green	Town Hall, 117 Butler Street, Bowling Green, VA 22427.
Town of Port Royal	Town Hall, 419 King Street, Port Royal, VA 22535.
Unincorporated Areas of Caroline County	Caroline County Planning and Building Department, 233 West Broaddus Avenue, Bowling Green, VA 22427.
Iron County, Wisconsin and Incorporated Areas Docket No.: FEMA–B–2114	
City of Hurley	City Hall, 405 5th Avenue North, Hurley, WI 54534.
City of Montreal	City Hall, 54 Wisconsin Avenue, Montreal, WI 54550.
Unincorporated Areas of Iron County	Iron County Comprehensive Planning, Land and Zoning Department, 300 Taconite Street, Suite 115, Hurley, WI 54534.

[FR Doc. 2022–27747 Filed 12–20–22; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2022–0002; Internal Agency Docket No. FEMA–B–2299]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each

community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Colorado:						
Jefferson	Unincorporated areas of Jefferson County (21–08–1089P).	The Honorable Andy Kerr, Chair, Jefferson County Board of Commissioners, 100 Jefferson County Parkway, Suite 5550, Golden, CO 80419.	Jefferson County Planning and Zoning Division, 100 Jefferson County Parkway, Suite 3550, Golden, CO 80419.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 3, 2023	080087
Mineral	City of Creede (21–08–1132P).	The Honorable Jeffrey Larson, Mayor, City of Creede, P.O. Box 457, Creede, CO 81130.	Town Hall, 2223 North Main Street, Creede, CO 81130.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 24, 2023	080118
Summit	Town of Breckenridge (22–08–0208P).	The Honorable Eric Mamula, Mayor, Town of Breckenridge, P.O. Box 168, Breckenridge, CO 80424.	Public Works Department, 1095 Airport Road, Breckenridge, CO 80424.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 27, 2023	080172
Summit	Unincorporated areas of Summit County (22–08–0208P).	The Honorable Tamara Pogue, Chair, Summit County Board of Commissioners, P.O. Box 68, Breckenridge, CO 80424.	Summit County Commons, 0037 Peak One Drive, Breckenridge, CO 80443.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 27, 2023	080290
Delaware: New Castle.	Unincorporated areas of New Castle County (22–03–0655P).	The Honorable Matthew Meyer, Executive, New Castle County, 87 Reads Way, New Castle, DE 19720.	New Castle County Land Use Department, 87 Reads Way, New Castle, DE 19720.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 23, 2023	105085
Florida:						
Hillsborough	Unincorporated areas of Hillsborough County (21–04–3923P).	Bonnie Wise, Administrator, Hillsborough County, 601 East Kennedy Boulevard, 26th Floor, Tampa, FL 33602.	Hillsborough County Center, 601 East Kennedy Boulevard, 22nd Floor, Tampa, FL 33602.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 2, 2023	120112
Monroe	Unincorporated areas of Monroe County (22–04–5025P).	The Honorable David Rice, Mayor, Monroe County Board of Commissioners, 9400 Overseas Highway, Suite 210, Marathon, FL 33050.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 16, 2023	125129
Monroe	Unincorporated areas of Monroe County (22–04–5380P).	The Honorable David Rice, Mayor, Monroe County Board of Commissioners, 9400 Overseas Highway, Suite 210, Marathon, FL 33050.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 13, 2023	125129
Orange	Unincorporated areas of Orange County (22–04–2597P).	The Honorable Jerry L. Demings, Mayor, Orange County, 201 South Rosalind Avenue, 5th Floor, Orlando, FL 32801.	Orange County Public Works Department, Stormwater Management Division, 4200 South John Young Parkway, Orlando, FL 32839.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 13, 2023	120179
Pasco	Unincorporated areas of Pasco County (22–04–4232P).	Dan Biles, Administrator, Pasco County, 8731 Citizens Drive, New Port Richey, FL 34654.	Pasco County Administration Building, 8731 Citizens Drive, New Port Richey, FL 34654.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 6, 2023	120230
Pinellas	City of Seminole (22–04–3011P).	The Honorable Leslie Waters, Mayor, City of Seminole, 9199 113th Street, Seminole, FL 33772.	Community Development Department, 9199 113th Street, Seminole, FL 33772.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 23, 2023	120257
Polk	Unincorporated areas of Polk County (21–04–3985P).	Bill Beasley, Manager, Polk County, 330 West Church Street, Drawer BC01, Bartow, FL 33830.	Polk County Administration Building, 330 West Church Street, Bartow, FL 33830.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 2, 2023	120261

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Georgia: Bryan	City of Pembroke (22–04–0157P).	The Honorable Judy B. Cook, Mayor, City of Pembroke, P.O. Box 130, Pembroke, GA 31321.	Administration Department, 353 North Main Steet, Pembroke, GA 31321.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 1, 2023	130017
Massassuchetts: Plymouth.	Town of Wareham (22–01–0708P).	Derek Sullivan, Administrator, Town of Wareham, 54 Marion Road, Wareham, MA 02571.	Town Hall, 54 Marion Road, Wareham, MA 02571.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 3, 2023	255223
New Mexico: Sandoval.	City of Rio Rancho (21–06–1075P).	The Honorable Greggory D. Hull, Mayor, City of Rio Rancho, 3200 Civil Center Circle Northeast, Rio Rancho, NM 87144.	City Hall, 3200 Civil Center Circle Northeast, Rio Rancho, NM 87144.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 17, 2023	350146
North Carolina:						
Cumberland ...	City of Fayetteville (22–04–2695P).	The Honorable Mitch Colvin, Mayor, City of Fayetteville, 433 Hay Street, Fayetteville, NC 28301.	Zoning Department, 433 Hay Street, Fayetteville, NC 28301.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 28, 2023	370077
Cumberland ...	Unincorporated areas of Cumberland County (22–04–2062P).	The Honorable Glenn Adams, Chair, Cumberland County Board of Commissioners, P.O. Box 1829, Fayetteville, NC 28301.	Cumberland County Planning and Inspections Department, 130 Gillespie Street, Fayetteville, NC 28301.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 1, 2023	370076
Franklin	Unincorporated areas of Franklin County (22–04–3395P).	The Honorable Michael S. Schriver, Chair, Franklin County Board of Commissioners, 113 Market Street, Louisburg, NC 27549.	Franklin County Planning and Inspections Department, 215 East Nash Street, Louisburg, NC 27549.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 10, 2023	370377
Harnett	Unincorporated areas of Harnett County (22–04–2062P).	Lewis Weatherspoon, Chair, Harnett County Board of Commissioners, P.O. Box 759, Lillington, NC 27546.	Harnett County Planning Services Department, 420 McKinney Parkway, Lillington, NC 27546.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 1, 2023	370328
Pennsylvania:						
Blair	Township of Freedom (22–03–0978P).	The Honorable Timothy James, Chair, Township of Freedom Board of Supervisors, 131 Municipal Street, East Freedom, PA 16637.	Township Hall, 131 Municipal Street, East Freedom, PA 16637.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 10, 2023	421388
Blair	Township of Greenfield (22–03–0978P).	The Honorable Jordan Oldham, Chair, Township of Greenfield Board of Supervisors, P.O. Box 313, Claysburg, PA 16625.	Township Hall, 477 Ski Gap Road, Claysburg, PA 16625.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 10, 2023	421389
Texas:						
Bexar	City of San Antonio (21–06–2378P).	The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capitol Improvements Department, Storm Water Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 6, 2023	480045
Bexar	City of San Antonio (21–06–3278P).	The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capitol Improvements Department, Storm Water Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 6, 2023	480045
Caldwell	City of Lockhart (22–06–0376P).	Steve Lewis, Manager, City of Lockhart, P.O. Box 239, Lockhart, TX 78644.	City Hall, 308 West San Antonio Street, Lockhart, TX 78644.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 10, 2023	480095
Caldwell	Unincorporated areas of Caldwell County (22–06–0376P).	The Honorable Hoppy Haden, Caldwell County Judge, 110 South Main Street, Room 101, Lockhart, TX 78644.	Caldwell County Main Historic Courthouse, 110 South Main Street, Room 201, Lockhart, TX 78644.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 10, 2023	480094
Collin	City of McKinny (21–06–3351P).	The Honorable George Fuller, Mayor, City of McKinney, P.O. Box 517, McKinney, TX 75070.	Engineering Department, 221 North Tennessee Street, McKinney, TX 75069.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 27, 2023	480135

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Collin	City of Plano (22–06–0995P).	The Honorable John Muns, Mayor, City of Plano, 1520 K Avenue, Plano, TX 75074.	City Hall, 1520 K Avenue, Plano, TX 75074.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 6, 2023	480140
Dallas	Town of Sunnyvale (22–06–1541P).	The Honorable Saji George, Mayor, Town of Sunnyvale, 127 North Collins Road, Sunnyvale, TX 75182.	Town Hall, 127 North Collins Road, Sunnyvale, TX 75182.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 21, 2023	480188
Denton	City of Denton (22–06–1168P).	The Honorable Gerard Hudspeth, Mayor, City of Denton, 215 East McKinney Street, Suite 100, Denton, TX 76201.	Engineering Department, 901–A Texas Street, Denton, TX 76209.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 24, 2023	480194
Denton	City of Fort Worth (22–06–1784P).	The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	Department of Transportation and Public Works, Engineering Vault & Map Repository, 200 Texas Street, Fort Worth, TX 76102.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 27, 2023	480596
Denton	Unincorporated areas of Denton County (22–06–1168P).	The Honorable Andy Eads, Denton County Judge, 1 Courthouse Drive, Suite 3100, Denton, TX 76208.	Denton County Development Services Department, 3900 Morse Street, Denton, TX 76208.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 24, 2023	480774
Denton	Unincorporated areas of Denton County (22–06–1784P).	The Honorable Andy Eads, Denton County Judge, 1 Courthouse Drive, Suite 3100, Denton, TX 76208.	Denton County Public Works Department, Engineering Department, 1505 East McKinney Street, Suite 175, Denton, TX 76209.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 27, 2023	480774
Kaufman	City of Dallas (22–06–1541P).	The Honorable Eric Johnson, Mayor, City of Dallas, 1500 Marilla Street, Suite 5EN, Dallas, TX 75201.	Water Utilities Department, 312 East Jefferson Boulevard, Room 307, Dallas, TX 75203.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 21, 2023	480171
Kaufman	Unincorporated areas of Kaufman County (22–06–1541P).	The Honorable Hal Richards, Kaufman County Judge, 100 West Mulberry Street, Kaufman, TX 75142.	Kaufman County Development Services Department, 106 West Grove Street, Kaufman, TX 75142.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 21, 2023	480411
Montgomery	City of Conroe (22–06–1057P).	The Honorable Jody Czajkoski, Mayor, City of Conroe, P.O. Box 3066, Conroe, TX 77305.	City Hall, 700 Metcalf Street, Conroe, TX 77301.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 2, 2023	480484
Montgomery	City of Shenandoah (22–06–1057P).	The Honorable John Escoto, Mayor, City of Shenandoah, 29955 I-45 North, Shenandoah, TX 77381.	City Hall, 29955 I-45 North, Shenandoah, TX 77381.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 2, 2023	481256
Montgomery	Unincorporated areas of Montgomery County (22–06–1057P).	The Honorable Mark J. Keough, Montgomery County Judge, 501 North Thompson Street, Suite 401, Conroe, TX 77301.	Montgomery County Commissioners Court Building, 501 North Thompson Street, Suite 100, Conroe, TX 77381.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 2, 2023	480483
Utah:						
Davis	City of Bountiful (22–08–0009P).	The Honorable Kendalyn Harris, Mayor, City of Bountiful, 795 South Main Street, Bountiful, UT 84010.	Engineering Department, 795 South Main Street, Bountiful, UT 84010.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 2, 2023	490039
Davis	City of Centerville (22–08–0009P).	The Honorable Clark Wilkinson, Mayor, City of Centerville, 250 North Main Street, Centerville, UT 84014.	Public Works Department, 655 North 1250 West, Centerville, UT 84014.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 2, 2023	490040
Salt Lake	City of West Valley City (22–08–0322P).	Wayne T. Pyle, Manager, City of West Valley City, 3600 South Constitution Boulevard, West Valley City, UT 84119.	City Hall, 3600 South Constitution Boulevard, West Valley City, UT 84119.	*https://msc.fema.gov/portal/advanceSearch.*	Feb. 21, 2023	490245
Virginia: Loudoun.	Unincorporated areas of Loudoun County (22–03–0302P).	Tim Hemstreet, Administrator, Loudoun County, 1 Harrison Street Southeast, 5th Floor, Leesburg, VA 20175.	Loudoun County Government Center, 1 Harrison Street Southeast, 3rd Floor, MSC #60, Leesburg, VA 20175.	*https://msc.fema.gov/portal/advanceSearch.*	Mar. 6, 2023	510090

[FR Doc. 2022–27745 Filed 12–20–22; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2022–0002; Internal Agency Docket No. FEMA–B–2296]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: Comments are to be submitted on or before March 21, 2023.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–2296, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

Community	Community map repository address
Maricopa County, Arizona and Incorporated Areas Project: 17–09–0411S Preliminary Dates: October 4, 2021 and August 26, 2022	
City of Buckeye	City Hall, 530 East Monroe Avenue, Buckeye, AZ 85326.
City of Goodyear	Development Counter, 1900 North Civic Square, Goodyear, AZ 85395.
Town of Gila Bend	Town Hall, 644 West Pima Street, Gila Bend, AZ 85337.
Unincorporated Areas of Maricopa County	Flood Control District of Maricopa County, 2801 West Durango Street, Phoenix, AZ 85009.
Riverside County, California and Incorporated Areas Project: 19–09–0025S Preliminary Date: May 25, 2022.	
City of Corona	City Hall, 400 South Vicentia Avenue, Corona, CA 92882.

Community	Community map repository address
City of Eastvale	City Hall, Public Works Department, 12363 Limonite Avenue, Suite 910, Eastvale, CA 91752.
City of Jurupa Valley	City Hall, 8930 Limonite Avenue, Jurupa Valley, CA 92509.
City of Norco	City Hall, 2870 Clark Avenue, Norco, CA 92860.
City of Riverside	Public Works, 3900 Main Street, 4th Floor, Riverside, CA 92522.
Unincorporated Areas of Riverside County	Riverside County Flood Control and Water Conservation District, 1995 Market Street, Riverside, CA 92501.
San Bernardino County, California and Incorporated Areas Project: 19–09–0025S Preliminary Date: May 25, 2022.	
City of Chino	City Hall, 13220 Central Avenue, Chino, CA 91710.
City of Chino Hills	City Hall, 14000 City Center Drive, Chino Hills, CA 91709.
City of Colton	Colton Corporate Yard, 160 South 10th Street, Colton, CA 92324.
City of Rialto	City Hall, 150 South Palm Avenue, Rialto, CA 92376.
Unincorporated Areas of San Bernardino County	San Bernardino County Department of Public Works, 825 East 3rd Street, Water Resources Department—Room 101, San Bernardino, CA 92415.
Ventura County, California and Incorporated Areas Project: 10–09–0024S Preliminary Dates: July 31, 2020 and August 19, 2022.	
City of Santa Paula	City Hall, 970 Ventura Street, Santa Paula, CA 93060.
Unincorporated Areas of Ventura County	Ventura County Government Center Hall of Administration, 800 South Victoria Avenue, Ventura, CA 93009.
Hutchinson County, South Dakota and Incorporated Areas Project: 18–08–0013S Preliminary Date: August 15, 2022.	
City of Freeman	City Hall, 185 East 3rd Street, Freeman, SD 57029.
City of Menno	City Hall, 236 South 5th Street, Menno, SD 57045.
City of Parkston	City Hall, 207 West Main Street, Parkston, SD 57366.
Town of Olivet	Town Hall, 125 South 3rd Street, Olivet, SD 57052.
Unincorporated Areas of Hutchinson County	Hutchinson County Courthouse, 201 West Mentor Street, Olivet, SD 57052.

[FR Doc. 2022–27746 Filed 12–20–22; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7056–N–56]

60-Day Notice of Proposed Information Collection: Capital Advance Section 811 Grant Application for Supportive Housing for Persons With Disabilities, OMB Control No.: 2502–0462

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

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* February 21, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Capital Advance Section 811 Grant Application for Supportive Housing for Persons with Disabilities.

OMB Approval Number: 2502–0462.

Type of Request: Reinstatement of a discontinued collection with change.

Form Number: HUD–92016–CA, HUD–92041, HUD–92042, HUD–92043, HUD–2880, HUD–2991, HUD–2530, HUD 424–B Standard grant forms: SF–424, SF–LLL, SF–424A, SF–424D.

Description of the need for the information and proposed use: This collection was discontinued in 2015 due to no funding being appropriated since

2011. The program received new funding in 2018 and 2019, and there was an attempt to reinstate the collection, but the process was not completed. With renewed funding for Fiscal Year 2022 and anticipated funding in the future, the Office of Asset Management and Portfolio Oversight (OAMPO) is submitting this request again. The information requested is necessary to the Department to assist HUD in determining applicant eligibility and ability to develop housing for persons with disabilities within statutory and program criteria. A thorough evaluation of an applicant's submission is necessary to protect the government's financial interest.

Respondents: Not-for-profit institutions, Nonprofit developers or disability organizations that provide housing for persons with disabilities.

Estimated Number of Respondents: 99.

Estimated Number of Responses: 99.

Frequency of Response: 1.

Average Hours per Response: 1.

Total Estimated Burden: 57.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Legal Status of Sponsor	99	1	99	2	2	$26.00	$5,148
Sponsor's purpose community ties, and experience	99	1	99	10	10	26.00	25,740
Project Information	99	1	99	15	15	26.00	38,610
Supportive Services Plan	99	1	99	20	20	26.00	51,480
List of applications submitted in response to this NOFO	99	1	99	1	1	26.00	2,574
A statement that identifies occupants and relocation costs	99	1	99	4	4	26.00	10,296
SF–424	99	1	99	0	0	0	
SF–424A	99	1	99	0	0	0	
SF–424B	99	1	99	0	0	0	
SF–424D	99	1	99	0	0	0	
SF–LLL	99	1	99	0	0	0	
HUD–2880	99	1	99	0	0	0	
HUD–92016–CA	99	1	99	1	1	26.00	2,574
HUD–92041	99	1	99	.5	.5	26.00	1,287
HUD–92042	99	1	99	.5	.5	26.00	1,287
HUD–92043	99	1	99	.5	.5	26.00	1,287
HUD–2991	99	1	99	1	1	26.00	2,574
HUD–92530	99	1	99	1.5	1.5	26.00	3,861
Total	99	1	99	57	57		146,718

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Jeffrey D. Little,

General Deputy Assistant Secretary, Office of Housing.

[FR Doc. 2022–27764 Filed 12–20–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R6–ES–2022–0136; FF06E24000–234–FXES11140600000]

Incidental Take Permit Application; Habitat Conservation Plan and Categorical Exclusion for the Preble's Meadow Jumping Mouse; Douglas County, Colorado

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability of documents; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the availability of documents related to an application for an incidental take permit (permit) under the Endangered Species Act. The St. Charles Town Company has applied for a permit, which, if granted, would authorize take of the federally threatened Preble's meadow jumping mouse (*Zapus hudsonius preblei*) that is likely to occur incidental to proposed construction of commercial and industrial building space known as Brookside Business Center. The documents available for review and comment are the applicant's habitat conservation plan, which is part of the permit application, and our draft environmental action statement and low-effect screening form, which support a categorical exclusion under the National Environmental Policy Act. We invite comments from the public

and local, State, Tribal, and Federal agencies.

DATES: We will accept comments received or postmarked on or before January 20, 2023. Comments submitted online at *https://www.regulations.gov* (see **ADDRESSES**) must be received by 11:59 p.m. Eastern Time on the closing date.

ADDRESSES:

Obtaining Documents: The documents this notice announces, as well as any comments and other materials that we receive, will be available for public inspection online in Docket No. FWS–R6–ES–2022–0136 at *https://www.regulations.gov*.

Submitting Comments: You may submit comments by one of the following methods:

- *Online: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R6–ES–2022–0136.
- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–R6–ES–2022–0136; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

We request that you send comments by only one of the methods described above.

FOR FURTHER INFORMATION CONTACT: Liisa M. Niva, by phone at 303–905–4543, or by email at *Liisa_Niva@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), have received an application from the St. Charles Town Company for a 10-year incidental take permit (permit) under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The application addresses the potential for take of the federally threatened Preble's meadow jumping mouse (*Zapus hudsonius preblei;* PMJM) that is likely to occur incidental to proposed construction of commercial and industrial building space.

The documents available for review and comment are the applicant's habitat conservation plan (HCP), which is part of the permit application, and our draft environmental action statement and low-effect screening form. These documents helped inform our conclusion that the activities proposed in the HCP will have a low effect on the species and the human environment. Accordingly, our issuance of a permit qualifies for a categorical exclusion under the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*).

Applicant's Habitat Conservation Plan

The St. Charles Town Company has submitted a low-effect HCP in support of an application for a permit to address take of the species that is likely to occur as the result of proposed construction of commercial and industrial building space (covered activities) on approximately 16.8 acres (ac) in Douglas County, Colorado. The covered activities are anticipated to affect 3.53 ac of PMJM habitat. The requested permit duration is for 10 years. The biological goals and objectives are to minimize and avoid impacts to PMJM habitat, avoid reduction of PMJM survival and recovery, and restore and enhance PMJM habitat post-construction. The proposed mitigation and minimization measures include protection of 5.15 acres of high-quality upland and riparian PMJM habitat. Impacts will be minimized by restricting human access to PMJM habitat, limiting the establishment and spread of noxious weeds, and restoration of areas temporarily impacted by construction.

Public Availability of Comments

Written comments we receive become part of the decision file associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Authority

We provide this notice under section 10(c) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.32(b)) and under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1506.6).

Drue DeBerry,

Acting Assistant Regional Director, Ecological Services, Mountain-Prairie Region, U.S. Fish and Wildlife Service.

[FR Doc. 2022–27695 Filed 12–20–22; 8:45 am]

BILLING CODE 4333–15–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 332–594]

Recent Trends in U.S. Services Trade, 2023 Annual Report

AGENCY: United States International Trade Commission.

ACTION: Schedule for 2023 report and opportunity to submit information.

SUMMARY: The Commission has prepared and published annual reports in this series, *Recent Trends in U.S. Services Trade,* since 1996.[1] The 2023 report, which the Commission plans to publish in May 2023, will provide aggregate data on cross-border trade in services for the period ending in 2021, and transactions by affiliates based outside the country of their parent firm for the period ending in 2020. The report's analysis will focus on distribution services (including e-commerce, retail, logistics services, port services, maritime transport services, and other transportation services). The Commission is inviting interested members of the public to furnish information and views in connection with the 2023 report.

DATES:

January 27, 2023: Deadline for filing written submissions.

May 26, 2023: Anticipated date for online publication of the report.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission Building, 500 E St. SW, Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E St. SW, Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket information system (EDIS) at *https://edis.usitc.gov/.*

FOR FURTHER INFORMATION CONTACT: Information specific to this investigation

[1] While previous reports in the Recent Trends series used investigation number 332–345, each report will now be issued with a separate investigation number upon approval of the initiating action jacket.

may be obtained from Art Chambers, Project Leader, Office of Industry and Competitiveness Analysis, Services Division (202–205–2766, *arthur.chambers@usitc.gov*), Rudy Telles, Deputy Project Leader, Office of Industry and Competitiveness Analysis, Services Division (202–205–3164, *rodolfo.telles@usitc.gov*), or Acting Services Division Chief Tamar Khachaturian (202–205–3299, *tamar.khachaturian@usitc.gov*). For information on the legal aspects of this investigation, contact Brian Allen (202–205–3034 or *brian.allen@usitc.gov*) or William Gearhart of the Commission's Office of the General Counsel (202–205–3091; *william.gearhart@usitc.gov*). The media should contact Jennifer Andberg, Office of External Relations (202–205–3404; *jennifer.andberg@usitc.gov*). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its website (*https://www.usitc.gov*). 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.

Background: The 2023 annual services trade report will provide aggregate data on cross-border trade in services for 2017–2021 and affiliate transactions in services for 2016–2020, and more specific data and information on trade in distribution services (including e-commerce, retail, logistics services, ports services, maritime transport services, and other transportation services). The Commission publishes two self-initiated annual reports, one on services trade (*Recent Trends in U.S. Services Trade*), and a second on merchandise trade (*Shifts in U.S. Merchandise Trade*). The Commission's 2022 *Recent Trends in U.S. Services Trade* report is now available online at *https://www.usitc.gov/research_and_analysis/recent_trends.htm.*

The initial notice of institution of this investigation was published in the **Federal Register** on September 8, 1993 (58 FR 47287) and provided for what is now the report on merchandise trade. The Commission expanded the scope of the investigation to cover services trade in a separate report, which it announced in a notice published in the **Federal Register** on December 28, 1994 (59 FR 66974). The separate report on services trade has been published annually since 1996, except in 2005. As in past years, the report will summarize U.S. trade in services in the aggregate and provide analyses of trends and developments in selected services industries during the latest period for which data are published by the U.S. Department of Commerce, Bureau of Economic Analysis.

Written Submissions: Interested parties are invited to file written submissions and other information concerning the matters to be addressed by the Commission in its 2023 report. For the 2023 report, the Commission is particularly interested in receiving information relating to trade in distribution services (including e-commerce, retail, logistics services, ports services, maritime transport services, and other transportation services). Submissions should be addressed to the Secretary. To be assured of consideration by the Commission, written submissions related to the Commission's report should be submitted at the earliest practical date and should be received not later than 5:15 p.m., January 27, 2023. All written submissions must conform to the provisions of section 201.8 of the Commission's Rules of Practice and Procedure (19 CFR 201.8), as temporarily amended by 85 FR 15798 (March 19, 2020). Under that rule waiver, the Office of the Secretary will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding electronic filing should contact the Office of the Secretary, Docket Services Division (202–205–1802), or consult the Commission's *Handbook on Filing Procedures.*

Confidential business information: Any submissions that contain confidential business information (CBI) must also conform with the requirements in section 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are confidential or non-confidential, and that the confidential business information be clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties.

The Commission intends to prepare only a public report in this investigation. The report that the Commission makes available to the public will not contain confidential business information. However, all information, including confidential business information, submitted in this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel solely for cybersecurity purposes. The Commission will not otherwise disclose any confidential business information in a manner that would reveal the operations of the firm supplying the information.

Summaries of Written Submissions: Persons wishing to have a summary of their position included in the report should include a summary with their written submission on or before January 27, 2023, and should mark the summary as having been provided for that purpose. The summary should be clearly marked as ''summary for inclusion in the report'' at the top of the page. The summary may not exceed 500 words and should not include any confidential business information. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. The Commission will list the name of the organization furnishing the summary and will include a link to the Commission's Electronic Document Information System (EDIS) where the written submission can be found.

By order of the Commission.

Issued: December 15, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–27663 Filed 12–20–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1315]

Certain Digital Set-Top Boxes and Systems and Services Including the Same; Notice of Commission Determination Not To Review an Initial Determination Terminating the Investigation Based on a Settlement Agreement; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 26) of the presiding administrative law judge (''ALJ'') granting a joint motion to terminate the investigation as to the remaining respondents Altice USA, Inc. and CSC Holdings, LLC, both of Long Island City, New York, and Cablevision Systems Corp. of Bethpage, New York (collectively, ''Altice'') based on a settlement agreement. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Lynde Herzbach, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3228. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On May 31, 2022, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based on a complaint filed by Broadband iTV, Inc., of Austin, Texas (''BBiTV''). *See* 87 FR 32459 (May 31, 2022). The complaint alleges a violation of section 337 based upon the importation into the United States, sale for importation, or sale after importation into the United States of certain set-top boxes and systems and services including the same by reason of infringement of certain claims of U.S. Patent Nos. 9,866,909; 9,936,240; 11,277,669; and 10,555,014 (''the '014 patent''). *Id.* The complaint further alleges that a domestic industry exists. *Id.* The notice of investigation names 10 respondents, including: Comcast Corporation and Comcast Cable Communications, LLC, both of Philadelphia, Pennsylvania, as well as NBCUniversal Media, LLC of Universal City, California (collectively, ''the Comcast Respondents''); Charter Communications, Inc. of Stamford, Connecticut and Charter Communications Operating, LLC, Charter Communications Holding, Company, LLC, and Spectrum Management Holding, Company, LLC, all of St. Louis, Missouri (collectively ''the Charter Respondents''); and Altice. *Id.* The Office of Unfair Import Investigations is not named as a party. *Id.*

The Commission previously terminated the investigation as to all asserted patent claims of the '014 patent based on BBiTV's partial withdrawal of the complaint. Order No. 18 (Sept. 9, 2022), *unreviewed by* Comm'n Notice (Oct. 3, 2022).

The Commission also previously terminated the Comcast Respondents and the Charter Respondents from the investigation based on partial withdrawal of the complaint. Order No. 23 (Oct. 18, 2022), *unreviewed by* Comm'n Notice (Nov. 14, 2022); Order No. 24 (Oct. 20, 2022), *unreviewed by* Comm'n Notice (Nov. 14, 2022).

On November 1, 2022, BBiTV and Altice filed a joint motion to terminate the investigation based on settlement. No response to the unopposed motion was filed.

On November 15, 2022, the presiding ALJ issued the subject ID (Order No. 26) granting the joint motion to terminate the investigation. The subject ID finds that the joint motion complies with Commission Rule 210.21(b)(1) (19 CFR 210.21(b)) and that no extraordinary circumstances prevent denying the motion. The ID also finds that termination of the investigation based on settlement would not be contrary to the public interest. No party petitioned for review of the subject ID.

The Commission has determined not to review the subject ID (Order No. 26). The investigation is terminated.

The Commission vote for this determination took place on December 14, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

By order of the Commission.

Issued: December 15, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–27662 Filed 12–20–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2010–0017]

Occupational Exposure to Noise Standard (29 CFR 1910.95) Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Occupational Exposure to Noise Standard.

DATES: Comments must be submitted (postmarked, sent, or received) by February 21, 2023.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov.* Documents in the docket are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627) for assistance in locating docket submissions.

Instructions: All submissions must include the agency name and OSHA docket number (OSHA–2010–0017) for the Information Collection Request (ICR). OSHA will place all comments, including any personal information, in the public docket, which may be made available online. Therefore, OSHA cautions interested parties about submitting personal information such as social security numbers and birthdates.

For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Seleda Perryman or Theda Kenney,

Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of the continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, the collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of effort in obtaining information (29 U.S.C. 657).

The following sections describe who uses the information collected under each requirement, as well as how they use it. The collections of information specified in the Noise Standard protect workers from suffering material hearing impairment. The collections of information contained in the Noise Standard include conducting noise monitoring; notifying workers when they are exposed at or above an 8-hour time-weighted average of 85 decibels; providing workers with initial and annual audiograms; notifying workers of a loss in hearing based on comparing audiograms; maintaining records of workplace noise exposure and workers' audiograms; and allowing workers access to materials and records required by the standard.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions to protect workers, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection, and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend the approval of the information collection requirements contained in Occupational Exposure to Noise Standard (29 CFR 1910.95). The agency is requesting an adjusted hour burden increase in the Standard from 2,240,636 to 2,368,281 (a total increase of 127,645 hours). The agency estimates that there are 283,524 establishments and 3,802,698 employees exposed to 85 dBA affected by the Standard. OSHA estimates that the number of establishments from the previous ICR increased by 0.76%, while the estimated number of employees from the previous ICR increased by 0.97%. These estimated increases are based on updated County Business Pattern data for manufacturing.

OSHA will summarize the comments submitted in response to this notice and will include this summary in the request to OMB to extend the approval of the information collection requirements.

Type of Review: Extension of a currently approved collection.

Title: The Occupational Exposure to Noise Standard (29 CFR 1910.95).

OMB Control Number: 1218–0048.

Affected Public: Business or other for-profits.

Number of Respondents: 283,524.

Number of Responses: 32,081,096.

Frequency of Responses: Annually; On occasion.

Average Time per Response: Varies.

Estimated Total Burden Hours: 2,368,281.

Estimated Cost (Operation and Maintenance): $39,771,368.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); if your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at 202–693–1648. or (3) by hard copy. *Please note:* While OSHA's Docket Office is continuing to accept and process submissions by regular mail due to the COVID–19 pandemic, the Docket Office is closed to the public and not able to receive submissions to the docket by hand, express mail, messenger, and courier service. All comments, attachments, and other material must identify the agency name and the OSHA docket number for the ICR (OSHA–2010–0017). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or a facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so that the agency can attach them to your comments.

Due to security procedures, the use of regular mail may cause a significant delay in the receipt of comments.

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link.

Contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627) for information about materials not available from the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 8–2020 (85 FR 58393).

Signed at Washington, DC.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2022–27646 Filed 12–20–22; 8:45 am]

BILLING CODE 4510–26–P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 22–19]

Notice of Entering Into a Compact With the Government of Niger

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: In accordance with the provisions of the Millennium Challenge Act of 2003, as amended, the Millennium Challenge Corporation (MCC) is publishing a summary of the Millennium Challenge Compact (Compact) between the United States of America, acting through MCC, and the Government of Niger. Representatives of MCC and the Government of Niger executed the Compact on December 14, 2022. The complete text of the Compact has been posted at: *https://assets.mcc.gov/content/uploads/niger-concurrent-compact.pdf*.

(Authority: 22 U.S.C. 7709(b)(3))

Dated: December 15, 2022.

Thomas G. Hohenthaner,

Acting VP/General Counsel and Corporate Secretary.

Summary of Niger Compact

Overview of MCC Niger Compact

MCC's five-year, $302,000,000 concurrent Compact with the Republic of Niger (Government) aims to further regional economic integration, increased regional trade, or cross-border collaboration with Niger. The Compact intends to reduce poverty through economic growth by addressing important market and institutional constraints along the transport corridor that connects Niamey, Niger and Cotonou, Benin (Corridor), enabling these countries to gain access to larger markets, attract increased private sector investment, and strengthen both intra-regional and global trade ties. The Compact will address these constraints through two projects that seek to achieve this goal by reducing transportation costs along the Corridor. The Government also will contribute approximately $15,000,000 to support the Compact program.

Project Summaries

The Compact is comprised of two projects:

1. *Corridor Infrastructure Project:*The objective of the Corridor Infrastructure Project is to reduce transportation costs along the Corridor with transportation costs including vehicle operating costs, time-related costs, and injuries and deaths. The Project includes two activities:

- *Road Rehabilitation Activity:* This activity aims to rehabilitate and upgrade approximately 127 km of the *Route Nationale* 1 road between the cities of Niamey and Dosso crossing the regions of Tillabéri and Dosso.
- *Road Maintenance Activity:* This activity aims to implement policy and institutional reforms in order to assist the *Agence de Maîtrise d'Ouvrage Délégué de l'Entretien Routier* to better undertake periodic road maintenance by improving the quality of the road maintenance work, optimizing the budget for such maintenance work, reducing the road maintenance funding gaps, and improving the coordination of planning and selection of roads for periodic maintenance as well as the road maintenance framework maintained by the Ministry of Equipment's *Direction de Gestion des Réseaux Routiers.*

2. *Efficient Corridor Operations Project:* The objective of the Efficient Corridor Operations Project is to reduce transportation costs along the Corridor including vehicle operating costs, time-related costs, injuries and deaths as well as costs related to unreliable processes and market inefficiencies. The Project includes two activities:

- *Freight Sector Operations Improvement Activity:* This activity aims to promote meaningful reforms intended to impact and improve the efficiency of truck freight sector operations by addressing axle load management, regulatory review and capacity building, freight vehicle regulation, and the organization and establishment of a corridor authority.
- *Customs Border Operations Improvement Activity:* This activity aims to support improvements to the Nigerien custom border operations at the Gaya-Malanville crossing between Niger and Benin, in order to improve the fluidity of corridor operations.

Niger Compact Budget

The table below presents the Compact budget and sets forth both the MCC funding allocation by Compact components and the Government's expected $15,000,000 contribution toward the objectives of the Compact.

NIGER COMPACT TOTAL BUDGET

Component	MCC funding
1. Corridor Infrastructure Project	$181,330,215
1.1 Road Rehabilitation Activity	157,012,348
1.2 Road Maintenance Activity	24,317,867
2. Efficient Corridor Operations Project	70,349,500
2.1 Freight Sector Operations Improvement Activity	21,030,000
2.2 Customs Border Operations Improvement Activity	49,319,500
3. Monitoring and Evaluation	1,500,000
4. Program Management and Administration	48,820,285
Total MCC Funding	302,000,000
Total compact funding	**Amount**
Total MCC Funding	302,000,000
Government of Niger Contribution	15,000,000
Total Compact	317,000,000

[FR Doc. 2022–27679 Filed 12–20–22; 8:45 am]

BILLING CODE 9211–03–P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 22–18]

Notice of Entering Into a Compact With the Government of Benin

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: In accordance with the provisions of the Millennium Challenge Act of 2003, as amended, the Millennium Challenge Corporation (MCC) is publishing a summary of the Millennium Challenge Compact (Compact) between the United States of America, acting through MCC, and the Government of Benin. Representatives of MCC and the Government of Benin executed the Compact on December 14, 2022. The complete text of the Compact has been posted at: *https://assets.mcc.gov/content/uploads/benin-concurrent-compact.pdf.*

(Authority: 22 U.S.C. 7709 (b)(3))

Dated: December 15, 2022.

Thomas G. Hohenthaner,

Acting VP/General Counsel and Corporate Secretary.

Summary of Benin Concurrent Compact

Overview of MCC Benin Compact

MCC's five-year, $202,000,000 concurrent Compact with the Republic of Benin (Government) aims to further regional economic integration, increased regional trade, or cross-border collaboration with Niger. The Compact intends to reduce poverty through economic growth by addressing important market and institutional constraints along the transport corridor that connects Cotonou, Benin and Niamey, Niger (Corridor), enabling these countries to gain access to larger markets, attract increased private sector investment, and strengthen both intra-regional and global trade ties. The Compact will address these constraints through two projects that seek to achieve this goal by reducing transportation costs along the Corridor. The Government also will contribute approximately $15,150,000 to support the Compact program.

Project Summaries

The Compact is comprised of two projects:

1. *Corridor Infrastructure Project:* The objective of the Corridor Infrastructure Project is to reduce transportation costs along the Corridor with transportation costs including vehicle operating costs, time-related costs, and injuries and deaths. The Project includes two activities:

- *Road Rehabilitation Activity:* This activity aims to rehabilitate and upgrade approximately 83 km of road between the cities of Bohicon and Dassa with the potential to add complementary traffic mitigation components.
- *Road Maintenance Activity:* This activity aims to support the newly established *Société des Infrastructures Routières et de l'Aménagement du Territoire* to implement the annual road maintenance program developed by the Ministry of Infrastructure and Transport's *Direction Générale des Infrastructures de Transport.*

2. *Efficient Corridor Operations Project:* The objective of the Efficient Corridor Operations Project is to reduce transportation costs along the Corridor including vehicle operating costs, time-related costs, injuries and deaths as well as costs related to unreliable processes and market inefficiencies. The Project includes two activities:

- *Freight Sector Operations Improvement Activity:* This activity aims to promote meaningful reforms intended to impact and improve the efficiency of truck freight sector operations by addressing axle load management, regulatory review and capacity building, freight vehicle regulation, and the organization and establishment of a corridor authority.
- *Customs Border Operations Improvement Activity:* This activity aims to support improvements to the Beninese custom border operations at the Malanville-Gaya crossing between Benin and Niger in order to improve the fluidity of corridor operations.

Benin Compact Budget

The table below presents the Compact budget and sets forth both the MCC funding allocation by Compact components and the Government's expected $15,150,000 contribution toward the objectives of the Compact.

BENIN COMPACT TOTAL BUDGET

Component	MCC funding
1. Corridor Infrastructure Project	$143,313,000
1.1 Road Rehabilitation Activity	139,113,000
1.2 Road Maintenance Activity	4,200,000
2. Efficient Corridor Operations Project	26,000,000
2.1 Freight Sector Operations Improvement Activity	20,555,000
2.2 Customs Border Operations Improvement Activity	5,445,000
3. Monitoring and Evaluation	1,500,000
4. Program Management and Administration	31,187,000
Total MCC Funding	202,000,000
Total compact funding	**Amount**
Total MCC Funding	202,000,000
Government of Benin Contribution	15,150,000
Total Compact	217,150,000

[FR Doc. 2022–27678 Filed 12–20–22; 8:45 am]

BILLING CODE 9211–03–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–22–0027; NARA–2023–012]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice of certain Federal agency requests for records disposition authority (records schedules). We publish notice in the **Federal Register** and on *regulations.gov* for records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on such records schedules.

DATES: We must receive responses on the schedules listed in this notice by February 6, 2023.

ADDRESSES: To view a records schedule in this notice, or submit a comment on one, use the following address: *https://www.regulations.gov/docket/NARA-22-0027/document.* This is a direct link to the schedules posted in the docket for this notice on *regulations.gov.* You may submit comments by the following method:

• *Federal eRulemaking Portal: https://www.regulations.gov.* On the website, enter either of the numbers cited at the top of this notice into the search field. This will bring you to the docket for this notice, in which we have posted the records schedules open for comment. Each schedule has a 'comment' button so you can comment on that specific schedule. For more information on *regulations.gov* and on submitting comments, see their FAQs at *https://www.regulations.gov/faq.*

If you are unable to comment via *regulations.gov*, you may email us at *request.schedule@nara.gov* for instructions on submitting your comment. You must cite the control number of the schedule you wish to comment on. You can find the control number for each schedule in parentheses at the end of each schedule's entry in the list at the end of this notice.

FOR FURTHER INFORMATION CONTACT: Eddie Germino, Strategy and Performance Division, by email at *regulation_comments@nara.gov* or at 301–837–3758. For information about records schedules, contact Records Management Operations by email at *request.schedule@nara.gov* or by phone at 301–837–1799.

SUPPLEMENTARY INFORMATION:

Public Comment Procedures

We are publishing notice of records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on these records schedules, as required by 44 U.S.C. 3303a(a), and list the schedules at the end of this notice by agency and subdivision requesting disposition authority.

In addition, this notice lists the organizational unit(s) accumulating the records or states that the schedule has agency-wide applicability. It also provides the control number assigned to each schedule, which you will need if you submit comments on that schedule. We have uploaded the records schedules and accompanying appraisal memoranda to the *regulations.gov* docket for this notice as ''other'' documents. Each records schedule contains a full description of the records at the file unit level as well as their proposed disposition. The appraisal memorandum for the schedule includes information about the records.

We will post comments, including any personal information and attachments, to the public docket unchanged. Because comments are public, you are responsible for ensuring that you do not include any confidential or other information that you or a third party may not wish to be publicly posted. If you want to submit a comment with confidential information or cannot otherwise use the *regulations.gov* portal, you may contact *request.schedule@nara.gov* for instructions on submitting your comment.

We will consider all comments submitted by the posted deadline and consult as needed with the Federal agency seeking the disposition authority. After considering comments, we may or may not make changes to the proposed records schedule. The schedule is then sent for final approval by the Archivist of the United States. After the schedule is approved, we will post on *regulations.gov* a ''Consolidated Reply'' summarizing the comments, responding to them, and noting any changes we made to the proposed schedule. You may elect at *regulations.gov* to receive updates on the docket, including an alert when we post the Consolidated Reply, whether or not you submit a comment. If you have a question, you can submit it as a comment, and can also submit any concerns or comments you would have to a possible response to the question. We will address these items in consolidated replies along with any other comments submitted on that schedule.

We will post schedules on our website in the Records Control Schedule (RCS) Repository, at *https://www.archives.gov/records-mgmt/rcs,* after the Archivist approves them. The RCS contains all schedules approved since 1973.

Background

Each year, Federal agencies create billions of records. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval. Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives or to destroy, after a specified period, records lacking continuing administrative, legal, research, or other value. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

Agencies may not destroy Federal records without the approval of the Archivist of the United States. The Archivist grants this approval only after thorough consideration of the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value. Public review and comment on these records schedules is part of the Archivist's consideration process.

Schedules Pending

1. Department of Homeland Security, Transportation Security Administration, Biometric and Biographic Passenger Screening Records (DAA–0560–2021–0001).

2. Department of State, Bureau of Population, Refugees, and Migration, Consolidated Schedule (DAA–0059–2020–0022).

3. Department of the Treasury, Internal Revenue Service, Enterprise External Audit Records (DAA–0058–2022–0003).

4. Federal Trade Commission, Office of International Affairs, OIA Records (DAA–0122–2022–0004).

Laurence Brewer,

Chief Records Officer for the U.S. Government.

[FR Doc. 2022–27645 Filed 12–20–22; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board's (NSB) Committee on Science and Engineering Policy hereby gives notice of the scheduling of videoconferences for the transaction of National Science Board business pursuant to the National Science Foundation Act and the Government in the Sunshine Act.

TIME AND DATE: Wednesday, January 4, 2023, from 3:00 p.m.–3:30 p.m. EST.

Tuesday, January 10, 2023, from 3:00 p.m.–3:30 p.m. EST

PLACE: These meetings will be held by videoconference through the National Science Foundation.

STATUS: Open

MATTERS TO BE CONSIDERED: The agenda for the January 4 meeting is: Chair's opening remarks; discussion of the narrative outline for the SEI 2024 Innovation thematic report.

The agenda for the January 10 meeting is: Chair's opening remarks; discussion of the narrative outline for the SEI 2024 Publications thematic report.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: (Chris Blair, *cblair@nsf.gov*), 703/292–7000.

The link to a You Tube livestream for the January 4 meeting is *https://www.youtube.com/watch?v=ucXG9obIV_Y.*

The link to a You Tube livestream for the January 10 meeting is *https://www.youtube.com/watch?v=2JkKE1qLBHs.*

Christopher Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2022–27847 Filed 12–19–22; 4:15 pm]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by January 20, 2023. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314 or *ACApermits@nsf.gov.*

FOR FURTHER INFORMATION CONTACT: Andrew Titmus, ACA Permit Officer, at the above address, 703–292–4479.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 671), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Application Details

Permit Application: 2023–026

1. *Applicant:* Michael Raabe, Leidos Innovations Group, Antarctic Support Contract, 7400 S Tucson Way, Centennial, CO. *environmental@usap.gov.*

Activity for Which Permit is Requested: Enter Antarctic Specially Protected Area. The applicant seeks an ACA permit for the purposes of marine transit of U.S. Antarctic Program chartered vessels through Antarctic Specially Protected Areas (ASPA) 145, 152, and 153. The permit would be used solely for marine transit and not for any scientific activity within these ASPAs. Marine transit would occur so long as the values to be protected within each ASPA are not jeopardized and would only occur as necessary in the best interests of the U.S. Antarctic Program. The ASPAs would be avoided whenever possible.

Location: ASPA 145—Port Foster, Deception Island, South Shetland Islands; ASPA 152—Western Bransfield Strait; ASPA 153—Eastern Dallmann Bay.

Dates of Permitted Activities: February 1, 2023–January 31, 2028.

Permit Application: 2023–027

2. *Applicant:* Michael Raabe, Leidos Innovations Group, Antarctic Support Contract, 7400 S Tucson Way, Centennial, CO. *environmental@usap.gov.*

Activity for Which Permit is Requested: Enter Antarctic Specially Protected Area. The applicant seeks an ACA permit for the purposes of recreational and educational visits to several historic huts in the vicinity of McMurdo Station. Visits would occur at Scott's hut at Cape Evans (ASPA 155), Shackleton's hut at Cape Royds (ASPA 157), Scott's Discovery hut at Hut Point (ASPA 158), and at Cape Adare (ASPA 159). Access to sites would be by tracked vehicle, helicopter, or on foot as appropriate. All visits would be conducted in accordance with the management plan for each specific site. Procedures for monitoring numbers of U.S. Antarctic Program visitors throughout the season would be implemented.

Location: ASPA 155—Cape Evans, Ross Island; ASPA 157—Backdoor Bay, Cape Royds, Ross Island; ASPA 158—Hut Point, Ross Island; ASPA 159—Cape Adare, Borchgrevink Coast.

Dates of Permitted Activities: February 1, 2023–January 31, 2028.

Permit Application: 2023–028

3. *Applicant* Michael Raabe, Leidos Innovations Group, Antarctic Support Contract, 7400 S Tucson Way, Centennial, CO. *environmental@usap.gov.*

Activity for Which Permit is Requested: Enter Antarctic Specially Protected Area. The applicant seeks an ACA permit for the purposes of entering Antarctic Specially Protected Areas (ASPA) to gather professional video footage, still photographs, and to interview scientists in support of National Science Foundation (NSF) directed news and public outreach projects and releases. Visits would occur to ASPAs in conjunction with valid scientific activities for the express purposes of gathering footage and information on scientific research, general scenic locations, and interviews with scientists working in the field. Within historic huts, only tripods or monopods with flat bottomed rubber bases would be used. All visits would

be conducted in accordance with the management plan for each specific site.

Location: ASPA 105—Beaufort Island, McMurdo Sound, Ross Sea; ASPA 113—Litchfield Island, Arthur Harbor, Anvers Island, Palmer Archipelago; ASPA 116—New College Valley, Caughley Beach, Cape Bird, Ross Island; ASPA 121—Cape Royds, Ross Island; ASPA 124—Cape Crozier, Ross Island; ASPA 131—Canada Glacier, Lake Fryxell, Taylor Valley, Victoria Land; ASPA 138—Linnaeus Terrace, Asgard Range, Victoria Land; ASPA 139—Biscoe Point, Anvers Island, Palmer Archipelago; ASPA 155—Cape Evans, Ross Island; ASPA 157—Backdoor Bay, Cape Royds, Ross Island; ASPA 158—Hut Point, Ross Island; ASPA 172—Lower Taylor Glacier and Blood Falls, Taylor Valley, McMurdo Dry Valleys, Victoria Land.

Dates of Permitted Activities: February 1, 2023–January 31, 2028.

Permit Application: 2023–029

4. *Applicant:* Michael Raabe, Leidos Innovations Group, Antarctic Support Contract, 7400 S. Tucson Way, Centennial, CO. *environmental@usap.gov.*

Activity for Which Permit is Requested: Take, Harmful Interference. The applicant seeks an ACA permit for take and harmful interference for the purposes of herding native mammal and bird species away from aircraft runways, roads, and the ice pier at McMurdo Station, or the pier and general station area at Palmer Station to protect operational safety and prevent potential harm to the animals. Herding activities would be conducted in accordance with procedures using humane and non-lethal techniques to move animals while causing as little disturbance to the animals as possible. Individuals tasked with herding would be specifically trained in the herding techniques and procedures. Most commonly encountered wildlife at McMurdo Station includes Weddell seals, Adelie penguins, Emperor penguins, and South Polar skuas. Most commonly encountered wildlife at Palmer Station includes Elephant seals, Antarctic fur seals, Crabeater seals, Adelie penguins, Gentoo penguins, Chinstrap penguins, and Brown skuas.

Location: McMurdo Station, Ross Sea; Palmer Station, Anvers Island, Antarctic Peninsula Area.

Dates of Permitted Activities: February 1, 2023–January 31, 2028.

Permit Application: 2023–030

5. *Applicant:* Michael Raabe, Leidos Innovations Group, Antarctic Support Contract, 7400 S. Tucson Way, Centennial, CO. *environmental@usap.gov.*

Activity for Which Permit is Requested: Enter Antarctic Specially Protected Area. The applicant seeks an ACA permit for entry into Arrival Heights, Antarctic Specially Protected Area (ASPA) 122 for ongoing scientific work by U.S. Antarctic Program principal investigators and their teams. Additionally Antarctic Support Contract (ASC) personnel would need access to the site daily for equipment monitoring, data acquisition, calibrations, and repairs. Official scientific visitors would also enter the site for educational and oversight purposes. Other ASC personnel may be called upon to perform inspections, maintenance, fueling, or repair functions at facilities within the ASPA. Environmental representatives may enter the site to observe and determine whether modifications to the management plan are warranted. All visits would be conducted in accordance with the management plan for each specific site.

Location: ASPA 122—Arrival Heights, Hut Point Peninsula, Ross Island.

Dates of Permitted Activities: February 1, 2023–January 31, 2028.

Permit Application: 2023–031

6. *Applicant:* Michael Raabe, Leidos Innovations Group, Antarctic Support Contract, 7400 S Tucson Way, Centennial, CO. *environmental@usap.gov.*

Activity for Which Permit is Requested: Enter Antarctic Specially Protected Area. The applicant seeks an ACA permit for the purposes of entering Antarctic Specially Protected Areas (ASPA) to support National Science Foundation (NSF) funded U.S. Antarctic Program science operations accessed using small boats from U.S. Antarctic Program research vessels or from Palmer Station. The ASPAs that would be entered are locations of routine support by Antarctic Support Contract station staff and marine technicians who commonly aid in transport, field camp put-in and take-out in support of science at these locations. Personnel would only enter ASPAs in support of science expeditions which would obtain separate ACA permits for entry to, and work within each specific ASPA. All visits would be conducted in accordance with the management plan for each specific site.

Location: ASPA 113—Litchfield Island, Arthur Harbor, Anvers Island, Palmer Archipelago; ASPA 117—Avian Island, Marguerite Bay, Antarctic Peninsula; ASPA 126—Byers Peninsula, Livingston Island; ASPA 128—Western Shore of Admiralty Bay, King George Island, South Shetland Islands; ASPA 139—Biscoe Point, Anvers Island, Palmer Archipelago; ASPA 149—Cape Shirreff and San Telmo Island, Livingston Island, South Shetland Islands; ASPA 161—Terra Nova Bay, Ross Sea; ASPA 173—Cape Washington and Silverfish Bay, Terra Nova Bay, Ross Sea.

Dates of Permitted Activities: February 1, 2023–January 31, 2028.

Permit Application: 2023–032

7. *Applicant:* Michael Raabe, Leidos Innovations Group, Antarctic Support Contract, 7400 S Tucson Way, Centennial, CO. *environmental@usap.gov.*

Activity for Which Permit is Requested: Introduce Non-Indigenous Species into Antarctica. The applicants seeks an ACA permit to introduce non-indigenous species into Antarctica for the purposes of wastewater treatment at McMurdo Station. The applicant would introduce commercially available, proprietary bacteria supplement D500A for municipal wastewater treatment plants, for use at the wastewater treatment plant at McMurdo Station, Antarctica. Benefits include better sludge settling, better dewatering, control of surface foam and filamentous growth, reduction of total sludge volume, and improved wastewater plant performance. Bacteria would not be released into the environment. Once expired, bacteria are captured in wastewater treatment plant solids that are retrograded to the United States. Effluent from the treatment plant is treated with UV sterilization before discharge.

Location: McMurdo Station, Ross Sea.

Dates of Permitted Activities: February 1, 2023–January 31, 2028.

Permit Application: 2023–033

8. *Applicant:* Michael Raabe, Leidos Innovations Group, Antarctic Support Contract, 7400 S Tucson Way, Centennial, CO. *environmental@usap.gov.*

Activity for Which Permit is Requested: Enter Antarctic Specially Protected Area. The applicant seeks an ACA permit for the purposes of entering Antarctic Specially Protected Areas (ASPA) to support National Science Foundation (NSF) funded U.S. Antarctic Program science operations. Antarctic Support Contract Operations and support personnel are required to conduct occasional operations, maintenance, construction, and rehabilitation activities in support of U.S. Antarctic Program science at designated ASPAs in the Ross Sea

region. ASPAs in this region are generally accessed via helicopter, thus a helicopter pilot and helicopter technician would accompany the operations personnel. No structures or scientific equipment would be erected within the ASPAs except as specified in separate science project specific ACA permits. All visits would be conducted in accordance with the management plan for each specific site.

Location: ASPA 121—Cape Royds, Ross Island; ASPA 124—Cape Crozier, Ross Island; ASPA 131—Canada Glacier, Lake Fryxell, Taylor Valley, Victoria Land; ASPA 137—North-West White Island, McMurdo Sound; ASPA 138—Linnaeus Terrace, Asgard Range, Victoria Land; ASPA 172—Lower Taylor Glacier and Blood Falls, Taylor Valley, McMurdo Dry Valleys, Victoria Land; ASPA 175—High Altitude Geothermal sites of the Ross Sea Region.

Dates of Permitted Activities: February 1, 2023–January 31, 2028.

Permit Application: 2023–034

9. *Applicant:* Michael Raabe, Leidos Innovations Group, Antarctic Support Contract, 7400 S Tucson Way, Centennial, CO. *environmental@usap.gov.*

Activity for Which Permit is Requested: Enter Antarctic Specially Protected Area. The applicant seeks an ACA permit for the purposes of entering Antarctic Specially Protected Areas (ASPA) to support National Science Foundation (NSF) environmental management responsibilities under Annex V of the Protocol on Environmental Protection to the Antarctic Treaty. A review of Antarctic Specially Protected Area (ASPA) management plans must be initiated at least every five years to; gather up to date information on site status; verify that the reasons for special protection remain valid; verify that the values being protected are being maintained; verify that the management measures in place are sufficient to provide protection; and recommend and management measures that may be necessary to maintain the values being protected. Antarctic Support Contract Environmental Engineering personnel would enter the listed ASPAs to collect information in support of 5-year ASPA management plan reviews, for general management and maintenance concerns, and to address any environmental concern or potential release within the ASPA. All visits would be conducted in accordance with the management plan for each specific site.

Location: ASPA 105—Beaufort Island, McMurdo Sound, Ross Sea; ASPA 106—Cape Hallett, Northern Victoria Land, Ross Sea; ASPA 113—Litchfield Island, Arthur Harbor, Anvers Island, Palmer Archipelago; ASPA 121—Cape Royds, Ross Island; ASPA 123—Barwick and Balham Valleys, Southern Victoria Land; ASPA 124—Cape Crozier, Ross Island; ASPA 128—Western Shore of Admiralty Bay, King George Island, South Shetland Islands; ASPA 131—Canada Glacier, Lake Fryxell, Taylor Valley, Victoria Land; ASPA 137—North-West White Island, McMurdo Sound; ASPA 138—Linnaeus Terrace, Asgard Range, Victoria Land; ASPA 139—Biscoe Point, Anvers Island, Palmer Archipelago; ASPA 149—Cape Shirreff and San Telmo Island, Livingston Island, South Shetland Islands; ASPA 154—Botany Bay, Cape Geology, Victoria Island; ASPA 172—Lower Taylor Glacier and Blood Falls, Taylor Valley, McMurdo Dry Valleys, Victoria Land; ASPA 175—High Altitude Geothermal sites of the Ross Sea Region; ASPA 176—Rosenthal Islands, Anvers Island, Palmer Archipelago.

Dates of Permitted Activities: February 1, 2023–January 31, 2028.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2022–27743 Filed 12–20–22; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

Licensing Support Network Advisory Review Panel

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of renewal of the charter of the Licensing Support Network Advisory Review Panel.

SUMMARY: The Licensing Support System Advisory Review Panel was established by the U.S. Nuclear Regulatory Commission (NRC) as a Federal Advisory Committee in 1989. Its purpose was to provide advice on the fundamental issues of design and development of an electronic information management system to be used to store and retrieve documents relating to the licensing of a geologic repository for the disposal of high-level radioactive waste, and on the operation and maintenance of the system. This electronic information management system was known as the Licensing Support System.

FOR FURTHER INFORMATION CONTACT: Russell E. Chazell, Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555; telephone: (301) 415–7469 or at *Russell.Chazell@nrc.gov.*

SUPPLEMENTARY INFORMATION: In November 1998, the Commission approved amendments to title 10 *Code of Federal Regulations* part 2 that renamed the Licensing Support System Advisory Review Panel as the Licensing Support Network Advisory Review Panel (LSNARP). The Licensing Support Network (LSN) was shut down in 2011 and the document collection was submitted to the Office of the Secretary. The document collection was made publicly available in the NRC's Agencywide Documents Access and Management System in August 2016 and contains over 3.69 million documents associated the proposed high-level waste facility at Yucca Mountain. Membership on the Panel will continue to be drawn from those whose interests could be affected by the use of the LSN document collection, including the Department of Energy, the NRC, the State of Nevada, the National Congress of American Indians, affected units of local governments in Nevada, the Nevada Nuclear Waste Task Force, and nuclear industry groups. Federal agencies with expertise and experience in electronic information management systems may also participate on the Panel.

The NRC has determined that renewal of the charter for the LSNARP until December 16, 2024, is in the public interest in connection with duties imposed on the Commission by law. This action is being taken in accordance with the Federal Advisory Committee Act after consultation with the Committee Management Secretariat, General Services Administration.

Dated at Rockville, Maryland this 16th day of December, 2022.

For the U.S. Nuclear Regulatory Commission.

Russell E. Chazell,

Federal Advisory Committee Management Officer, Office of the Secretary.

[FR Doc. 2022–27697 Filed 12–20–22; 8:45 am]

BILLING CODE 7590–01–P

POSTAL SERVICE

International Product Change—International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service With Reseller Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add an International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service with Reseller contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: *Date of notice:* December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 12, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service with Reseller Contract 7 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–78 and CP2023–79.

Ruth B. Stevenson,

Chief Counsel, Ethics and Legal Compliance.

[FR Doc. 2022–27631 Filed 12–20–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

International Product Change—International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add an International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: *Date of notice:* December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 13, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 14 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–89 and CP2023–90.

Ruth B. Stevenson,

Chief Counsel, Ethics and Legal Compliance.

[FR Doc. 2022–27635 Filed 12–20–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

International Product Change—International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add an International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: *Date of notice:* December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 13, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 13 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–88 and CP2023–89.

Ruth B. Stevenson,

Chief Counsel, Ethics and Legal Compliance.

[FR Doc. 2022–27634 Filed 12–20–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

International Product Change—International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service With Reseller Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add an International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service with Reseller contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: *Date of notice:* December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 13, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service with Reseller Contract 8 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–86 and CP2023–87.

Ruth B. Stevenson,

Chief Counsel, Ethics and Legal Compliance.

[FR Doc. 2022–27632 Filed 12–20–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 12, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 97 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–79, CP2023–80.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–27748 Filed 12–20–22; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

International Product Change—International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add an International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: *Date of notice:* December 21, 2022.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 13, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 12 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–87 and CP2023–88.

Ruth B. Stevenson,

Chief Counsel, Ethics and Legal Compliance.

[FR Doc. 2022–27633 Filed 12–20–22; 8:45 am]

BILLING CODE 7710–12–P

RAILROAD RETIREMENT BOARD

Appointment to the Senior Executive Service Performance Review Board

AGENCY: Railroad Retirement Board.

ACTION: Notice.

SUMMARY: The Railroad Retirement Board (Board) is announcing the alternate member of its Senior Executive Service Performance Review Board.

DATES: This appointment is effective on the date of publication of this notice.

FOR FURTHER INFORMATION CONTACT: Ana Kocur, General Counsel, Railroad Retirement Board, 844 North Rush Street, Chicago, IL 60611–1275, (312) 751–4948.

SUPPLEMENTARY INFORMATION: Under title 5, chapter 43, subchapter II, section 4314(c)(4) of the United States Code as added by section 405(a) of the Civil Service Reform Act of 1978, Pub. L. 95–454 (5 U.S.C. 4314(c)(4)), the Board must publish in the **Federal Register** a list of persons who may be named to serve on the Performance Review Board that oversees the evaluation of performance appraisals for Senior Executive Service members of the Railroad Retirement Board. The alternate member of the Performance Review Board is: Mark Blythe.

Dated: December 16, 2022.

By Authority of the Board.

Stephanie Hillyard,

Secretary to the Board.

[FR Doc. 2022–27706 Filed 12–20–22; 8:45 am]

BILLING CODE P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96506; File No. SR–IEX–2022–13]

Self-Regulatory Organizations: Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend its Fee Schedule To Reflect Adjustments to FINRA's Registration Fees Related to the Central Registration Depository

December 15, 2022.

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 December 13, 2022, the Investors Exchange LLC (''IEX'' 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

Pursuant to the provisions of Section 19(b)(1) under the Act, and Rule 19b–4 thereunder, IEX is filing with the Commission a proposed rule change pursuant to IEX Rule 15.110(a) to amend its Fee Schedule to reflect adjustments to FINRA's Registration Fees related to the Central Registration Depository, which will be collected by FINRA. The Exchange has designated this proposal as establishing or changing a due, fee, or other charge imposed by the self-regulatory organization, whether or not the person is a member of the self-regulatory organization, which renders the proposed rule change effective upon filing, pursuant to Section 19(b)(3(A)(ii) of the Act.[4]

The text of the proposed rule change is available at the Exchange's website at *www.iextrading.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 these statements may be examined at the places specified in Item IV below. The self-regulatory organization 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

IEX is proposing, pursuant to IEX Rule 15.110(a), to amend its Fee Schedule [5] to reflect adjustments to FINRA's Registration Fees and Fingerprinting Fees in connection with the Central Registration Depository (''CRD system'').[6] The FINRA fees are

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78s(b)(3)(A)(ii).

[5] *See https://exchange.iex.io/resources/trading/fee-schedule/.*

[6] The CRD system is the central licensing and registration system for the U.S. securities industry.

collected and retained by FINRA via Web CRD for the registration of employees of IEX Members who are not FINRA members. Because FINRA separately collects the CRD system fee for any IEX Member [7] that is also a FINRA member, [8] this fee filing only applies to IEX Members who are not FINRA members.

Effective January 2, 2023, FINRA expects to increase (1) from $110 to $155 the fee it charges for the additional processing of each initial or amended Form U4, Form U5 or Form BD that includes the initial reporting, amendment, or certification of one or more disclosure events or proceedings; (2) from $45 to $70 the annual fee for each of the Member's registered representatives and principals for system processing; and (3) from $15 to $20 the fee [9] for processing and posting to the CRD system each set of fingerprint cards submitted electronically by the Member.[10] Accordingly, IEX is proposing to update the corresponding fees on its Fee Schedule to reflect the new FINRA processing fees. IEX proposes to have these new fees take effect starting January 2, 2023. Because these costs are borne by FINRA when a non-FINRA member uses the CRD system, FINRA will continue to collect and retain these fees for the registration of associated persons of IEX Members that are not also FINRA members.

2. Statutory Basis

IEX believes that the proposed rule change is consistent with the provisions of Section 6(b) of the Act, [11] of the Act in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act, [12] in particular, in that it provides for the equitable allocation of reasonable fees and other charges among its members, and does not unfairly discriminate between customers, issuers, brokers and dealers. All similarly situated Members are subject to the same fee structure, and every Member firm must use the CRD system for registration and disclosure.

The proposed fee is reasonable because it is identical to the fee adopted by FINRA for use of the Web CRD system for disclosure and the registration of associated persons of FINRA members.[13] Thus, the Exchange's Fee Schedule will reflect the current registration rate that will be assessed by FINRA as of January 2, 2023 for any IEX Members that are not also FINRA members. IEX also believes the proposed fee change is reasonable, because, as noted in the FINRA Fee Filing, FINRA is increasing the CRD system fees to provide enough revenue to support its regulatory mission.[14]

The Exchange believes that its proposal to increase (1) from $110 to $155 the fee it charges for the additional processing of each initial or amended Form U4, Form U5 or Form BD that includes the initial reporting, amendment, or certification of one or more disclosure events or proceedings; (2) from $45 to $70 the annual fee for each of the Member's registered representatives and principals for system processing; and (3) from $15 to $20 the fee for processing and posting to the CRD system each set of fingerprint cards submitted electronically by the Member is equitable and not unfairly discriminatory because the equivalent fees will be charged by FINRA of all users of the CRD system, whether or not they are FINRA members.[15] Therefore, all users of the CRD system will equally bear the cost of maintaining the system.[16]

FINRA further noted its belief that the proposed fees are reasonable because they help to ensure the integrity of the information in the CRD system, which is important because the Commission, FINRA, other self-regulatory organizations and state securities regulators use the CRD system to make licensing and registration decisions, among other things.[17]

B. Self-Regulatory Organization's Statement on Burden on Competition

IEX 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, as amended. Specifically, the Exchange believes that the proposed fees will result in the same regulatory fees being charged to all Members required to report information to the CRD system and for services performed by FINRA, regardless of whether or not such Members are FINRA members.

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

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) [18] of the Act.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [19] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. 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–IEX–2022–13 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–IEX–2022–13. This file number should be included on the subject line if email is used. To help the

The CRD system enables individuals and firms seeking registration with multiple states and self-regulatory organizations to do so by submitting a single form, fingerprint card and a combined payment of fees to FINRA. Through the CRD system, FINRA maintains the qualification, employment and disciplinary histories of registered associated persons of broker dealers.

[7] *See* IEX Rule 1.160(s).

[8] IEX Members that are also FINRA members are charged CRD system fees according to Section (4) of Schedule A to the FINRA By-Laws.

[9] This increase is in addition to a pass-through of any other charge imposed by the United States Department of Justice for processing each set of fingerprints. The FBI fingerprint charge is currently $11.25. *See* Securities Exchange Act Release No. 67247 (June 25, 2012) 77 FR 38866 (June 29, 2012) (SR–FINRA–2012–030).

[10] *See* Securities Exchange Act Release No. 90176 (October 14, 2020), 85 FR 66592 (October 20, 2020) (SR–FINRA–2020–032) (''FINRA Fee Filing'').

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4) and (5).

[13] *See supra* note 10.

[14] *See supra* note 10.

[15] Because the Exchange will not be collecting or retaining these fees, therefore, the Exchange will also not be in a position to apply them in an inequitable or unfairly discriminatory manner.

[16] *See supra* note 10.

[17] *See supra* note 10.

[18] 15 U.S.C. 78s(b)(3)(A)(ii).

[19] 15 U.S.C. 78s(b)(2)(B).

Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the IEX's principal office and on its internet website at *www.iextrading.com.* 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–IEX–2022–13 and should be submitted on or before January 11, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–27653 Filed 12–20–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96501; File No. SR–NYSEAMER–2022–55]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify the NYSE American Options Fee Schedule

December 15, 2022.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on December 9, 2022, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE American Options Fee Schedule (''Fee Schedule'') regarding the Firm Monthly Fee Cap. The Exchange proposes to implement the fee change effective December 9, 2022.[4] The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing to amend the Fee Schedule to modify the Firm Monthly Fee Cap. The Exchange proposes to implement the rule change on December 9, 2022.

The Exchange proposes to modify the Firm Monthly Fee Cap, which is set forth in Section I.I. of the Fee Schedule.[5] Currently, a Firm's fees associated with Manual transactions are capped at $100,000 per month per Firm. A Firm currently may also qualify for a decreased fee cap by achieving tier levels in the American Customer Engagement Program (the ''ACE Program'').[6]

The Exchange proposes to raise the Firm Monthly Fee Cap to $150,000 per month per Firm and to eliminate the decreased fee caps for Firms that achieve ACE Program tiers, such that all Firms would be eligible for a $150,000 monthly fee cap. Accordingly, the Exchange proposes to modify Section I.I. to replace references to a $100,000 cap with references to a $150,000 cap and to delete the sentence and table describing decreased fee caps offered to Firms that qualify for ACE Program tiers.[7] The Exchange does not otherwise propose any changes to the provisions of the Firm Monthly Fee Cap. The incremental service fee of $0.01 per contract for Firm Manual transactions other than QCC Transactions will continue to apply once the Firm Monthly Fee Cap has been reached, and Royalty Fees and fees or volumes associated with Strategy Executions will continue to be excluded from the calculation of fees towards the Firm Monthly Fee Cap. Firm Facilitation Manual trades will also continue to be executed at the rate of $0.00 per contract regardless of whether a Firm has reached the Firm Monthly Fee Cap.

The Exchange believes that the proposed change, despite increasing the amount of the Firm Monthly Fee Cap, would continue to incentivize Firms to direct order flow to the Exchange to achieve the benefits of cap on their Manual transaction fees. The Exchange also notes that the proposed change would provide for a uniform fee cap amount that would be applicable to all Firms and sets the Firm Monthly Fee Cap at an amount similar to the firm fee cap established by another options exchange.[8]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[10] in particular, because it provides for the equitable allocation of reasonable dues, fees, and

[20] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange previously filed to amend the Fee Schedule on December 1, 2022 (SR–NYSEAMER–2022–54) and withdrew such filing on December 9, 2022.

[5] *See* Fee Schedule, Section I.I., Firm Monthly Fee Cap, *available at: https://www.nyse.com/publicdocs/nyse/markets/american-options/NYSE_American_Options_Fee_Schedule.pdf.*

[6] *See id.,* Section I.E., American Customer Engagement (''ACE'') Program.

[7] The Exchange also proposes a conforming change to footnote 4 in Section I.A. (Rates for Options transactions) of the Fee Schedule, which cross-references the Firm Monthly Fee Cap as set forth in Section I.I. The Exchange likewise proposes to modify footnote 4 to replace the reference to a $100,000 cap with a reference to a $150,000 cap.

[8] *See, e.g.,* Nasdaq PHLX LLC, Options 7 Pricing Schedule, Section 4 (providing for a ''Monthly Firm Fee Cap'' capping firm fees at $150,000).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) and (5).

other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Rule Change Is Reasonable

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [11]

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[12] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in October 2022, the Exchange had less than 8% market share of executed volume of multiply-listed equity and ETF options trades.[13]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees. Stated otherwise, changes to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow.

The proposed change to the Firm Monthly Fee Cap is reasonable because the Exchange believes the fee cap would continue to incentivize Firms to direct order flow to the Exchange to receive the benefits of capped fees for their Manual transactions. The Exchange also believes the proposed change is reasonable because it would provide for a fee cap amount that would be applicable to all Firms (regardless of their qualification for ACE Program tiers) and establishes a cap amount similar to that offered by another options exchange.[14]

To the extent that the proposed change continues to attract volume to the Exchange, this order flow would continue to make the Exchange a more competitive venue for order execution, which, in turn, promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system. The Exchange notes that all market participants stand to benefit from any increase in volume, which could promote market depth, facilitate tighter spreads and enhance price discovery, particularly to the extent the proposed change encourages market participants to utilize the Exchange as a primary trading venue, and may lead to a corresponding increase in order flow from other market participants.

Finally, to the extent the proposed change continues to attract greater volume and liquidity, the Exchange believes the proposed change would improve the Exchange's overall competitiveness and strengthen its market quality for all market participants. In the backdrop of the competitive environment in which the Exchange operates, the proposed rule change is a reasonable attempt by the Exchange to increase the depth of its market and improve its market share relative to its competitors. The Exchange's fees are constrained by intermarket competition, as market participants can choose to direct their order flow to any of the 16 options exchanges, including an exchange offering a monthly firm fee cap of a similar amount.[15] The Exchange believes that proposed rule change is designed to continue to incent market participants to direct liquidity to the Exchange, and, to the extent they continue to be incentivized to aggregate their trading activity at the Exchange, that increased liquidity could promote market depth, price discovery and improvement, and enhanced order execution opportunities for all market participants.

The Proposed Rule Change Is an Equitable Allocation of Credits and Fees

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits. The proposed change is equitable because the modified Firm Monthly Fee Cap would apply to all Firms equally and, by eliminating the decreased caps available to Firms that achieve ACE Program tiers, would provide for the same fee cap amount for all Firms on their Manual transactions. The Exchange believes that the proposed changes are designed to continue to incent Firms to aggregate their executions at the Exchange as a primary execution venue. To the extent that the proposed change achieves its purpose in attracting more volume to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for, among other things, order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange, thereby improving market-wide quality and price discovery.

The Proposed Rule Change Is Not Unfairly Discriminatory

The Exchange believes that the modification of the Firm Monthly Fee Cap is not unfairly discriminatory because the fee cap, as proposed, would be available to all similarly situated Firms, any of which could continue to be incentivized to direct order flow to the Exchange to qualify for the fee cap. Moreover, the proposed change to the Firm Monthly Fee Cap is not unfairly discriminatory because it would apply the same fee cap amount to all Firms, regardless of whether they achieve ACE Program tiers.

Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange, thereby improving market-wide quality and price discovery. The resulting increased volume and liquidity would provide more trading opportunities and tighter spreads to all market participants and thus would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the

[11] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (''Reg NMS Adopting Release'').

[12] The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, *available here: https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthy-Weekly-Volume-Statistics.*

[13] Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of ETF-based options, *see id.,* the Exchange's market share in equity-based options was 7.68% for the month of October 2021 and 7.25% for the month of October 2022.

[14] *See* note 8, *supra.*

[15] *See id.*

Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [16]

Intramarket Competition. The proposed change is designed to continue to attract order flow to the Exchange, which could increase the volumes of contracts traded on the Exchange. Greater liquidity benefits all market participants on the Exchange, and the Exchange believes that the proposed modification of the Firm Monthly Fee Cap (even though it would raise the amount of the fee cap) would continue to incentivize Firms to direct order flow to the Exchange to be eligible for the benefits of capped fees on Manual transactions, thereby promoting liquidity on the Exchange to the benefit of all market participants.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the 16 competing option exchanges if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[17] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in October 2022, the Exchange had less than 8% market share of executed volume of multiply-listed equity and ETF options trades.[18]

The Exchange believes that the proposed rule change reflects this competitive environment because it modifies the Exchange's fees in a manner designed to continue to incent market participants to direct trading interest to the Exchange, to provide liquidity and to attract order flow. To the extent that Firms are incentivized to utilize the Exchange as a primary trading venue for all transactions, all of the Exchange's market participants should benefit from the improved market quality and increased opportunities for price improvement. The Exchange also notes that the proposed change increases the Firm Monthly Fee Cap to an amount similar to the fee cap offered by another options exchange. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [19] of the Act and subparagraph (f)(2) of Rule 19b–4 [20] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [21] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEAMER–2022–55 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2022–55. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2022–55, and should be submitted on or before January 11, 2023.

[16] *See* Reg NMS Adopting Release, *supra* note 11, at 37499.

[17] *See* note 12, *supra.*

[18] *See* note 13, *supra.*

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(2).

[21] 15 U.S.C. 78s(b)(2)(B).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Sherry R. Haywood,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96514; File No. SR–NYSE–2022–14]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Approving a Proposed Rule Change, as Modified by Amendment No. 2, To Modify Certain Pricing Limitations for Securities Listed on the Exchange Pursuant to a Primary Direct Floor Listing

December 15, 2022.

I. Introduction

On April 7, 2022, New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''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 modify certain pricing limitations for securities listed on the Exchange pursuant to a direct listing in which the company will sell shares itself in the opening auction on the first day of trading on the Exchange. The proposed rule change was published for comment in the **Federal Register** on April 19, 2022.[3]

On May 26, 2022, pursuant to Section 19(b)(2) of the Exchange Act,[4] the Commission designated a longer period within which to either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On July 18, 2022, the Commission instituted proceedings under Section 19(b)(2)(B) of the Exchange Act[6] to determine whether to approve or disapprove the proposed rule change.[7] On October 11, 2022, the Commission extended the time period for approving or disapproving the proposal to December 15, 2022.[8]

On November 8, 2022, the Exchange filed Amendment No. 2 to the proposed rule change, which superseded the original filing in its entirety.[9] The proposed rule change, as modified by Amendment No. 2, was published for comment in the **Federal Register** on November 15, 2022.[10] The Commission is approving the proposed rule change, as modified by Amendment No. 2.

II. Description of the Proposal, as Modified by Amendment No. 2

Section 102.01B, Footnote (E) of the of the Listed Company Manual (the ''Manual'') provides that, in certain cases, a company that has not previously had its common equity securities registered under the Exchange Act may wish to list its common equity securities on the Exchange at the time of effectiveness of a registration statement[11] pursuant to which the company will sell shares itself in the opening auction on the first day of trading on the Exchange (a ''Primary Direct Floor Listing'').[12] In the Exchange's prior approved proposal to initially allow for a Primary Direct Floor Listing, the Exchange also adopted Rule 7.31(c)(1)(D) defining an Issuer Direct Offering Order (''IDO Order'')[13] for use by a company that wishes to sell its shares through a Primary Direct Floor Listing. In addition, the Exchange modified Rule 7.35A to describe how the IDO Order would participate in a Direct Listing Auction, establish additional requirements for a Designated Market Maker (''DMM'') when conducting a Direct Listing Auction for a Primary Direct Floor Listing, and specify how the Indication Reference Price would be determined for a security to be opened in a Direct Listing.[14] Currently, under Rule 7.35A(g)(2), the DMM will not conduct a Direct Listing Auction for a Primary Direct Floor Listing if (i) the Auction Price[15] would be outside of the price range specified by the company in its effective registration statement (the ''Price Range Limitation'')[16] or (ii) there

[22] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 94708 (Apr. 13, 2022), 87 FR 23300 (Apr. 19, 2022). Comments received on the proposal are available on the Commission's website at: *https://www.sec.gov/comments/sr-nyse-2022-14/srnyse202214.htm.* The comments expressed by one commenter are not relevant to the proposed rule change. *See* Letter from Andrew Robison (Apr. 22, 2022).

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 94991 (May 26, 2022), 87 FR 33518 (June 2, 2022). The Commission designated July 18, 2022, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 95312 (July 18, 2022), 87 FR 43914 (July 22, 2022) (''OIP'').

[8] *See* Securities Exchange Act Release No. 96023 (Oct. 11, 2022), 87 FR 62902 (Oct. 17, 2022.

[9] On November 4, 2022, the Exchange filed Amendment No. 1 to the proposed rule change. Amendment No. 1 was withdrawn on November 8, 2022. Amendment No. 2 to the proposed rule change revised the proposal: (i) to require the retention of an underwriter with respect to the primary sales of shares by the company and identification of the underwriter in the company's effective registration statement; (ii) to clarify that the 20% and 80% thresholds used in determining the Primary Direct Floor Listing Auction Price Range will be calculated based on the highest price of the Issuer Price Range; (iii) to require that the Auction Price cannot be above the price that is 80% above the highest price of the Issuer Price Range; (iv) to require that if the issuer certifies to the Exchange a maximum Auction Price that is below the price that is 80% above the highest price of the Issuer Price Range, the Auction Price may not be above such price; and (v) to make other clarifying changes.

[10] *See* Securities Exchange Act Release No. (Nov. 8, 2022), 87 FR 68558 (Nov. 15, 2022) (''Notice'').

[11] The reference to a registration statement refers to a registration statement effective under the Securities Act of 1933 (''Securities Act'').

[12] A Primary Direct Floor Listing includes listings where either: (i) only the company itself is selling shares in the opening auction on the first day of trading; or (ii) the company is selling shares and selling shareholders may also sell shares in such opening auction. *See* Section 102.01B, Footnote (E) of the Manual. *See also* Securities Exchange Act Release No. 90768 (Dec. 22, 2020), 85 FR 85807 (Dec. 29, 2020) (SR–NYSE–2019–67) (Order Setting Aside Action by Delegated Authority and Approving a Proposed Rule Change, as Modified by Amendment No. 2, to Amend Chapter One of the Listed Company Manual to Modify the Provisions Relating to Direct Listings) (''Approval Order'').

[13] *See* Approval Order, *supra* note 12, 85 FR 85813. An IDO Order is a Limit Order to sell that is to be traded only in a Direct Listing Auction. *See* Rule 7.31(c)(1)(D). *See also* Rule 7.31(a)(2) for the definition of ''Limit Order,'' Rule 7.35(a)(1) for the definition of ''Auction,'' and Rule 7.35(a)(1)(E) for the definition of ''Direct Listing Auction.'' The IDO Order has the following requirements: (i) only one IDO Order may be entered on behalf of the issuer and only by one member organization; (ii) the limit price of the IDO Order must be equal to the lowest price of the price range established by the issuer in its effective registration statement; (iii) the IDO Order must be for the quantity of shares offered by the issuer, as disclosed in the prospectus in the effective registration statement; (iv) an IDO Order may not be cancelled or modified; and (v) an IDO Order must be executed in full in the Direct Listing Auction. *See* Rule 7.31(c)(1)(D)(i)–(v).

[14] *See* Approval Order, *supra* note 12, 85 FR 85813. *See also* Notice, *supra* note 10, 87 FR 68563. *See* Rule 7.35A(d)(2)(A)(v) for a description about how the ''Indication Reference Price'' is determined for a security that is a Primary Direct Floor Listing.

[15] The Exchange defines Auction Price in Rule 7.35(a)(6) as the price at which an Auction is conducted. In addition, Rule 7.35A sets forth requirements relating to the determination of the Auction Price by the DMM. For purposes of the proposal, ''Auction Price'' refers to the price at which trading would commence in a security to be opened in a Direct Listing Auction for a Primary Direct Floor Listing. *See* Notice, *supra* note 10, 87 FR 68559 n.13.

[16] The Exchange states that references in the proposal to the price range established by the issuer in its effective registration statement are to the price range disclosed in the prospectus in such registration statement. *See* Notice, *supra* note 10, 87 FR 68559 n.14. Currently, the Exchange defines the price range established by the issuer in its effective registration statement as the ''Primary Direct Floor Listing Auction Price Range.'' *See* Rule 7.31(c)(1)(D)(ii). As discussed further below, the Exchange proposes to redefine the price range established by the issuer in its effective registration

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is insufficient interest to satisfy both the IDO Order and all better-priced sell orders in full.[17]

The Exchange proposes to modify the Price Range Limitation to provide that a Direct Listing Auction for a Primary Direct Floor Listing may be conducted if the Auction Price determined by the DMM is outside of the Issuer Price Range (*i.e.,* the price range established by the issuer in its effective registration statement), but only if the Auction Price is (1) at or above the price that is 20% below the lowest price of the Issuer Price Range [18] and (2) at or below the price that is 80% above the highest price of the Issuer Price Range (the ''80% Upside Limit'').[19] The Exchange proposes that a Direct Listing Auction for a Primary Direct Floor Listing could proceed in these circumstances at a price outside of the Issuer Price Range (whether lower or higher), provided that the issuer has specified the quantity of shares registered in its registration statement, as permitted by Securities Act Rule 457, and certified to the Exchange and publicly disclosed that: (i) it does not expect that the Auction Price would materially change the issuer's previous disclosure in its effective registration statement; (ii) the price range in the preliminary prospectus included in the effective registration statement is a bona fide price range in accordance with Item 501(b)(3) of Regulation S–K; and (iii) such registration statement contains a sensitivity analysis explaining how the issuer's plans would change if the actual proceeds from the offering differ from the amount assumed in the disclosed price range.[20] In addition, if the issuer certifies to the Exchange an upper price limit that is below the 80% Upside Limit, the Exchange proposes that the Direct Listing Auction for a Primary Direct Floor Listing may not proceed if the Auction Price determined by the DMM exceeds the certified price limit.

The Exchange also proposes to require that a company offering securities for sale in a Primary Direct Floor Listing must retain an underwriter with respect to the primary sales of shares by the company and identify the underwriter in its effective registration statement.[21] In addition, the Exchange proposes to require that for the purposes of determining the Primary Direct Floor Listing Auction Price Range, the 20% and 80% thresholds will be calculated based on the highest price of the Issuer Price Range.[22]

The Exchange states its belief that, while many companies are interested in alternatives to the traditional initial public offering (''IPO''), companies and their advisors may be reluctant to use the Primary Direct Floor Listing under current Exchange rules because of concerns about the Price Range Limitation.[23] The Exchange states it believes that ''[t]he Price Range Limitation—which is imposed on a Primary Direct Floor Listing but not on an IPO—increases the probability of a failed offering because it contemplates there also being too much investor interest. In other words, if investor interest is greater than the company and its advisors anticipated, an offering would need to be delayed or cancelled.'' [24]

The Exchange states that, under current Exchange Rules, the DMM would not conduct a Direct Listing Auction for a security subject to a Primary Direct Floor Listing if the Auction Price determined is above the highest price of the price range established by the issuer in its effective registration statement.[25] The Exchange further states that, in this case, the offering would be cancelled or postponed until the company amends its effective registration statement, and at a minimum, such a delay could expose the company to risks associated with changing investor sentiment in the event of an adverse market event.[26] The Exchange states its belief that, as a result, companies may be reluctant to use this alternative method of going public despite its expected potential benefits because of the restrictions of the Price Range Limitation.[27]

The Exchange has proposed to modify the Price Range Limitation such that a Direct Listing Auction for a Primary Direct Floor Listing could proceed if the Auction Price is at or above the price that is 20% below the lowest price of the Issuer Price Range and at or below the 80% Upside Limit.[28] Therefore, the Exchange proposes that the DMM could conduct the Direct Listing Auction even if the Auction Price is outside of the Issuer Price Range, provided all other necessary conditions are met, if the Auction Price would not be more than 20% below the lowest price or more than 80% above the highest price of the Issuer Price Range and the company has, in its effective registration statement, specified the quantity of shares registered, as permitted by Securities Act Rule 457.[29]

The Exchange proposes that when the Auction Price is outside of the Issuer Price Range, but not more than 20% below such price range and higher than the 80% Upper Limit, the Direct Listing Auction would not proceed unless the company has previously certified to the Exchange and publicly disclosed that (i) the company does not expect that such offering price would materially change the company's previous disclosure in its effective registration statement; (ii) the price range in the preliminary prospectus included in the effective registration statement is a bona fide price range in accordance with Item 501(b)(3) of Regulation S–K; and (iii) the company's registration statement contains a sensitivity analysis explaining how the company's plans would change if the actual proceeds from the offering differ from the amount assumed in the disclosed price range.[30] In addition, if the company's certification submitted to the Exchange includes a price limit that is below the 80% Upper Limit, the Direct Listing Auction would not take place if the Auction Price is determined by the DMM to be above such limit.[31]

When the Auction Price is outside of the Issuer Price Range (whether it is lower or higher than such price range), the Exchange also proposes to provide the issuer with the opportunity to provide any necessary additional disclosures that are dependent on the price of the offering so that any such disclosures would be available to investors prior to the completion of the offering.[32] The Exchange proposes that a Direct Listing Auction for a Primary Direct Floor Listing would only proceed outside the Issuer Price Range if the issuer also confirms to the Exchange that no additional disclosures are

statement as the ''Issuer Price Range.'' *See* proposed Rule 7.31(c)(1)(D)(ii). Throughout this order, we also refer to this ''Issuer Price Range'' as the ''disclosed price range.''

[17] *See* Notice, *supra* note 10, 87 FR 68559.

[18] The Exchange proposes to define the ''Primary Direct Floor Listing Auction Price Range'' in Rule 7.31(c)(1)(D)(ii) as the price range that includes 20% below the lowest price and 80% above the highest price of the Issuer Price Range. *See* Notice, *supra* note 10, 87 FR 68559.

[19] As provided in proposed Rule 7.31(c)(1)(D)(ii), the Exchange proposes to calculate the 20% and 80% thresholds to determine the Primary Direct Floor Listing Auction Price Range based on the highest price of the Issuer Price Range. For example, if the Issuer Auction Price Range is $28.00 to $30.00, the Primary Direct Floor Listing Auction Price Range would be $22.00 to $54.00. *See* Notice, *supra* note 10, 87 FR 68559.

[20] *See* Notice, *supra* note 10, 87 FR 68559. *See also* proposed Rule 7.35A(g)(2)(B)(i).

[21] *See* Notice, *supra* note 10, 87 FR 68559.

[22] *See id.* at 68563.

[23] *See id.* at 68559.

[24] *Id.*

[25] *See id.* at 68560.

[26] *See id.*

[27] *See id.*

[28] *See id.*

[29] *See id.*

[30] *See id.*

[31] *See id.*

[32] *See id.*

required under federal securities laws based on the Auction Price determined by the DMM.[33]

The Exchange states its belief that the additional requirements to permit a Direct Listing Auction to take place at an Auction Price that is outside of the Issuer Price Range (whether it is lower or higher than such price range but within the Primary Direct Floor Listing Auction Price Range), as proposed, would provide sufficient disclosures to allow investors to evaluate whether to participate in the Direct Listing Auction for a Primary Direct Floor Listing, including the opportunity to see how changes in share price may impact the company's disclosures.[34]

The Exchange states that it believes its proposal with respect to the Price Range Limitation for a Primary Direct Floor Listing can be analogized with Securities Act Rule 430A and staff guidance, which, according to the Exchange, generally allow a company to price a public offering 20% outside of the disclosed price range without regard to the materiality of the changes to the disclosure contained in the company's registration statement.[35] According to the Exchange, it believes that such guidance would also allow for deviation of greater than 20% above the highest price of the disclosed price range, provided that such change would not materially change the previous disclosure.[36] The Exchange states that, accordingly, it believes that a company listing in connection with a Primary Direct Floor Listing could specify the quantity of shares registered, as permitted by Securities Act Rule 457, and, if an Auction prices outside of the disclosed price range, use a Rule 424(b) prospectus, rather than a post-effective amendment, when either (i) the 20% threshold noted in Rule 430A is not exceeded, regardless of the materiality or non-materiality of resulting changes to the registration statement disclosure that would be contained in the Rule 424(b) prospectus, or (ii) there is a deviation above the price range beyond the 20% threshold noted in Rule 430A if such deviation would not materially change the previous disclosures, in each case assuming the number of shares issued is not increased from the number of shares disclosed in the prospectus.[37]

The Exchange states that the burden of complying with the disclosures required under federal securities laws, including providing any disclosure necessary to avoid any material misstatements or omissions, remains with the issuer.[38] Under the proposal, therefore, the Direct Listing Auction for a Primary Direct Floor Listing would not take place outside of the Issuer Price Range until the issuer confirms to the Exchange that no additional disclosures are required under the federal securities laws based on the Auction Price determined by the DMM.[39]

The Exchange states it believes that an underwriter plays an important role in a traditional IPO and, therefore, proposes to require that a company listing securities on the Exchange in connection with a Primary Direct Floor Listing must retain an underwriter with respect to the primary sales of shares by the company and identify the underwriter in its effective registration statement.[40] The Exchange believes that investor protection provisions are necessary in a Primary Direct Floor Listing if an offering can price outside of the disclosed price range, subject to the proposed limitations, because such provisions allow investors to make reasonable pricing decisions with clarity that the company's underwriter would face statutory liability.[41]

The Exchange further states it believes that the requirement to retain a named underwriter mitigates concerns raised by the Commission in the OIP regarding the usefulness of price range disclosure provided to investors in a Securities Act registration statement filed in connection with a Primary Direct Floor Listing.[42] The Exchange believes that an underwriter retained in connection with a Primary Direct Floor Listing would perform substantially similar functions, including those related to establishing and adjusting the price range, to those performed by an underwriter in a ''typical'' IPO because the underwriter would be subject to similar liability and reputational risk.[43]

The Exchange also states it believes that the requirement to retain a named underwriter, as described above, may mitigate concerns raised by the Commission in the OIP regarding challenges to bringing claims under Section 11 of the Securities Act due to the potential assertion of tracing defenses because an underwriter may choose to impose lock-up arrangements.[44] The Exchange states that, as in a traditional firm commitment underwritten IPO, in which lock-up arrangements are often imposed, an underwriter in connection with a Primary Direct Floor Listing would be able to impose lock-up agreements for the same reasons that make lock-up agreements common in an IPO.[45]

The Exchange states that its proposal to require that the securities of a company listing in connection with a Primary Direct Floor Listing cannot price above the 80% Upper Limit further mitigates concerns regarding the usefulness of the price range disclosure provided to investors.[46] The Exchange states that the 80% Upper Limit would incentivize the company and its underwriter to set the disclosed price range to avoid the failed offering consequences and would also encourage an issuer to adjust the price range disclosed in their registration statement prior to effectiveness in response to pricing feedback received from market analysts and potential investors.[47]

The Exchange states that given that, as proposed, there may be a Primary Direct Floor Listing that could price outside of the disclosed price range subject to the 80% Upper Limit above which the Direct Listing Auction could not proceed, the Exchange proposes ''to support price discovery transparency by providing readily available, real time

[33] *See id. See* proposed Rule 7.35A(g)(2)(B)(ii).

[34] *See* Notice, *supra* note 10, 87 FR 68560.

[35] *See id.* According to the Exchange, Securities Act Rule 457 permits issuers to register securities either by specifying the quantity of shares registered, pursuant to Rule 457(a), or the proposed maximum aggregate offering amount. The Exchange proposes to require that companies selling shares through a Primary Direct Floor Listing will register securities by specifying the quantity of shares registered and not a maximum offering amount. *See id.* at 68560 n.20. The Exchange also states that the Exchange believes that the proposed modification of the Price Range Limitation would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest, because, according to the Exchange, this approach is similar to the pricing of an IPO where an issuer is permitted to price outside of the disclosed price range in accordance with the SEC Staff's guidance. *See id.* at 68564.

[36] *See id.* at 68560.

[37] *See* Notice, *supra* note 10, 87 FR 68560. *See supra* note 20 and accompanying text.

[38] *See id.* According to the Exchange, the Commission previously stated that while Securities Act Rule 430A permits companies to omit specified price-related information from the prospectus included in the registration statement at the time of effectiveness, and later file the omitted information with the Commission as specified in the rule, it neither prohibits a company from conducting a registered offering at prices beyond those that would permit a company to provide pricing information through a Securities Act Rule 424(b) prospectus supplement nor absolves any company relying on the rule from any liability for potentially misleading disclosure under the federal securities laws. *See id.* at 68560–61 (citing Securities Exchange Act Release No. 93119 (Sept. 24, 2021), 86 FR 54262 (Sept. 30, 2021)).

[39] *See* Notice, *supra* note 10, 87 FR 68561.

[40] *See id.*

[41] *See id.*

[42] *See id.* at 68562.

[43] *See id.*

[44] *See id.* at 68561.

[45] *See id.* at 68561–62.

[46] *See id.* at 68562.

[47] *See id.*

pricing information to investors.'' [48] Specifically, the Exchange represents that the DMM's pre-opening indications for a security to be opened in a Direct Listing Auction for a Primary Direct Floor Listing would continue to be published via the securities information processor (''SIP'') and proprietary data feeds.[49] The Exchange states that it would also make the Indication Reference Price available, free of charge, on a public website (such as *www.nyse.com*) on the day such auction is anticipated to take place.[50] The Exchange also proposes to require member organizations to provide to a customer, before that customer places an order to participate in a Direct Listing Auction for a Primary Direct Floor Listing, a notice describing the mechanics of pricing a security subject to a Direct Listing Auction for a Primary Direct Floor Listing, including information regarding the availability of pre-opening indications via the SIP and proprietary data feeds and the location of the public website where the Exchange would disseminate information relating to the Indication Reference Price.[51]

The Exchange further proposes to distribute, at least one business day prior to the commencement of trading of a security listing in connection with a Primary Direct Floor Listing, a regulatory bulletin that describes any special characteristics of the offering and the Exchange rules that apply to the pricing of a Primary Direct Floor Listing.[52] The Exchange states that the regulatory bulletin would also include information about the notice that member organizations would be required to provide customers, as proposed, and remind member organizations of their obligations pursuant to the Exchange rules that (1) require member organizations to use reasonable diligence in regard to the opening and maintenance of every account, to know (and retain) the essential facts concerning every customer and concerning the authority of each person acting on behalf of such customer (Rule 2090); and (2) require member organizations in recommending transactions for a security subject to a Direct Listing Auction for a Primary Direct Floor Listing to have a reasonable basis to believe that: (i) the recommendation is suitable for a customer given reasonable inquiry concerning the customer's investment objectives, financial situation, needs, and any other information known by such member organizations, and (ii) the customer can evaluate the special characteristics, and is able to bear the financial risks, of an investment in such security (Rule 2111).[53] The Exchange states that these member organization requirements are intended to remind members of their obligations to ''know their customers'' and would also serve to increase transparency regarding the pricing mechanisms applicable to a Primary Direct Floor Listing and help provide investors with sufficient price discovery information.[54] The Exchange represents that, for each Primary Direct Floor Listing, the Exchange's regulatory bulletin would also inform market participants that the Auction Price could be up to 20% below the lowest price of the disclosed price range and would specify that price.[55] The Exchange also represents that this regulatory bulletin would indicate the price above which the Direct Listing Auction for the Primary Direct Floor Listing could not proceed, based on the company's certification.[56]

The Exchange also proposes to amend certain aspects of the Manual. Specifically, Section 102.01B, Footnote (E) of the Manual currently provides that, with respect to a Primary Direct Floor Listing, the Exchange will deem a company to have met the applicable aggregate market value of publicly-held shares requirement [57] if the company will sell at least $100,000,000 in market value of shares in the Exchange's opening auction on the first day of trading on the Exchange. The Manual further provides that, where a company is conducting a Primary Direct Floor Listing and will sell shares in the opening auction with a market value of less than $100,000,000, the Exchange will determine that such company has met its market-value of publicly-held shares requirement if the aggregate market value of the shares the company will sell in the opening auction on the first day of trading and the shares that are publicly held immediately prior to the listing is at least $250,000,000 with such market value calculated using a price per share equal to the lowest price of the disclosed price range.[58]

The Exchange states that, to effect the changes to the Price Range Limitation and facilitate the possibility of a Direct Listing Auction for a Primary Direct Floor Listing pricing up to 20% below the disclosed price range, the Exchange proposes to modify Section 102.01B, Footnote (E) of the Manual to provide that the Exchange would calculate the market value of such company's shares using a price per share equal to the lowest price of the disclosed price range, minus an amount equal to 20% of the highest price included in such price range, which would be referred to as the ''Primary Direct Floor Listing Minimum Price.'' [59] The Exchange also proposes to amend Section 102.01B, Footnote (E) to include the requirement, as discussed above, that a company listing its securities on the Exchange pursuant to a Primary Direct Floor Listing must have specified the quantity of shares registered, as permitted by Securities Act Rule 457, in its effective registration statement and retained an underwriter with respect to the primary sales of shares by the company and identified the underwriter in its effective registration statement.[60]

The Exchange states that, to implement the changes to the Price Range Limitation described above, the Exchange is proposing the following changes to Rules 7.31 and 7.35A.[61] The Exchange proposes to modify Rule 7.31(c)(1)(D)(ii) to provide that the limit price of an IDO Order would be equal to the lowest price of the Primary Direct Floor Listing Auction Price Range and to redefine the ''Primary Direct Floor Listing Auction Price Range'' as 20% below the lowest price and 80% above the highest price of the disclosed price range.[62] The Exchange also proposes to define ''Issuer Price Range'' as the price range established by the issuer in its

[48] *See id.*

[49] *See id. See also* proposed Rule 7.35A(d)(2)(A)(v). The Exchange states that its dissemination of pre-opening indications for a security to be opened in a Direct Listing Auction for a Primary Direct Floor Listing via the SIP and proprietary data feeds is consistent with the availability of the same for securities opened in IPOs and believes that interested investors have found pre-opening indications to be readily accessible and to provide useful real time pricing information to inform their participation in such auctions. The Exchange thus believes that its proposal addresses the concerns raised in the OIP regarding the sufficiency of price discovery transparency for investors. *See* Notice, *supra* note 10, 87 FR 68562 n.29.

[50] *See* Notice, *supra* note 10, 87 FR 68562. The Indication Reference Price for a security that is a Primary Direct Floor Listing is the lowest price of the Primary Direct Floor Listing Auction Price Range. This price would be known before the opening process begins and would not change once established.

[51] *See id. See also* proposed Rule 7.35A, Commentary .20(3).

[52] *See* Notice, *supra* note 10, 87 FR 68562. *See also* proposed Rule 7.35A, Commentary .20.

[53] *See* Notice, *supra* note 10, 87 FR 68562. *See also* proposed Rule 7.35A, Commentary .20(1) and (2).

[54] *See* Notice, *supra* note 10, 87 FR 68562.

[55] *See id.*

[56] *See id.*

[57] *See* Section 102.01B of the Manual.

[58] *See* Section 102.01B, Footnote (E) of the Manual.

[59] *See* Notice, *supra* note 10, 87 FR 68563.

[60] *See id.*

[61] *See id.*

[62] *See id.*

effective registration statement.[63] The Exchange states that Rule 7.31(c)(1)(D)(ii), as modified, would facilitate the proposed changes to the Price Range Limitation by providing that the limit price of an IDO Order would be equal to the price that is 20% below the lowest price of the Issuer Price Range.[64] The Exchange further proposes to specify in Rule 7.31(c)(D)(ii) that, for purposes of determining the Primary Direct Floor Listing Auction Price Range, the 20% and 80% thresholds would be calculated based on the highest price of the Issuer Price Range.[65]

Currently, Rule 7.35A(d)(2)(A)(v) provides that, for a security that is a Primary Direct Floor Listing, the Indication Reference Price will be the lowest price of the Primary Direct Floor Listing Auction Price Range.[66] The Exchange proposes to add the requirement that the Exchange disseminate the Indication Reference Price on a public website to Rule 7.35A(d)(2)(A)(v).[67] The Exchange also states that, based on the proposed revision to the definition of Primary Direct Floor Listing Auction Price Range in Rule 7.31(c)(1)(D)(ii), the Indication Reference Price for a Primary Direct Floor Listing would be the price that is 20% below the lowest price of the Issuer Price Range, consistent with the proposed changes to the Price Range Limitation.[68]

Currently, Rule 7.35A(g)(2) specifies the circumstances under which a DMM may not conduct a Direct Listing Auction for a Primary Direct Floor Listing.[69] The Exchange proposes to amend Rule 7.35A(g)(2) such that the rule would specify requirements for a Direct Listing Auction for a Primary Direct Floor Listing to proceed, rather than specifying circumstances under which a DMM would not conduct a Direct Listing Auction for a Primary Direct Floor Listing.[70] The Exchange proposes to modify this rule to specify that the Auction Price for a Direct Listing Auction for a Primary Direct Floor Listing may not be lower than the price that is 20% below the lowest price of the Issuer Price Range or higher than the 80% Upper Limit.[71] In other words, the Auction Price may not be outside of the Primary Direct Floor Listing Auction Price Range, as defined in amended Rule 7.31(c)(1)(D)(ii).[72] The Exchange proposes that Rule 7.35A(g)(2)(A) would further provide that, if an issuer has certified to the Exchange a maximum Auction Price that is lower than the 80% Upper Limit, the Auction Price may not exceed such lower certified price.[73]

The Exchange proposes to amend Rule 7.35A(g)(2)(B) to provide that a Direct Listing Auction could proceed when the Auction Price is outside of the Issuer Price Range but within the Primary Direct Floor Listing Auction Price Range (as described in proposed Rule 7.35A(g)(2)(A)) if the issuer has previously certified to the Exchange and publicly disclosed that: (a) the issuer does not expect that the Auction Price would materially change its previous disclosure in its effective registration statement (proposed Rule 7.35A(g)(2)(B)(i)(a)); (b) the price range in the preliminary prospectus included in the effective registration statement is a bona fide price range in accordance with Item 501(b)(3) of Regulation S–K (proposed Rule 7.35A(g)(2)(B)(i)(b)); and (c) the registration statement contains a sensitivity analysis explaining how the issuer's plans would change if the actual proceeds from the offering differ from the amount assumed in the price range established by the issuer in its effective registration statement (proposed Rule 7.35A(g)(2)(B)(i)(c)).[74]

The Exchange states that proposed Rule 7.35A(g)(2)(B)(ii) would further provide that, when the Auction Price determined by the DMM is outside of the Issuer Price Range (whether lower or higher), the issuer would be required to confirm to the Exchange that no additional disclosures are required under the federal securities laws based on such price.[75] According to the Exchange, this proposed change would permit issuers to comply with their disclosure obligations under federal securities laws and provide investors with access to the requisite disclosures before the offering would proceed.[76] The Exchange states that, upon receiving confirmation from the issuer that any such obligations have been met, the Exchange would relay that information to the DMM to proceed with the Direct Listing Auction.[77]

The Exchange states that proposed Rule 7.35A(g)(2)(C)(i) would reflect the requirement set forth in current Rule 7.35A(g)(2)(B) that the DMM may not conduct a Direct Listing Auction for a Primary Direct Floor Listing if there is insufficient buy interest to satisfy both the IDO Order and all better-priced sell orders in full.[78] The Exchange does not propose to change this requirement, other than adding clarifying text to specify that such orders would be satisfied at the Auction Price.[79]

The Exchange states that proposed Rule 7.35A(g)(2)(C)(ii) would provide that the DMM would not proceed with a Direct Listing Auction for a Primary Direct Floor Listing until it has been notified by the Exchange that the additional conditions set forth in new Commentary .20 to Rule 7.35A have been satisfied.[80] The Exchange also states that proposed Commentary .20 to Rule 7.35A would provide that the Direct Listing Auction for a Primary Direct Floor Listing for a security may not be conducted until the Exchange has notified the DMM that, at least one business day prior to the commencement of trading in such security, the Exchange has distributed a regulatory bulletin describing: (i) any special characteristics of the offering and the Exchange rules that apply to the pricing of the Primary Direct Floor Listing; (ii) the obligations of member organizations pursuant to Exchange Rules 2090 and 2111; and (iii) the requirement that a member organization provide its customers with a notice with information regarding the Direct Listing Auction for a Primary Direct Floor Listing.[81] The Exchange states that this proposed change would: (i) facilitate the requirements described above to provide member organizations with sufficient information so that they may in turn inform their customers; (ii) remind member organizations of their obligations to ''know their customers''; (iii) increase transparency around the pricing mechanisms of a Primary Direct Floor Listing; and (iv) help provide investors with sufficient price discovery information.[82]

[63] *See id.*

[64] *See id.* The Exchange further proposes to specify in Rule 7.31(c)(1)(D)(ii) that, for purposes of determining the Primary Direct Floor Listing Auction Price Range, the 20% and 80% thresholds would be calculated based on the highest price of the disclosed price range, consistent with the Instruction to paragraph (a) of Securities Act Rule 430A. *See id.*

[65] *See supra* note 22.

[66] *See* Notice, *supra* note 10, 87 FR 68563.

[67] *See id.*

[68] *See id.*

[69] *See id.*

[70] *See id.*

[71] *See id.*

[72] *See id.*

[73] *See id.*

[74] *See id.* at 68564.

[75] *See id.*

[76] *See id.* As stated above, the Exchange also notes that the burden of complying with the disclosures required under the federal securities laws, including providing any disclosure necessary to avoid any material misstatements or omission, remains with the issuer. *See* Notice, *supra* note 10, 87 FR 68561.

[77] *See id.*

[78] *See id.*

[79] *See id.*

[80] *See id.*

[81] *See id. See also supra* notes 52–53 and accompanying text.

[82] *See* Notice, *supra* note 10, 87 FR 68564.

Finally, the Exchange states that proposed Rule 7.35A(g)(2)(C)(iii) would provide that the DMM would not conduct a Direct Listing Auction for a Primary Direct Floor Listing if the Auction Price is outside of the Issuer Price Range and the issuer has not satisfied the conditions set forth in proposed Rules 7.35A(g)(2)(A) and 7.35A(g)(2)(B)(i) and (ii).[83] The Exchange states that it proposes this rule to reinforce that a Direct Listing Auction for a Primary Direct Floor Listing could not proceed in these circumstances unless the issuer has made the requisite disclosures described in proposed Rule 7.35A(g)(2)(B).[84]

III. Discussion and Commission Findings

The Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange.[85] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Section 6(b)(5) of the Exchange Act,[86] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission has consistently recognized the importance and significance of national securities exchange listing standards. Among other things, such listing standards help ensure that exchange-listed companies will have sufficient public float, investor base, and trading interest to provide the depth and liquidity necessary to promote fair and orderly markets.[87]

The Exchange's listing standards currently provide the Exchange with discretion to list a company whose stock has not been previously registered under the Exchange Act, where such company is listing in connection with a Primary Direct Floor Listing, without a firm commitment underwritten offering, either selling shares to raise capital alone or in conjunction with shares by selling shareholders.[88] The Exchange proposes to modify its rules concerning pricing limitations for securities listing on the Exchange pursuant to a Primary Direct Floor Listing. Instead of the current Price Range Limitation, which limits the Auction Price to the price range disclosed in the issuer's effective registration statement,[89] the proposal would allow the Direct Listing Auction for a Primary Direct Floor Listing to proceed at a price up to either 20% below or 80% above the disclosed price range if certain additional conditions are met. The Exchange also proposes changes to the procedures for a Direct Listing Auction for a Primary Direct Floor Listing to accommodate the proposed changes to the Price Range Limitation.

As explained further below, the following aspects of the proposal, as modified by Amendment No. 2, demonstrate that the Exchange's proposal is consistent with the protection of investors and the public interest under Section 6(b)(5) of the Exchange Act as well as the maintenance of fair and orderly markets: (i) by modifying the Price Range Limitation such that, provided other requirements are satisfied, a Primary Direct Floor Listing can be executed in the Direct Listing Auction at a price that is above the highest price of the disclosed price range only if the Auction Price is at or below the 80% Upside Limit; (ii) by adding conditions that must be satisfied before the Direct Listing Auction could proceed at a price outside of the disclosed price range that provide some assurance that issuers are complying with the disclosure requirements under federal securities laws, including conditions that require an issuer to provide a prior certification to NYSE to include a sensitivity analysis in its registration statement and to also confirm that no additional disclosures are required under the federal securities laws to open the Direct Listing Auction at the Auction Price; (iii) by requiring that a company offering securities for sale in connection with a Primary Direct Floor Listing must retain an underwriter with respect to the primary sales of shares by the company and identify the underwriter in its effective registration statement; and (iv) by making clarifying changes regarding calculation of the 20% threshold below the disclosed price range and other clarifying changes.

The Commission discusses below the Exchange's proposed modifications to Primary Direct Floor Listing. First, the Commission addresses the modifications to the Price Range Limitation, and the certification process and other conditions, that would allow a Primary Direct Floor Listing to execute in the Direct Listing Auction at a price that is outside the disclosed price range (*i.e.,* up to 20% below the lowest price in the disclosed price range or no higher than the 80% Upside Limit). Second, the Commission addresses the availability of pricing information to investors during the course of a Direct Listing Auction. Third, the Commission addresses the Exchange's proposed requirement that a company offering securities for sale in connection with a Primary Direct Floor Listing must retain an underwriter with respect to the primary sales of shares by the company and identify the underwriter in its effective registration statement and addresses concerns about Section 11 liability and how requiring an underwriter may mitigate such concerns. Finally, the Commission discusses additional clarifications to the proposal. As discussed throughout this

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[83] *See id.*

[84] *See id.*

[85] 15 U.S.C. 78f(b). In approving this proposed rule change, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[86] 15 U.S.C. 78f(b)(5).

[87] The Commission has stated in approving national securities exchange listing requirements that the development and enforcement of adequate standards governing the listing of securities on an exchange is an activity of critical importance to the financial markets and the investing public. In addition, once a security has been approved for initial listing, maintenance criteria allow an exchange to monitor the status and trading characteristics of that issue to ensure that it continues to meet the exchange's standards for market depth and liquidity so that fair and orderly markets can be maintained. *See, e.g.,* Approval Order, *supra* note 11, 85 FR 85807, 85811 n.55 (Dec. 29, 2020) (SR–NYSE–2019–67) (''NYSE 2020 Order''); 82627 (Feb. 2, 2018), 83 FR 5650, 5653 n.53 (Feb. 8, 2018) (SR–NYSE–2017–30) (''NYSE 2018 Order''); 81856 (Oct. 11, 2017), 82 FR 48296, 48298 (Oct. 17, 2017) (SR–NYSE–2017–31); 81079 (July 5, 2017), 82 FR 32022, 32023 (July 11, 2017) (SR–NYSE–2017–11). The Commission has stated that adequate listing standards, by promoting fair and orderly markets, are consistent with Section 6(b)(5) of the Exchange Act, in that they are, among other things, designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, and protect investors and the public interest. *See, e.g.,* NYSE 2020 Order, 85 FR 85811 n.55; NYSE 2018 Order, 83 FR 5653 n.53; Securities Exchange Act Release Nos. 87648 (Dec. 3, 2019), 84 FR 67308, 67314 n.42 (Dec. 9, 2019) (SR–NASDAQ–2019–059); 88716 (Apr. 21, 2020), 85 FR 23393, 23395 n.22 (Apr. 27, 2020) (SR–NASDAQ–2020–001).

[88] *See* Section 102.01B, Footnote (E) of the Manual and *supra* note 12. *See also* Approval Order, *supra* note 11, 85 FR 85807. The listing standards under Section 102.01B, Footnote (E) of the Manual also allow for direct listings in connection with the sale of shares by selling shareholders only.

[89] *See* Rule 7.31(c)(1)(D)(ii). The Commission previously approved the Exchange's proposal to allow Primary Direct Floor Listings as long as the Direct Listing Auction occurred within the Price Range Limitation. *See* Approval Order, *supra* note 12.

order, the Commission concludes that the Exchange has met its burden to demonstrate that its proposal is consistent with the Exchange Act, and therefore finds the proposed rule change is consistent with the requirements of the Exchange Act.

A. Modification of Price Range Limitation and Required Certification

The Exchange proposes to modify its rules concerning pricing restrictions for the Direct Listing Auction for a Primary Direct Floor Listing. Provided that other requirements are satisfied, a Primary Direct Floor Listing will be able to be executed in the Direct Listing Auction at a price that is at or above the price that is as low as 20% below the lowest price in the disclosed price range, or at a price that is as high as 80% above the highest price of the disclosed price range (*i.e.,* at or below the 80% Upside Limit).

In all such cases where the execution price would be outside of the disclosed price range, the company will be required to specify the quantity of shares registered in its registration statement, as permitted by Securities Act Rule 457, and that registration statement will be required to contain a sensitivity analysis explaining how the company's plans would change if the actual proceeds from the offering are less than or exceed the amount assumed in the disclosed price range. Prior to the Direct Listing Auction, the company must certify to NYSE that the registration statement contains the required sensitivity analysis.[90] The company will also be required to publicly disclose and certify to NYSE that the company does not expect that such offering price would materially change the company's previous disclosure in its effective registration statement and that the price range in the preliminary prospectus included in the effective registration statement is a bona fide price range in accordance with Item 501(b)(3) of Regulation S–K. If the company's certification submitted to NYSE in that regard includes a price limit that is below the 80% Upside Limit, NYSE will not execute the Direct Listing Auction if it results in an Auction Price above such limit.

The Exchange also proposes to require that the securities of a company listing in connection with a Primary Direct Floor Listing cannot price above the 80% Upside Limit (*i.e.,* at a price that is more than 80% above the highest price of the disclosed price range). The Exchange believes this will incentivize the company and its named underwriter to take steps to help ensure the accuracy of the disclosed price range so as to avoid the consequences of a failed offering. In the OIP, the Commission asked questions about the potential usefulness and reliability of the price range disclosure in the registration statement if issuers could price up to 20% below and anywhere above the disclosed price range.[91] The changes that the Exchange made subsequent to the OIP, including the imposition of the 80% Upside Limit and the named underwriter requirement, is a reasonable response to address these concerns, and eliminates the open-ended nature of the original proposal that would have allowed the opening to occur at any price above the high end of the disclosed price range, with no limitations.

The Exchange's proposal to expand the Price Range Limitation for Primary Direct Floor Listing would not allow the Direct Listing Auction to proceed at a price outside of the disclosed price range if the company is unable to provide NYSE with the required certification about the adequacy of the disclosure to allow the offering to execute at a price that is up to 20% below the low end of the disclosed price range or is up to the 80% Upside Limit. In addition, the Direct Listing Auction could not proceed at a price outside of the disclosed price range if the company is unable to confirm to the Exchange that no additional disclosures are required under the federal securities laws to open the Direct Listing Auction at the Auction Price. The DMM would not conduct a Direct Listing Auction for a Primary Direct Floor Listing if, among other things, the Auction Price would be outside the disclosed price range and the company has not satisfied the conditions described above. We believe these provisions, taken together, will provide an opportunity for the company to meet its disclosure obligations under the federal securities laws prior to the opening auction on the NYSE proceeding if the Direct Listing Auction for a Primary Direct Floor Listing will execute at a price that is up to 20% below the low end of the disclosed price range or is up to the 80% Upside Limit. Issuers also must comply with separate disclosure obligations under the federal securities laws, and compliance with the specific requirements of NYSE's proposed listing standards may not be sufficient to comply with the federal securities laws. In particular, an issuer using Rule 430A to omit pricing-related information would need to consider whether a post-effective amendment to a registration statement containing a price range would be required if a change in price materially alters the disclosure in the registration statement at effectiveness. In addition, for purposes of Securities Act Sections 12(a)(2) and 17(a)(2), information delivered to purchasers after the time of sale is not taken into account in determining whether there were material misstatements or omissions.[92] The Commission has interpreted Section 12(a)(2) and Section 17(a)(2) as reflecting a core concept of the Securities Act—that materially accurate and complete information regarding an issuer and the securities being sold should be available to investors at the time of the contract of sale, when they make their investment decisions.[93] Based on the above, the Commission believes that this aspect of the proposal is consistent with the investor protection and public interest provisions under Section 6(b)(5) of the Exchange Act.[94]

B. Availability of Pricing Information

In the OIP, the Commission asked whether providing pricing information during the course of the auction process only through pre-opening indications via data feeds that charge subscription fees would be consistent with, as stated by the Exchange, ''providing readily available, real time pricing information to investors.'' [95] The Exchange stated in response that its dissemination of pre-opening indications for a security to be opened in a Direct Listing Auction for a Primary Direct Floor Listing via the SIP and proprietary data feeds is consistent with the availability of the same for securities opened in IPOs and the Exchange believes that interested investors have found pre-opening indications to be readily accessible and to provide useful real time pricing information to inform their participation in such auctions.[96] In its proposal, the Exchange also stated that by providing real time pricing information by

[90] As the Exchange states, the sensitivity analysis would allow investors to see how changes in the share price ripple through critical elements of a company's disclosure.

[91] *See* OIP, *supra* note 7. One commenter raised similar concerns. *See* Letter from Jeffrey P. Mahoney, General Counsel, Council of Institutional Investors (July 28, 2022) (''CII Letter I'').

[92] *See* Securities Act Rule 159. *See also* Securities Exchange Act Release No. 93119 (Sept. 23, 2021), 86 FR 54262, 54266 n.47 (Sept. 30, 2021).

[93] *See* Securities Offering Reform Proposing Release, Securities Act Release No. 8501 (Nov. 3, 2004) (proposing current Rule 159 as an interpretation of Section 12(a)(2) and Section 17(a)(2)) and Securities Offering Reform Adopting Release, Securities Act Release No. 8591 (Aug. 3, 2005) (adopting Rule 159 as proposed).

[94] *See* OIP, *supra* note 7.

[95] *See* OIP, *supra* note 7.

[96] *See* Notice, *supra* note 10, 87 FR 68562 n.29.

disseminating pre-opening indications, as stated above, market participants would have ready access to up-to-date pricing information leading up to the Direct Listing Auction for a Primary Direct Floor Listing and this should support price discovery transparency to investors.[97] The Exchange further stated that, under the proposal, member organizations would be required to provide to a customer, before that customer places an order to participate in a Direct Listing Auction for a Primary Direct Floor Listing, a notice describing the mechanics of pricing a security subject to a Direct Listing Auction for a Primary Direct Floor Listing, including information regarding the availability of pre-opening indications via the SIP and proprietary data feeds and the location of the public website where the Exchange would disseminate information relating to the Indication Reference Price.[98] The Exchange also represented that it would issue a regulatory bulletin describing any special characteristics of the offering and the rules that apply to the pricing of the Primary Direct Floor Listing. Further, the Exchange represented that its regulatory bulletin would indicate the highest price at which the Direct Listing Auction for the Primary Direct Floor Listing could proceed.[99]

The Exchange has further stated that the pre-opening indications, based on the DMM's assessment of interest eligible to participate in the Direct Listing Auction, would provide notice of when ''price volatility has subsided and price equilibrium has been met with respect to the orders wishing to participate in such Auction.'' [100] In particular, the Exchange highlighted three existing rules concerning pre-opening indication procedures: Exchange Rule 7.35A(d)(4)(C) provides that the DMM should aim to publish a pre-opening indication with a spread of less than $1.00 before opening a security; Rule 7.35A(d)(4)(D) provides that the DMM must wait for certain minimum specified periods of time after publishing a pre-opening indication before opening a security; [101] and Rule 7.35A(d)(4)(G) provides that the DMM may not open a security outside of the last-published pre-opening indication. These pre-opening indication procedures apply to Direct Listings, including Primary Direct Floor Listings, as well as other IPOs on the Exchange. Further, the Exchange has represented that the availability of pre-opening indications for Primary Direct Floor Listings are consistent with the availability of the same information for securities opened in IPOs on the Exchange.

The Commission believes that the availability of pre-opening indications, which must be provided in accordance with these existing procedures to investors in Primary Direct Floor Listings, could help to provide investors with useful information as to the pricing of the security in the Direct Listing Auction and help to inform investors in making decisions about entering, modifying, or cancelling orders to participate in such auction. The Commission also believes that the 80% Upside Limit, or other lower maximum price based on the company's certification, will provide a cap to an investor's financial obligation on its buy order that would be executed in the opening auction and that the regulatory bulletin should help inform investors of this price.[102] Based on the above, the Commission finds these procedures are consistent with the protection of investors, the public interest, and the other requirements of Section 6(b)(5) of the Exchange Act.

C. Addition of Named Underwriter Requirement in a Primary Direct Floor Listing and Securities Act Section 11 Standing

Given the broad definition of ''underwriter'' in the Securities Act,[103] parties, such as the issuers' financial advisor, may, depending on the facts and circumstances including the nature and extent of that party's activities, be deemed a statutory underwriter with respect to a direct listing, with attendant underwriter liabilities. In the OIP, the Commission asked several questions about potential issues related to the lack of a named underwriter (as opposed to a statutory underwriter) in a Primary Direct Floor Listing where an offering can price outside of the range established by the issuer in its effective registration statement.[104] The Commission questioned whether a party who may meet the statutory underwriter definition but is not named as an underwriter would review and adequately conduct due diligence on the information contained in the registration statement for a Primary Direct Floor Listing where the Direct Listing Auction is executed outside of the disclosed price range. The Commission also stated that permitting a Primary Direct Floor Listing could potentially result in increased regulatory arbitrage if and to the extent that issuers and intermediaries, including financial advisors, are not subject to equivalent liability standards in the direct listings context as they would be in traditional firm commitment underwritten IPOs.[105]

In the proposed rule change as modified by Amendment No. 2, the Exchange proposes to require that a company offering securities for sale in connection with a Primary Direct Floor Listing retain an underwriter with respect to the primary sales of shares by the company and identify the underwriter in its effective registration statement.[106] The Exchange states that it believes that underwriters provide significant investor protections that are necessary in a Primary Direct Floor Listing where an offering can price outside of the range established by the issuer in its effective registration statement.[107] For example, the Exchange states that underwriters are exposed to potential Securities Act liability, which provides a strong incentive for them to take steps to help ensure the accuracy of disclosure in a registration statement.[108] The Exchange states that it ''believes that these significant investor

[97] *See id.* at 68565.

[98] *See id.* at 68562. The Exchange will also make the Indication Reference Price available, free of charge, on a public website (such as *www.nyse.com*) on the day the Direct Listing Auction is anticipated to take place. As stated above, this price is the lowest price of the Primary Direct Floor Listing Auction Price Range and would be known before the opening process begins and would not change once established.

[99] *See id.* The Exchange also represented that the regulatory bulletin would specify the price that is 20% below the lowest price of the disclosed price range. *See id.*

[100] *See id.* at 68565.

[101] A DMM must wait for a minimum of three minutes between publication of the first indication and a security's opening or reopening. If more than one indication has been published, a security may be opened or reopened one minute after the last published indication provided that at least three minutes have elapsed from the dissemination of the first indication. *See* NYSE Rule 7.35A(d)(4)(D).

[102] *But see* discussion in Section III A, *supra,* concerning an issuer's disclosure obligations with respect to pricing and pricing changes.

[103] Section 2(a)(11) of the Securities Act defines ''underwriter'' to mean ''any person who has purchased from an issuer with a view to, or offers or sells for an issuer in connection with, the distribution of any security, or participates or has a direct or indirect participation in any such undertaking, or participates or has a participation in the direct or indirect underwriting of any such undertaking.''

[104] *See* OIP, *supra* note 7. One commenter stated it was concerned, consistent with the statements in the OIP, about the lack of a named underwriter in a Primary Direct Floor Listing where the offering could price outside of the range established by the issuer in its effective registration statement and stated it also had concerns about challenges to bringing claims under Section 11 of the Securities Act due to potential tracing issues. *See* CII Letter I, at 4.

[105] *See* OIP, *supra* note 7.

[106] *See* Notice, *supra* note 10, 87 FR 68559.

[107] *See id.* at 68561.

[108] *See id.*

protection provisions are necessary in a Primary Direct Floor Listing if an offering can price outside the price range established in the issuer's effective registration statement, subject to the proposed limitations, because such provisions allow investors to make reasonable pricing decisions with clarity that the company's underwriter would face statutory liability.'' [109] Earlier in the amended proposal, the Exchange notes the Commission's recent explanation that ''[t]he civil liability provisions of the Securities Act reflect the unique position underwriters occupy in the chain of distribution of securities and provide strong incentives for underwriters to take steps to help ensure the accuracy of disclosure in a registration statement.'' [110] Accordingly, the Exchange proposes to require named underwriters for listings of securities on the Exchange in connection with a Primary Direct Floor Listing.

The Commission believes that the Exchange's proposed requirement that a company conducting a Primary Direct Floor Listing must retain and name an underwriter will help address the investor protection concerns discussed in the OIP that can arise in a Primary Direct Floor Listing that prices outside of the disclosed price range. With respect to disclosure, for example, for an offering to proceed at a price outside of the disclosed price range, the Exchange's proposal would require the company to initially provide certifications to the Exchange and publicly disclose that the company does not expect that such a price would materially change its effective registration statement disclosure. The company's registration statement also would need to contain a sensitivity analysis explaining how the company's plans would change if the actual proceeds from the offering are less than or exceed the amount assumed in the disclosed price range. In addition, the company would be required to confirm to the Exchange that no additional disclosures are required under the federal securities laws based on the actual price. The required presence of named underwriters who are subject to Securities Act liability should help ensure the accuracy of these disclosures that potential investors receive in a Primary Direct Floor Listing. This disclosure includes information, such as the use of proceeds and the required sensitivity analysis, that becomes even more important when an offering prices outside of the range established by the company in its registration statement. Investors should also benefit from the knowledge that underwriters with Securities Act liability are required as companies consider the certifications they must provide to the Exchange with respect to the impact of price changes on their registration statement disclosure and on their obligation to provide additional disclosures under the federal securities laws.

The Commission also asked questions in the OIP about shareholders' ability to pursue claims under Section 11 of the Securities Act due to potential traceability issues.[111] The Exchange states that it believes that the requirement to retain a named underwriter in a Primary Direct Floor Listing may mitigate traceability concerns because the underwriter ''would be able to impose lock-up arrangements for the same reasons that make lock-up agreements common in an IPO.'' [112] The Commission agrees that the requirement to retain a named underwriter may help mitigate traceability concerns. However, the actual impact of the named underwriter requirement is far from certain, particularly because tracing is a judicially-developed doctrine and there is limited judicial precedent addressing tracing requirements in the context of direct listings. In addition, because of the many factors that go into an underwriter's decision to request or require lock-up arrangements in public offerings, whether, and if so to what extent, underwriters in Primary Direct Floor Listing would impose lock-up arrangements on all company shareholders is unclear. Although the Commission's findings in this order are based on the specific proposed rule change filed with the Commission, including how the proposed rule operates under the circumstances discussed in this order, the Commission recognizes that, over time, those circumstances may change. Some of the circumstances that may change involve tracing and may include developments in case law involving tracing in the direct listing context.

In view of the totality of the Exchange's proposal, including the requirement that a company seeking to conduct a Primary Direct Floor Listing retain and name an underwriter, the Commission does not expect any such tracing challenges in this context to be of such magnitude as to render the proposal inconsistent with the Exchange Act.[113] The Commission therefore concludes that the proposed rule change, as modified by Amendment No. 2, is consistent with the protection of investors and the public interest under Section 6(b)(5) of the Exchange Act.

D. Additional Clarifications

In the OIP, the Commission asked questions about how the Exchange would calculate the 20% threshold below the disclosed price range under proposed Rule 7.31(c)(1)(D)(ii) and whether that computation would lead to the same minimum price contemplated by the proposed revisions to Section 102.01B, Footnote (E) of the Manual.[114] Subsequently, the Exchange revised its proposal to provide that the 20% threshold below the disclosed price range, along with the 80% threshold used to determine the 80% Upper Limit, would be calculated using the highest price of the Issuer Price Range.[115] In addition, the Exchange made clarifying changes to the description of the 20% threshold used for evaluating whether the company has satisfied the market value requirement in Section 102.01B, Footnote (E) of the Manual.[116] The Commission finds that these changes will help ensure that the calculations are consistent throughout the Exchange's rules and set forth a clear process for how the Exchange will calculate the 20% and 80% thresholds, thereby providing clarity to investors

[109] *See id.* at 68561.

[110] *See id.* (quoting Special Purpose Acquisition Companies, Shell Companies, and Projections, Securities Exchange Act Release No. 94546 (Mar. 30, 2022), 87 FR 29458 (May 13, 2022)).

[111] *See* OIP, *supra* note 7. One commenter raised similar concerns. *See* CII Letter I and Letter from Jeffery P. Mahoney, General Counsel, Council of Institutional Investors (Dec. 1, 2022) (''CII Letter II''). This commenter also stated that the Exchange does not address how its proposal ''might alleviate the poor corporate governance practices that appear endemic to companies that become public through a direct listing.'' CII Letter II. As the Commission stated previously, the Commission does not believe that investors will be precluded from raising concerns about governance structures in the context of direct listings; to the extent a company's corporate governance practices are of sufficient concern to investors, they may be able to influence companies' governance practices through signaling their unwillingness to purchase a company's shares through a direct listing. In this way, investors may be able to persuade companies to adopt preferred governance provisions, whether the company becomes listed through a direct listing or a firm commitment IPO. *See* Securities Exchange Act Release No. 91947 (May 19, 2021), 86 FR 28169, 28177 (May 25, 2021) (SR–NASDAQ–2020–057) (''Nasdaq 2021 Order'').

[112] *See* Notice, *supra* note 10, 87 FR 68561.

[113] *See* Approval Order, *supra* note 12, 85 FR 85816. *See also* Nasdaq 2021 Order, *supra* note 111, 86 FR 28176.

[114] *See* OIP, *supra* note 7.

[115] *See* proposed Rule 7.31(c)(1)(D)(ii). *See also* Notice, *supra* note 10, 87 FR 68563. Under the Exchange's original proposal, the 20% threshold would have been calculated based on the maximum offering price set forth in the registration fee table, consistent with the Instruction to paragraph (a) of the Securities Act.

[116] *See* proposed Section 102.01B, Footnote (E) of the Manual. *See also* Notice, *supra* note 10, 87 FR 68562.

and market participants on the lowest and highest price outside of the disclosed price range at which the Direct Listing Auction can occur consistent with the protection of investors and the public interest under Section 6(b)(5) of the Exchange Act.

IV. Conclusion

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange.

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,[117] that the proposed rule change (SR–NYSE–2022–14), as modified by Amendment No. 2 thereto, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[118]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–27659 Filed 12–20–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96510; File No. SR–CBOE–2022–061]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fees Schedule To Adopt Global Trading Hours XSP Lead Market-Makers Incentive Programs

December 15, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 12, 2022, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to update its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule to adopt Global Trading Hours (''GTH'') XSP Lead Market-Makers (''LMMs'') Incentive Programs (collectively, the ''Programs''), effective December 12, 2022. The Exchange anticipates listing XSP options for trading during the GTH session, effective trade date December 12, 2022. In connection with the proposed launch of XSP options during GTH, the Exchange proposes to adopt financial programs for LMMs appointed to the Programs during GTH. Particularly, the Exchange proposes to adopt (i) a ''GTH1 XSP LMM Incentive Program'' (''GTH1 Program'') under which LMMs appointed to the proposed program would have to provide continuous electronic quotes during GTH from 7:15 p.m. CST to 2:00 a.m. CST (''GTH1'') that meet or exceed the proposed quoting standards under the program (as described in further detail below) and (ii) a ''GTH2 XSP LMM Incentive Program'' (''GTH2 Program'') under which LMMs appointed to the proposed program would have to provide continuous electronic quotes during GTH from 2:00 a.m. CST to 9:15 a.m. [sic] CST (''GTH2''). The Exchange similarly maintains separate LMM Incentive Programs for the GTH1 and GTH2 trading sessions in the two other products that are currently listed during GTH.[3]

As proposed, the GTH1 Program provides that if the LMM appointed to the Program provides continuous electronic quotes during GTH1 that meet or exceed the proposed heightened quoting standards (below) in at least 85% of the series 90% of the time in a given month, the LMM will receive (i) a payment for that month in the amount of $10,000 and (ii) a credit of $0.03 per contract applied to all XSP contracts executed in a Market-Maker capacity which provide liquidity in the Simple Book during Regular Trading Hours (''RTH'') (or pro-rated amounts if an appointment begins after the first trading day of the month or ends prior to the last trading day of the month).[4]

Premium level	Expiring		Near term		Mid term		Long term	
	7 days or less		8 days to 60 days		61 days to 270 days		271 days to 500 days	
	Width	Size	Width	Size	Width	Size	Width	Size
VIX Value at Prior Close <20								
$0.01–$1.00	$0.04	10	$0.05	10	$0.07	5	$0.15	5
$1.01–$5.00	0.06	10	0.09	10	0.12	5	0.20	5
$5.01–$8.00	0.10	10	0.16	10	0.25	5	0.40	5
$8.01–$12.00	0.40	5	0.70	5	1.00	5	1.25	5
$12.01–$20.00	0.80	5	1.20	5	1.60	5	2.00	5

[117] *Id.*

[118] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Cboe Options Fees Schedule, GTH1 VIX/VIXW LMM Incentive Program, GTH2 VIX/VIXW LMM Incentive Program, GTH1 SPX/SPXW LMM Incentive Program and GTH2 SPX/SPXW LMM Incentive Program.

[4] For the month of December 2022, the Exchange proposes to pro-rate the incentives and apply the heightened quoting standard from trade date December 12 to December 30, in light of the mid-month launch of XSP options during the GTH session.

Premium level	Expiring		Near term		Mid term		Long term	
	7 days or less		8 days to 60 days		61 days to 270 days		271 days to 500 days	
	Width	Size	Width	Size	Width	Size	Width	Size
>20.00	1.60	5	2.00	5	2.40	5	3.20	5
VIX Value at Prior Close from 20–30								
$0.01–$1.00	0.06	10	0.07	10	0.09	5	0.17	5
$1.01–$5.00	0.09	10	0.11	10	0.14	5	0.22	5
$5.01–$8.00	0.14	10	0.18	10	0.30	5	0.45	5
$8.01–$12.00	0.60	5	0.80	5	1.10	5	1.35	5
$12.01–$20.00	1.00	5	1.30	5	1.80	5	2.20	5
>20.00	2.00	5	2.40	5	2.80	5	3.60	5
VIX Value at Prior Close >30								
$0.01–$1.00	0.07	10	0.09	10	0.11	5	0.20	5
$1.01–$5.00	0.10	10	0.14	10	0.18	5	0.27	5
$5.01–$8.00	0.14	10	0.20	10	0.35	5	0.50	5
$8.01–$12.00	0.60	5	0.90	5	1.20	5	1.50	5
$12.01–$20.00	1.20	5	1.50	5	2.00	5	2.40	5
>20.00	2.40	5	2.80	5	3.20	5	4.00	5

As proposed, the GTH2 Program will provide that if an LMM appointed to the Program provides continuous electronic quotes during GTH2 that meet or exceed the proposed heightened quoting standards set forth above (the same as GTH1) in at least 85% of the series 90% of the time in a given month, the LMM will receive a payment for that month in the amount of $20,000 (or pro-rated amount if an appointment begins after the first trading day of the month or ends prior to the last trading day of the month).[5]

Meeting or exceeding the heightened quoting standards in XSP, as proposed, to receive the proposed compensation payment(s) is optional for any LMM appointed to either program. The Exchange may consider other exceptions to this quoting standard based on demonstrated legal or regulatory requirements or other mitigating circumstances. In calculating whether an LMM met the heightened quoting standard each month, the Exchange will exclude from the calculation in that month the business day in which the LMM missed meeting or exceeding the heightened quoting standard in the highest number of series. The heightened quoting requirements offered by the Programs are designed to incentivize LMMs appointed to the Program to provide significant liquidity in XSP options during the GTH session upon their listing and trading on the Exchange during GTH, which, in turn, would provide greater trading opportunities, added market transparency and enhanced price discovery for all market participants in XSP.

In connection with the launch of XSP during GTH, the Exchange also proposes to update Footnote 37 which footnote provides a description of GTH and lists the applicable products available for trading during GTH (currently only VIX and SPX/SPX). Particularly, the Exchange proposes to add a reference to XSP in Footnote 37 to reflect its availability for trading during GTH. The Exchange notes that on December 12, 2022, it also anticipates launching XSP during the Curb Trading Hours session, which session commences at 3:15PM CT and terminates at 4:00PM CT. Footnote 42 of the Fees Schedule similarly describes the Curb Trading Hours session and lists the available products for trading (currently also only VIX and SPX/SPXW) and the Exchange therefore proposes to update the footnote to add a reference to XSP. The exchange notes that all fees currently applicable to XSP during the RTH session will continue to apply to XSP during the GTH and Curb Trading Hours sessions.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[6] in general, and furthers the objectives of Section 6(b)(4),[7] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and issuers and other persons using its facilities. The Exchange also believes that the proposed rule change is consistent with the objectives of Section 6(b)(5)[8] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and, particularly, is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed XSP GTH LMM Incentive Programs are reasonable, equitable and not unfairly discriminatory. Particularly, the proposed Programs are reasonable financial incentive programs because the proposed heightened quoting standards and rebate amounts for meeting the heightened quoting standards in XSP series during GTH1 and GTH2, respectively are reasonably designed to incentivize LMMs appointed to the Programs to meet the proposed heightened quoting standards during GTH for XSP, thereby providing liquid and active markets, which facilitates tighter spreads, increased trading opportunities, and overall enhanced market quality to the benefit of all market participants, particularly in a newly listed and traded product during the GTH session on the Exchange.

The Exchange believes that the proposed heightened quoting standards are reasonable because they are similar to the detail and format (VIX Index value indicator, corresponding premiums, quote widths, and sizes) of the quoting standards currently in place

[5] For the month of December 2022, the Exchange proposes to pro-rate the incentives and apply the heightened quoting standard from trade date December 12 to December 30, in light of the mid-month launch of XSP options during the GTH session.

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4).

[8] 15 U.S.C. 78f(b)(5).

for LMM Incentive Programs for other proprietary Exchange products during GTH.[9] The Exchange also believes that proposed heightened quoting requirements are reasonably tailored to reflect market characteristics of XSP. For example, the Exchange believes the generally smaller premium levels, widths and quote sizes appropriately reflect the lower-priced and smaller nationalize sized XSP product (XSP options are 1/10th the size of SPX options). Indeed, the Exchange believes the proposed finer premiums, smaller quote widths and smaller sizes (comparatively) in the proposed heightened quoting standards for the XSP GTH LMM Incentive Programs reasonably reflect what the Exchanges believes are typical market characteristics in XSP options, given their smaller notional value.

The Exchange further believes the proposed heighten quoting requirements are also reasonably tailored to reflect then-current market conditions and market characteristics, as the proposed quoting standards that are applicable depend on the VIX Index value at the prior market close (*i.e.,* at the close of the preceding RTH session). Spreads in SPX-based options, including XSP, generally widen when the market experiences higher volatility (*i.e.,* the VIX Index level is higher in value). Therefore, to encourage LMMs to meet the proposed quoting standards regardless of market volatility, the proposed rule change adopts generally wider widths where the market may be experiencing higher volatility (*i.e.,* when the value of the VIX Index in the proposed VIX value categories becomes relatively higher compared to the closing index value from the preceding trading session). The Exchange notes that the quoting standards currently in place under the GTH1 and GTH2 VIX/VIXW and SPX/SPXW LMM Incentive Programs are tailored in a similar manner.

The Exchange also believes that the proposed incentive payments for appointed LMMs that meet the proposed heightened quoting standards in XSP in a month is reasonable and equitable as they are comparable to the rebates offered for other LMM Incentive Programs for other proprietary products. For example, the GTH1 and GTH2 LMM Incentive Programs for SPX/SPXW and for VIX/VIXW offer compensation payments between $15,000 and $35,000 per month, in which an appointed LMM meets the given quoting standards.[10] The GTH1 and GTH2 VIX/VIXW LMM Incentive Programs also provides an additional per contract credit for Market-Maker VIX/VIXW orders executed in RTH.[11] Additionally, the Exchange believes the proposed incentives are reasonably designed to continue to incentivize appointed LMMs to meet the proposed quoting standards for XSP, thereby providing liquid and active markets, which facilitates tighter spreads, increased trading opportunities, and overall enhanced market quality to the benefit of all market participants.

Finally, the Exchange believes it is equitable and not unfairly discriminatory to offer the financial incentive to LMMs appointed to the XSP GTH LMM Incentive Programs because it will benefit all market participants trading in XSP during GTH by encouraging the appointed LMMs to satisfy the heightened quoting standards, which incentivizes continuous increased liquidity and thereby may provide more trading opportunities and tighter spreads. Indeed, the Exchange notes that these LMMs serve a crucial role in providing quotes and the opportunity for market participants to trade XSP, which can lead to increased volume, providing for robust markets. The Exchange ultimately proposes to offer the XSP GTH LMM Incentive Programs to sufficiently incentivize the appointed LMMs to provide key liquidity and active markets in XSP options which will be newly listed and traded during the GTH session to encourage liquidity, thereby protecting investors and the public interest. The Exchange also notes that an LMM appointed to the Programs may undertake added costs each month to satisfy that heightened quoting standards (*e.g.,* having to purchase additional logical connectivity). The Exchange believes the proposed program is equitable and not unfairly discriminatory because similar programs currently exist for LMMs appointed to programs in other proprietary products,[12] and the proposed program will equally apply to any TPH that is appointed as an LMM to the GTH1 or GTH2 LMM Incentive Programs. Additionally, if an appointed LMM does not satisfy the heightened quoting standard in XSP for any given month, then it simply will not receive the offered payments for that month.

Lastly, the Exchange believes updating Footnotes 37 and 42 of the Fees Schedule provides clarity in the fees schedule as to the products available during the GTH and Curb Trading Hours sessions, alleviating potential confusion, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system, and, in general, protecting investors and the public interest.

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 intramarket or intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed change would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution and price improvement opportunities for all TPHs. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [13]

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Indeed, the proposed GTH1 XSP and GTH2 XSP LMM Incentive Programs will apply to all LMMs appointed to each program in a uniform manner. To the extent the LMMs appointed to one of the proposed programs receive a benefit that other market participants do not, as stated, these LMMs in their role as Market-Makers on the Exchange have different obligations and are held to different standards. For example, Market-Makers play a crucial role in providing active and liquid markets in their appointed products, thereby providing a robust market which benefits all market participants. Such Market-Makers also have obligations and regulatory requirements that other participants do not have. An LMM appointed to a program may undertake added costs each month that it needs to satisfy the quoting standards (*e.g.,* having to purchase additional logical

[9] *See* Cboe Options Fees Schedule, ''GTH1 VIX/VIXW LMM Incentive Program'', ''GTH2 VIX/VIXW LMM Incentive Program'', ''GTH1 SPX/SPXW LMM Incentive Program'', and ''GTH2 SPX/SPXW LMM Incentive Program''.

[10] *See id.*

[11] *See* Cboe Options Fees Schedule, ''GTH2 VIX/VIXW LMM Incentive Program''.

[12] *See supra* note 11.

[13] Securities Exchange Act Release No. 51808, 70 FR 37495, 37498–99 (June 29, 2005) (S7–10–04) (Final Rule).

connectivity). The programs are ultimately designed to attract additional order flow in XSP options to the Exchange during GTH, wherein greater liquidity will benefit all market participants by providing more trading opportunities, tighter spreads, and added market transparency and price discovery, and signals to other market participants to direct their order flow to those markets, thereby contributing to robust levels of liquidity during new trading hours. The Exchange also does not believe that the proposed changes will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the Act because the proposed programs are applicable to transactions in a product exclusively listed on the Exchange. Additionally, the Exchange notes that it operates in a highly competitive market. TPHs have numerous alternative venues that they may participate on and direct their order flow, including 15 other options exchanges, as well as off-exchange venues, where competitive products are available for trading. Based on publicly available information, no single options exchange has more than 18% of the market share.[14] Therefore, no exchange possesses significant pricing power in the execution of option order flow. Indeed, participants can readily choose to send their orders to other exchange, and, additionally off-exchange venues, if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [15] The fact that this market is competitive has also long been recognized by the courts. In NetCoalition v. Securities and Exchange Commission, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[16] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [17] and paragraph (f) of Rule 19b–4 [18] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2022–061 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2022–061. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2022–061 and should be submitted on or before January 11, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–27656 Filed 12–20–22; 8:45 am]

BILLING CODE 8011–01–P

[14] *See* Cboe Global Markets U.S. Options Market Volume Summary, Month-to-Date (December 9, 2022), available at *https://markets.cboe.com/us/options/market_statistics/*.

[15] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[16] NetCoalition v. SEC, 615 F.3d 525, 539 (DC Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96507; File No. SR–NASDAQ–2022–073]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Market Maker Requirements in Equity 2, Sections 4, 5, and 11

December 15, 2022.

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 December 2, 2022, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Equity 2, Section 4, Section 5 and Section 11 related to certain Market Maker requirements, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/bx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Equity 2 establishes rules for Nasdaq market participants. The Exchange is proposing to (1) amend Equity 2, Section 4 (Registration as a Nasdaq Market Maker) to require a Market Maker[3] to provide written notice of termination as a Market Maker, (2) amend Equity 2, Section 11 (Voluntary Termination of Registration) to require a Market Maker to provide written notice of withdrawal of its two-sided quotations when terminating its registration in a security and to lower the time period for re-registering in a security, (3) update Equity 2, Section 5 (Market Maker Obligations) to eliminate certain provisions that are no longer applicable and to make a clarifying amendment, and (4) make non-substantive changes throughout these three sections.

Currently, the Exchange has no requirements for a Market Maker to provide notification prior to withdrawing its registration as a Market Maker. The lack of a notification process impedes the Exchange's recordkeeping. Without formal written notice of withdrawal as a Market Maker, the Exchange is not always able to determine the specific date on which the Market Maker's registration withdrawal became effective.

Therefore, the Exchange is proposing to adopt Equity 2, Section 4(d) to require a Market Maker to terminate its registration as a Market Maker by giving written notice to the Exchange. A Market Maker's termination of registration will become immediately effective. A Market Maker who fails to notify Nasdaq in writing of its termination of registration prior to such termination may be subject to formal disciplinary action pursuant to Nasdaq General 5. The written notification requirement is similar to another exchange.[4] In conjunction with proposed Equity 2, Section 4(d), Nasdaq is also proposing to change the title of Section 4 to include ''and Termination''.

Similarly, Equity 2, Section 11 does not require a Market Maker to provide written notification when terminating its registration in a specific security. Currently, a Market Maker may voluntarily terminate its registration in a security by withdrawing its two-sided quotation from the Nasdaq Market Center, but the Market Maker is not required to provide written notification of its withdrawal and termination. A lack of written notification of withdrawal limits the Exchange's ability to effectively enforce its rules and ensure that Market Makers are complying with its rules. Additionally, the Market Maker that voluntarily terminates its registration in a specific security is prohibited from re-registering in that specific symbol for twenty business days in the case of Nasdaq-listed securities or for one business day in the case of intermarket trading system (''ITS'') securities.[5] Lack of written notification inhibits the Exchange's ability to monitor compliance with those requirements.

The Exchange is proposing to amend Equity 2, Section 11(a) to require a Market Maker to provide written notice that the Nasdaq Market Maker will withdraw its two-sided quotation from the Nasdaq Market Center. A Market Maker that fails to provide written notice of termination to Nasdaq prior to withdrawing its two-sided quotation may be subject to formal disciplinary action pursuant to Nasdaq General 5. Additionally, the Exchange is removing the time period distinction between Nasdaq-listed securities and non-Nasdaq listed securities by lowering the re-registration waiting period to five business days for Nasdaq-listed securities and increasing the re-registration waiting period to five business days for ITS (non-Nasdaq listed) securities. As a result of eliminating the waiting period distinction between Nasdaq-listed and non-Nasdaq listed securities, the Exchange is also proposing to remove references in this rule to the term ''ITS securities''. Amending the waiting period and removing the distinction between Nasdaq and non-Nasdaq listed securities provides Market Makers with a more reasonable amount of time to re-register in the Nasdaq-listed security and aligns the waiting period irrespective of where the security is listed. Additionally, increasing the waiting period to re-register in a non-Nasdaq listed security will incentivize Market Makers to maintain their

[3] ''Nasdaq Market Makers'' or ''Market Makers'' are members that are registered as Nasdaq Market Makers for purposes of participation in the Nasdaq Market Center (or ''System'') on a fully automated basis with respect to one or more System securities. *See* Nasdaq Equity 1, Section 1(a)(5)(B).

[4] *See* Cboe EDGX Exchange, Inc. Rule 11.17(d).

[5] The rule text currently uses the term ''ITS securities'' but the Exchange is removing the language related to ITS because the ITS Plan no longer exists. *See* Securities Exchange Act Release No. 55397 (March 5, 2007), 72 FR 11066 (March 12, 2007) (Elimination of ITS Plan). Non-Nasdaq listed securities are currently subject to the one business day period that the rule specifically applies to ITS securities.

registrations and ongoing quoting obligations in non-Nasdaq listed securities without being overly burdensome. The written notification requirement for termination of registration in a security is similar to another exchange.[6] The Exchange is also proposing to make non-substantive changes to Equity 2, Section 11(a) to remove redundant language, and to Equity 2, Section 11(b) to conform the language to Section 11(a).

Additionally, the Exchange is proposing to amend Equity 2, Section 11(d) to clarify that a Nasdaq Market Maker will not be subject to formal disciplinary action for the failure to give written notice of withdrawal in a security to Nasdaq, if the Nasdaq Market Maker's two-sided quotation in the subject security is withdrawn by Nasdaq's systems due to an issuer corporate action related to a dividend, payment or distribution, or due to a trading halt, and if certain other conditions are satisfied. This change is a conforming change to the changes being made to Equity 2, Section 11(a). The Exchange is also proposing a non-substantive change to include the word ''written'' in Section 11(d)(3) to clarify that the Nasdaq Market Maker's request to enter a new two-sided quotation must be in writing.

Lastly, the Equity 2, Section 5 currently makes references to a Market Maker's and an Electronic Communications Network's (''ECN'') use of a Primary MPID and additional MPIDs (''Supplemental MPIDs''). By way of background, in 2003, the Exchange made additional MPIDs available to Market Makers and ECNs as a pilot program to allow Market Makers to contribute more liquidity and better manage order flow.[7] The program became permanent in 2008 and removed any restrictions on the number of Supplemental MPIDs that a Market Maker or ECN could obtain.[8] If a Market Maker or ECN failed to fulfill the obligations appurtenant to its primary MPID (*e.g.,* by being placed into an unexcused withdrawal), it would not be permitted to use any Supplemental MPIDs for any purpose in that security.[9] Member firms were also assessed a monthly fee for each Supplemental MPID issued by the Exchange, unless the Supplemental MPIDs were used exclusively for reporting information to facilities of the Financial Industry Regulatory Authority (''FINRA'') (*e.g.,* FINRA/Nasdaq Trade Reporting Facility).[10] The Exchange subsequently eliminated the distinction between Primary and Supplemental MPIDs and began assessing the same fee per month, per MPID.[11]

The Exchange does not believe that it is necessary to draw a distinction between the terms ''Primary MPID'' and ''Supplemental MPID'' in its rule because a Market Maker is required to fulfill its quoting obligations and comply with applicable self-regulatory organization and Commission rules in all MPIDs that the Market Maker has registered with the Exchange as a Market Maker MPID. Therefore, the Exchange is proposing to remove discussion of the terms by deleting Equity 2, Section 5(a)(2)(J) and Section 5(a)(2)(K) because the Exchange no longer distinguishes between Primary and Supplemental MPIDs.[12] Moreover, the Exchange believes that removing references to these terms will provide further clarification that a Market Maker must satisfy its Two-Sided Quoting Obligations, and comply with excused withdrawal procedures for all MPIDs that it has registered as a Market Maker MPID. Moreover, even though the Exchange is proposing to delete Equity 2, Section 5(a)(2)(K), to the extent a Nasdaq member wishes to engage in passive market making or enter a stabilizing bid on the Exchange, the member must continue to comply with all Nasdaq (Equity 2, Sections 6 and 10), FINRA and SEC rules that govern passive market making and stabilizing bids, even if the Nasdaq member generally uses multiple MPIDs.

The Exchange is also proposing to clarify in Equity 2, Section 5(a)(1) that only Attributable Quotes/Orders are eligible to meet a Market Maker's Two-Sided Quoting Obligation, which is current practice. Additionally, the Exchange is proposing to remove language from Section 5(a)(1) that reiterates that a Market Maker may augment its Two-Sided Obligation size to display similarly priced limit orders priced at the same price as the Two-Sided Obligation. The Exchange also believes that Section 5(a)(1) already makes clear that the minimum displayed quotation size must be at least one normal unit of trading. Therefore, the additional explanation regarding augmentation of a Market Maker's Two-Sided Obligation size is redundant and may cause confusion to the Market Maker requirements under Section 5(a)(1). Therefore, the Exchange's proposal to remove the explanatory language will help to clarify Section 5(a)(1). Additionally, the Exchange is proposing to make a non-substantive conforming change to make the term ''Nasdaq Market Maker'' consistent throughout Equity 2, Sections 4, 5 and 11.

2. Statutory Basis

The Exchange believes that this proposal is consistent with Section 6(b) of the Act,[13] in general, and furthers the objectives of Section 6(b)(5) of the Act,[14] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. Ensuring that the Exchange can effectively surveil for and pursue disciplinary actions when market participants are not operating in accordance with its rules is of the utmost importance to the Exchange. Therefore, from time to time, the Exchange will review its rulebook to amend any rules that use obsolete concepts or terms, or that make it difficult to take disciplinary actions against market participants who are in violation of the Exchange's rules. The Exchange believes that the proposed amendments will provide market participants with a clearer understanding of the Exchange's rules related to registration and obligations as a Nasdaq Market Maker, voluntary termination of registration as a Market Maker in a security, and termination of registration in a security due to

[6] *See* Cboe EDGX Exchange, Inc. Rule 11.19(b) (Similar to this proposal, Cboe EDGX requires written notice for voluntarily termination of registration in a security and may place other conditions on withdrawal and re-registration in a security; however, unlike this proposal, Cboe EDGX does not specify a waiting period for re-registration).

[7] Supplemental MPIDs were initially referred to as ''Secondary MMIDs.'' *See* Securities Exchange Act Release No. 47954 (May 30, 2003), 68 FR 34017 (June 6, 2003) (SR–NASD–2003–87). However, in 2004, the term was changed to ''Supplemental MPIDs.'' *See* Securities Exchange Act Release Nos. 49471 (March 25, 2004), 69 FR 17006 (March 31, 2004) (SR–NASD–2004–037); 50140 (August 3, 2004), 69 FR 48535 (August 10, 2004) (SR–NASD–2004–097).

[8] *See* Securities Exchange Act Release No. 57452 (March 7, 2008), 73 FR 13596 (March 13, 2008) (SR–NASDAQ–2008–004) (Approval Order).

[9] *Id.*

[10] *See* Securities Exchange Act Release No. 62564 (July 23, 2010), 75 FR 44830 (July 29, 2010) (SR–NASDAQ–2010–089).

[11] *See* Securities Exchange Act Release No. 73705 (December 1, 2014), 79 FR 47221 (December 5, 2014) (SR–Nasdaq–2014–118). The Exchange currently assesses a $550 per month fee, per MPID. *See* Nasdaq Equity 7, Section 10.

[12] Nasdaq Equity 2, Section 5(a)(2)(J) and Section 5(a)(2)(K) also discuss the term ''ECN.'' The Exchange is also removing discussions of the term because the Exchange no longer distinguishes between Primary and Supplemental MPIDs for ECNs. Therefore, all MPIDs of ECNs would be required to comply with applicable rules.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

accidental withdrawal of the Market Maker's two-sided quotations in a security.

In particular, the Exchange believes that proposed Equity 2, Section 4(d) is reasonable because without receiving formal written notice from the Market Maker, the Exchange is not always able to determine the specific date on which the Market Maker's terminated registration became effective. The Exchange's proposal to require a Market Maker to provide written notice of termination of its registration as a Market Maker will allow the Exchange to improve its recordkeeping process and ensure that its Market Makers are adhering to the Exchange's Market Maker rules. Additionally, the Exchange's rule is similar to rules established by another exchange.[15]

For similar reasons, the Exchange believes that it is reasonable to require a Market Maker to provide written notice of its termination of registration in a security prior to withdrawing its two-sided quotation from the Nasdaq Market Center pursuant to proposed Equity 2, Section 11(a). Requiring a Market Maker to provide formal written notice of its voluntary termination of registration in a security will allow the Exchange to improve its surveillance by gaining a clearer understanding of when a Market Maker has voluntarily terminated its registration in a security and when it is simply not meeting its Market Maker obligations. This also allows the Exchange to know when to take formal disciplinary action against a Market Maker that fails to meet its Two-Sided Quoting Obligations in a particular security and also fails to provide the Exchange with written notice of its termination of registration in a security. The notice requirement is also similar to another exchange.[16] The Exchange also believes that lowering the re-registration waiting period to five business days for Nasdaq-listed securities provides Market Makers with a more reasonable amount of time to re-register in the Nasdaq-listed security than the previous twenty business day period, and increasing the waiting period to re-register in a non-Nasdaq listed security will incentivize Market Makers to maintain ongoing quoting obligations in non-Nasdaq listed securities without being overly burdensome. Moreover, the Exchange believes that it is reasonable to make conforming changes in Equity 2, Section 11(d) to provide that a Market Maker will not be subject to formal disciplinary action for failing to provide written notification of termination of registration in a security when the Market Maker's two-sided quotation in the security is withdrawn by Nasdaq's systems due to certain circumstances. The Exchange does not believe that a Market Maker should be subject to disciplinary action for not providing prior notice of withdrawal in those circumstances because the termination was not within the control of the Market Maker.

The Exchange also believes that it is important to periodically update its rules and remove language that has the potential for causing discrepancies or confusion. The Exchange no longer distinguishes between Primary and Supplemental MPIDs for ECNs. Additionally, ECNs registered as Market Makers on the Exchange are required to follow the same Quoting Obligation rules as Market Makers. Therefore, removing references to ECNs from Equity 2, Section 5(a)(2) will update and clarify the rule. Moreover, a Market Maker is required to fulfill its quoting obligations in all MPIDs that the Market Maker has registered with the Exchange, and the Exchange no longer makes the distinction between Primary and Supplemental MPIDs for Market Makers. Therefore, the Exchange believes eliminating the differentiation between the terms ''Supplemental MPID'' and ''Primary MPID'' by removing discussions of the terms in Equity 2, Section 5(a)(2)(J) and Section 5(a)(2)(K) will eliminate confusion about which MPIDs are required to meet a Market Maker's Two-Sided Quoting Obligations and comply with the excused withdrawal procedures and allow the Exchange to improve its surveillance of any Market Maker that fails to meet its obligations.[17] Furthermore, the Exchange has already eliminated this distinction of these terms in its fees by assessing the same fee per month, per MPID.

Additionally, Market Makers are already aware that only Attributable Quotes/Orders may satisfy the Two-Sided Quoting Obligation. Therefore, the Exchange's proposal to add the term Attributable Quotes/Orders to Equity 2, Section 5(a)(1) is merely an update to align the Exchange's rules with the understanding of market participants. Moreover, Section 5(a)(1) makes clear that the minimum displayed quotation size for a Market Maker's Two-Sided Obligation must be at least one normal unit of trading. Therefore, the Exchange believes that the additional explanation regarding augmentation of a Market Maker's Two-Sided Obligation size is redundant and may cause confusion to the Market Maker requirements under Section 5(a)(1). Therefore, the Exchange's proposal to remove the explanatory language will help to clarify Section 5(a)(1).

Lastly, the Exchange is also proposing technical changes to (1) Equity 2, Section 4, to include the word ''termination'' within the title; (2) Equity 2, Section 11 to remove the term ''voluntary'' and include the phrase ''in a security'' within the title; and (3) Equity 2 Sections 4, 5 and 11 to use the term ''Nasdaq Market Maker'' throughout. The Exchange believes that these changes will provide consistency and clarity throughout these sections of the rule text.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Every market participant who chooses to register as a Market Maker on the Exchange is required to meet the Exchange's Market Maker obligations. Furthermore, the proposals will help to update and correct the Exchange's Market Maker obligations by removing references to Primary MPID and Supplemental MPID, thereby eliminating confusion about which MPIDs are required to meet a Market Maker's Two-Sided Quoting Obligations and excused withdrawal procedures.

Also, the removal of obsolete language such as ITS and explanatory language related to a Market Maker augmenting its Two-Sided Obligation size, and the addition of the term Attributable Quotes/Orders, would not impose a burden on competition and the proposed changes would provide clarification to the Exchange's Market Maker obligations and reflect current practice.

In addition, the Exchange does not believe that aligning the waiting periods to re-register in a specific security irrespective of where the security is listed would cause any burden on competition because, as discussed above, increasing the waiting period to re-register in a non-Nasdaq listed security will incentivize Market Makers

[15] *See* Cboe EDGX Exchange, Inc. Rule 11.17(d).

[16] *See* Cboe EDGX Exchange, Inc. Rule 11.19(b) (Although Cboe EDGX requires written notice and may place other conditions on re-registration in a security, the exchange does not specify a waiting period for re-registration).

[17] To the extent a Nasdaq member wishes to engage in passive market making or enter a stabilizing bid on the Exchange, the member must continue to comply with all Nasdaq (Equity 2, Sections 6 and 10), FINRA and SEC rules that govern passive market making and stabilizing bids, even if the Nasdaq member generally uses multiple MPIDs.

to maintain their registrations and ongoing quoting obligations in non-Nasdaq listed securities while decreasing the waiting period to re-register in a Nasdaq-listed security would decrease the burden on Market Makers.

Moreover, the Exchange does not believe that the removal of references to Primary and Secondary MPID will impose any burden on competition because to the extent a Nasdaq member wishes to engage in passive market making or enter a stabilizing bid on the Exchange, it must continue to comply with all Nasdaq (Equity 2, Sections 6 and 10), FINRA and SEC rules that govern passive market making and stabilizing bids.

Additionally, as discussed above, similar notification provisions for termination of Market Maker registration and voluntary termination of registration in a specific security currently exist on another exchange. These notification requirements are intended to better allow the Exchange to enforce Market Maker compliance with applicable rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[18] and Rule 19b–4(f)(6) thereunder.[19]

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: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act.

[18] 15 U.S.C. 78s(b)(3)(A).

[19] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2022–073 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2022–073. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2022–073, and should be submitted on or before January 11, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Sherry R. Haywood,

Assistant Secretary.

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[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96511; File No. SR–NSCC–2022–015]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing a Proposed Rule Change To Make Certain Enhancements to the Gap Risk Measure and the VaR Charge

December 15, 2022.

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 December 2, 2022, National Securities Clearing Corporation (''NSCC'') 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.[3] 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

(a) The proposed rule change of NSCC consists of modifications to NSCC's Rules & Procedures (''Rules'')[4] in order to enhance the calculation of the volatility component of the Clearing Fund formula that utilizes a parametric Value-at-Risk (''VaR'') model (''VaR Charge'') by (1) making the result of the gap risk measure (''Gap Risk Measure'') calculation an additive component of the VaR Charge when it is applicable, rather than being applied as the applicable VaR Charge when it is the largest of three separate calculations, (2) modifying the language relating to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] NSCC filed this proposed rule change as an advance notice (SR–NSCC–2022–802) with the Commission pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010, 12 U.S.C. 5465(e)(1), and Rule 19b–4(n)(1)(i) under the Act, 17 CFR 240.19b–4(n)(1)(i). A copy of the advance notice is *available at https://www.dtcc.com/legal/sec-rule-filings.aspx.*

[4] Capitalized terms not defined herein are defined in the Rules, *available at https://dtcc.com/~/media/Files/Downloads/legal/rules/nscc_rules.pdf.*

which ETF (as defined below) positions are excluded from the Gap Risk Measure, (3) adjusting both the trigger for applying the Gap Risk Measure and the calculation of the Gap Risk Measure to be based on the two largest positions in a portfolio, rather than based on the single largest position, (4)(a) removing the description of the methodology in the Rules for calculating the gap risk haircut, (b) providing that, like the concentration threshold, gap risk haircuts would be calibrated from time to time based on backtesting and impact analysis and (c) changing the floor of the gap risk haircut from 10 percent to 5 percent for the largest position and adding a floor of the gap risk haircut of 2.5 percent for the second largest position subject to the Gap Risk Measure and (5) making certain clarifications to the description of Gap Risk Measure, 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

NSCC is proposing to enhance the calculation of the VaR Charge by (1) making the result of the Gap Risk Measure calculation an additive component of the VaR Charge when it is applicable, rather than being applied as the applicable VaR Charge when it is the largest of three separate calculations, (2) modifying the language relating to which ETF positions are excluded from the Gap Risk Measure, (3) adjusting both the trigger for applying the Gap Risk Measure and the calculation of the Gap Risk Measure to be based on the two largest positions in a portfolio, rather than based on the single largest position, (4)(a) removing the description of the methodology in the Rules for calculating the gap risk haircut, (b) providing that, like the concentration threshold, gap risk haircuts would be calibrated from time to time based on backtesting and impact analysis and (c) changing the floor of the gap risk haircut from 10 percent to 5 percent for the largest position and adding a floor of the gap risk haircut of 2.5 percent for the second largest position subject to the Gap Risk Measure and (5) making certain clarifications to the description of Gap Risk Measure, as described in greater detail below.

The proposed changes would enhance the flexibility of the Gap Risk Measure to broaden the scope of gap risk event coverage and result in more frequent gap risk charges. NSCC conducted an impact study for the period January 1, 2021 through December 31, 2021 (''Impact Study'') which reviewed the overall impact of the proposed changes on the VaR Charge amounts, the Clearing Fund amounts (at the NSCC level and Member level) and the effect on the Members during the Impact Study period. The Impact Study looked at the impacts during the Impact Study period as if all of the proposed changes had been made and did not look at the impacts of each of the proposed changes individually. The Impact Study indicated that the proposed changes would have resulted in a 10.66% increase for the daily total VaR Charge on average and would have resulted in a 4.04% increase in the daily total Clearing Fund on average during that period.

The three Members with the largest average daily VaR Charge increases in dollar amount during the Impact Study period would have had increases of $60,113,514, $30,054,385 and $22,237,892 representing an average daily increase for such Members of 31.68%, 14.97% and 28.11%, respectively. The three Members with the largest average daily VaR Charge increases as a percentage of production Clearing Fund paid by such Members during the Impact Study period would have had an average daily increase of 31.78%, 29.07% and 28.99%, respectively, had the proposed changes been in place. Approximately 14% of Members would have had either a decrease or an increase of less than 1% in their average daily VaR Charge had the proposed changes been in place.

Prior to implementation of the proposed changes, NSCC would conduct Member outreach to discuss the proposed changes and the impact of the proposed changes on the Members. Following implementation, NSCC would also incorporate the proposed changes into the NSCC Risk Client Portal and VaR Calculator.

(i) Overview of the Required Fund Deposit and NSCC's Clearing Fund

As part of its market risk management strategy, NSCC manages its credit exposure to Members by determining the appropriate Required Fund Deposits to the Clearing Fund and monitoring its sufficiency, as provided for in the Rules.[5] The Required Fund Deposit serves as each Member's margin.

The objective of a Member's Required Fund Deposit is to mitigate potential losses to NSCC associated with liquidating a Member's portfolio in the event NSCC ceases to act for that Member (hereinafter referred to as a ''default'').[6] The aggregate of all Members' Required Fund Deposits constitutes the Clearing Fund of NSCC. NSCC would access its Clearing Fund should a defaulting Member's own Required Fund Deposit be insufficient to satisfy losses to NSCC caused by the liquidation of that Member's portfolio.

The volatility component of each Member's Required Fund Deposit is designed to measure market price volatility of the start of day portfolio and is calculated for Members' Net Unsettled Positions and Net Unsettled Balance Order Positions (hereinafter collectively referred to as ''Net Unsettled Positions'').[7] The volatility component is designed to capture the market price risk [8] associated with each Member's portfolio at a 99th percentile level of confidence. NSCC has two methodologies for calculating the volatility component—a ''VaR Charge'' and a haircut-based calculation. The VaR Charge applies to the majority of Net Unsettled Positions and is calculated as the greater of: (1) the larger of two separate calculations that utilize a parametric Value at Risk (''VaR'') model (''Core Parametric Estimation''); (2) the calculation of the Gap Risk Measure, which is based on the

[5] *See* Rule 4 (Clearing Fund) and Procedure XV (Clearing Fund Formula and Other Matters), *supra* note 4. NSCC's market risk management strategy is designed to comply with Rule 17Ad–22(e)(4) under the Act, where these risks are referred to as ''credit risks.'' 17 CFR 240.17Ad–22(e)(4).

[6] The Rules identify when NSCC may cease to act for a Member and the types of actions NSCC may take. For example, NSCC may suspend a firm's membership with NSCC or prohibit or limit a Member's access to NSCC's services in the event that Member defaults on a financial or other obligation to NSCC. *See* Rule 46 (Restrictions on Access to Services) of the Rules, *supra* note 4.

[7] Net Unsettled Positions refer to net positions that have not yet passed their settlement date or did not settle on their settlement date. *See* Procedure XV (Clearing Fund Formula and Other Matters) of the Rules, *supra* note 4.

[8] Market price risk refers to the risk that volatility in the market causes the price of a security to change between the execution of a trade and settlement of that trade. This risk is also referred to herein as market risk and volatility risk.

concentration threshold of the largest non-index position in a portfolio, as described in greater detail below; and (3) a portfolio margin floor calculation based on the market values of the long and short positions in the portfolio (''Portfolio Margin Floor'').[9] The VaR Charge usually comprises the largest portion of a Member's Required Fund Deposit.

Certain Net Unsettled Positions are excluded from the calculation of the VaR Charge pursuant to Sections I(A)(1)(a)(ii) and I(A)(2)(a)(ii) of Procedure XV and are instead subject to a haircut-based calculation.[10] The charge that is applied to a Member's Required Fund Deposit with respect to the volatility component is referred to as the volatility charge and is the sum of the applicable VaR Charge and the haircut-based calculation.

NSCC regularly assesses the risks it may face as a central counterparty as such risks relate to its margining methodologies to evaluate whether margin levels are commensurate with the particular risk attributes of each relevant product, portfolio and market. In connection with this assessment, NSCC is proposing to enhance the Gap Risk Measure calculation. These proposed enhancements have been developed in response to regulatory feedback and in light of recent market events that led to a reconsideration of the idiosyncratic risks that the Gap Risk Measure is designed to mitigate, as described in greater detail below.

The proposed changes would enhance the calculation of the VaR Charge by making the result of the Gap Risk Measure calculation an additive component of the VaR Charge, rather than being applied as the VaR Charge only when it is the largest of three separate calculations. The proposed changes would modify the language relating to which positions are excluded from the Gap Risk Measure. The proposed changes would also adjust both the trigger for applying the Gap Risk Measure and the calculation of the Gap Risk Measure, when applicable, to be based on the two largest positions in a portfolio, rather than based on the single largest position. The proposed changes would also adjust the calculation and description of the gap risk haircut and make certain other clarifications discussed below.

[9] Procedure XV, Sections I(A)(1)(a)(i) and I(A)(2)(a)(i) of the Rules, *supra* note 4.

[10] Procedure XV, Sections I(A)(1)(a)(ii) and I(A)(2)(a)(ii) of the Rules, *supra* note 4.

(ii) Overview of Idiosyncratic Risks and the Gap Risk Measure

The Gap Risk Measure was designed to address the risks presented by a portfolio that is more susceptible to the effects of gap risk events due to the idiosyncratic nature of the Net Unsettled Positions in that portfolio (such risks may be referred to as idiosyncratic risks).[11] Gap risk events have been generally understood as idiosyncratic issuer events (for example, earning reports, management changes, merger announcements, insolvency, or other unexpected, issuer-specific events) that cause a rapid shift in general market price volatility levels. The Gap Risk Measure is designed to address the risk that a gap risk event affects the price of a security in which a portfolio holds a Net Unsettled Position that represents more than a certain percent of the entire portfolio's value, such that the event could impact the entire portfolio's value. Currently, the Gap Risk Measure serves as a substitution to the calculation of the Core Parametric Estimation in case the Gap Risk Measure is greater in magnitude.

The risk of large, unexpected price movements, particularly those caused by a gap risk event, are more likely to have a greater impact on portfolios with large Net Unsettled Positions in securities that are susceptible to those events. Generally, index-based exchange-traded funds (''ETFs'') that track closely to diversified indices are less prone to the effects of gap risk events. As such, if the concentration threshold is met, NSCC currently calculates the Gap Risk Measure for Net Unsettled Positions in the portfolio other than positions in ETFs that track diversified indices, as determined by NSCC from time to time (''non-index Net Unsettled Positions'').

The Gap Risk Measure is only applied for a Member if the non-index Net Unsettled Position with the largest absolute market value in the portfolio represents more than a certain percent of the entire portfolio's value (''concentration threshold''). The concentration threshold was initially set at 30 percent of a Member's entire portfolio value.[12] The concentration threshold can be set no higher than 30 percent and is evaluated periodically based on Members' backtesting results over a twelve month look-back period to determine if it may be appropriate to lower the threshold.[13] Currently, the concentration threshold is set at 5%.[14]

When applicable, NSCC calculates the Gap Risk Measure by multiplying the gross market value of the largest non-index Net Unsettled Position in the portfolio by a percent of not less than 10 percent (''gap risk haircut'').[15] Currently, NSCC determines the gap risk haircut empirically as no less than the larger of the 1st and 99th percentiles of three-day returns of a set of CUSIPs that are subject to the VaR Charge pursuant to the Rules, giving equal rank to each to determine which has the highest movement over that three-day period. NSCC uses a look-back period of not less than ten years that includes a one-year stress period. If the one-year stress period overlaps with the look-back period, only the non-overlapping period would be combined with the look-back period. The result is then rounded up to the nearest whole percentage.

NSCC is proposing changes to the calculation of the Gap Risk Measure that are designed to allow NSCC to apply this charge based on more than one position and more frequently. Recent extreme market events, including both the impacts of the COVID–19 pandemic and volatility caused by social media sentiments (referred to as the ''meme stock events''), have led NSCC to reconsider the causes and characteristics of idiosyncratic risks that the Gap Risk Measure was designed to mitigate. More specifically, these events have indicated that price changes due to gap risk events seem to occur more frequently and in higher severity; and may not be isolated to issuer events but driven by new mechanisms that drive concurrent market price moves involving unconventionally correlated securities. The Gap Risk Measure provides an insurance against various permutations of idiosyncratic risk moves, however, it is not targeted to capture and cover all such instances, especially when they are extreme, including certain meme stock events. NSCC believes the proposed enhancements to the Gap Risk Measure calculation, described below, would improve its ability to measure and mitigate against these idiosyncratic risks.

[11] *See* Section I(A)(1)(a)(i)II and I(A)(2)(a)(i)II of Procedure XV of the Rules, *supra* note 4. *See also* Securities Exchange Act Release Nos. 82780 (February 26, 2018), 83 FR 9035 (March 2, 2018) (SR–NSCC–2017–808); 82781 (February 26, 2018), 83 FR 9042 (March 2, 2018) (SR–NSCC–2017–020) (''Initial Filing'').

[12] *See Id.*

[13] *Id.*

[14] See *Important Notice a9055, dated September 27, 2021, at https://www.dtcc.com/-/media/Files/pdf/2021/9/27/a9055.pdf (notifying Members that the concentration threshold had been changed from 10% to 5%).*

[15] *See* Section I(A)(1)(a)(i)II and I(A)(2)(a)(i)II of Procedure XV, *supra* note 4.

(iii) Proposed Changes To Enhance the Gap Risk Measure and Enhance Transparency

With a goal of enhancing the Gap Risk Measure to broaden the scope of gap risk event coverage, NSCC explored a number of alternatives in particular by (1) using the Gap Risk Measure as an additive component rather than a substitutive component of the VaR Charge and (2) applying the Gap Risk Measure to one or more positions in a portfolio. NSCC also conducted impact studies based on various permutations of the parameters and NSCC is proposing enhancements to the Gap Risk Measure that would improve NSCC's ability to mitigate against idiosyncratic risks as described below. NSCC is also proposing enhancements to the transparency of the Rules by making certain clarifications to the description of the Gap Risk Measure.

NSCC is proposing to make the following enhancements to the Gap Risk Measure: (1) make the Gap Risk Measure an additive component of the Member's total VaR Charge when it is applicable, rather than being applied as the applicable VaR Charge when it is the largest of three separate calculations, (2) modify the language relating to which ETF positions are excluded from the Gap Risk Measure, (3) adjust both the trigger for applying the Gap Risk Measure and the calculation of the Gap Risk Measure to be based on the two largest positions in a portfolio, rather than based on the single largest position,(4)(a) remove the description of the methodology in the Rules for calculating the gap risk haircut, (b) provide that, like the concentration threshold, gap risk haircuts would be calibrated from time to time based on backtesting and impact analysis and (c) change the floor of the gap risk haircut from 10 percent to 5 percent for the largest position and add a floor of the gap risk haircut of 2.5 percent for the second largest position subject to the Gap Risk Measure, and (5) make certain clarifications to the description of the Gap Risk Measure.

Proposed Changes to Application and Calculation of the Gap Risk Measure

First, NSCC is proposing to make the result of the Gap Risk Measure calculation an additive component of Members' total VaR Charge, rather than applicable as the VaR Charge only when it is the highest result of three calculations. Following implementation of this proposed change, the total VaR Charge would be equal to the sum of (1) the greater of (a) the Core Parametric Estimation and (b) the Portfolio Margin Floor calculation; and (2) the Gap Risk Measure calculation. This proposed change would allow NSCC to collect the amount that results from a calculation of the Gap Risk Measure every time the concentration threshold is met which could improve NSCC's ability to mitigate idiosyncratic risks that it could face through the collection of the VaR Charge. Rather than being applied only if the Gap Risk Measure calculation exceeds the Core Parametric Estimation and the Portfolio Margin Floor calculation, the Gap Risk Measure calculation would apply every time the top two positions exceed the concentration threshold. Based on impact studies, NSCC believes this broader application together with the other proposed changes outlined below would better protect against more idiosyncratic risk scenarios than the current methodology.

Second, NSCC is proposing to modify the Rules regarding the ETF positions that are excluded from the Gap Risk Measure calculation. The Rules currently state that only ''non-index'' positions are included in the Gap Risk Measure.[16] NSCC is proposing to replace the reference to ''non-index'' positions with a reference to ''non-diversified'' positions and add a footnote to Sections I(A)(1)(a)(i) and I(A)(2)(a)(i) of Procedure XV of the Rules to state that NSCC would exclude ETF positions from the calculation if the ETFs have characteristics that indicate that such positions are less prone to the effects of gap risk events, as determined by NSCC from time to time. NSCC has determined that certain ETFs, both index based and non-index based, are less prone to the effects of gap risk events as a result of having certain characteristics and, therefore, are less likely to pose idiosyncratic risks that the Gap Risk Measure is designed to mitigate. Such characteristics include whether the ETF tracks to an index that is linked to a broad based market index, contains a diversified underlying basket, is unleveraged or tracks an asset class that is less prone to gap risk. For instance, NSCC has determined to include certain commodity ETFs from the Gap Risk Measure that track to an index but that are not linked to a broad-based diversified commodity index. The proposed change would result in these commodity ETFs that track to an index but that are not linked to a broad-based diversified commodity index to be subject to the Gap Risk Measure whereas they are currently excluded. NSCC has determined to exclude certain non-index based ETFs from the Gap Risk Measure that track to an asset that are less prone to gap risk, such as unleveraged U.S. dollar based ETFs. The proposed change would result in certain non-index based ETFs being excluded from the Gap Risk Measure whereas they are currently included.

NSCC currently identifies those positions that are less likely to pose idiosyncratic risks and excludes those positions from the calculation of the Gap Risk Measure.[17] The proposed change would provide Members with further transparency regarding which positions are excluded from this calculation by reflecting that certain non-index ETFs that have characteristics that indicate that such positions are less prone to the effects of gap risk events would be excluded and by reflecting that index based ETFs would only be excluded if they have characteristics that indicate that such positions are less prone to the effects of gap risk events. NSCC would also indicate in the Rules that such characteristics include whether the ETF tracks to an index that is linked to a broad based market index, contains a diversified underlying basket, is unleveraged or tracks an asset class that is less prone to gap risk.

Third, NSCC is proposing to adjust the trigger of the Gap Risk Measure to be based on the sum of the absolute values of the two largest non-diversified Net Unsettled Positions in a portfolio, rather than based on the absolute value of the single largest non-diversified Net Unsettled Position. More specifically, the Gap Risk Measure would be applicable if the sum of the absolute values of the two largest non-diversified Net Unsettled Positions in the portfolio represents more than the concentration threshold determined by NSCC from time to time.

In addition, the Gap Risk Measure would be calculated using the two largest non-diversified Net Unsettled Positions by multiplying each of the positions with a gap risk haircut and adding the sum of the resulting products. By applying the Gap Risk Measure to the two largest non-diversified positions in the portfolio, the Gap Risk Measure calculation would cover concurrent gap moves involving more than one concentrated position adding more flexibility and coverage to the Gap Risk Measure. The Gap Risk Measure charge for the two largest

[16] *See* Section I(A)(1)(a)(i)II and I(A)(2)(a)(i)II of Procedure XV of the Rules, *supra* note 6. *See also* Initial Filing, *supra* note 11.

[17] NSCC uses a third-party market provider to identify ETFs that meet its defined criteria of being diversified. ETFs that do not meet the criteria specified by NSCC are not included the Gap Risk Measure calculation.

positions would also provide coverage for gap events for smaller positions in the portfolio.

Fourth, NSCC would be adjusting the calculation of the gap risk haircut and replacing the current description with a description like the description of the calculation for the concentration threshold. Currently, the gap risk haircut is determined by selecting the largest of the 1st and 99th percentiles of three day returns of a composite set of equities, using a look-back period of not less than 10 years that includes a one year stress period.[18] With the current methodology, there is implicit overlapping of the risk covered by the core Parametric VaR and the Gap Risk Measure. Because NSCC would be using the Gap Risk Measure as an additive component to the VaR Charge rather than a substitutive component, NSCC does not believe that the current methodology for the gap risk haircut would result in an appropriate level. Instead of using the current methodology to calculate the gap risk haircut, NSCC would determine and calibrate the concentration threshold and the gap risk haircut from time to time based on backtesting and impact analysis. More specifically, the concentration threshold and the gap risk haircuts would be selected from various combinations of concentration thresholds and gap risk haircuts based on backtesting and impact analysis across all member portfolios initially over a five year look-back period. This would provide more flexibility to set the parameters from time to time to provide improved backtesting performance, broader coverage for idiosyncratic risk scenarios and flexibility for model tuning to balance performance and cost considerations.

In connection with the proposed expansion of the calculation of the Gap Risk Measure to be based on the two largest non-diversified Net Unsettled Positions in the portfolio, NSCC is also proposing to lower the gap risk haircut that would be applied to the largest non-diversified Net Unsettled Position to be a percent that is no less than 5 percent. Currently, the percent that is applied to the largest non-index Net Unsettled Positions in the portfolio is no less than 10 percent.[19] Given the proposed expansion of the calculation of the Gap Risk Measure to cover the two largest non-diversified Net Unsettled Positions, rather than only the single largest non-diversified Net Unsettled Position, NSCC believes it is appropriate to set a lower floor for the gap risk haircut that applies to the largest of those two positions. Given that the Gap Risk Measure would be additive rather than a substitutive component of the VaR Charge and would be triggered more frequently, NSCC believes that the flexibility to set a lower floor for the largest position would be appropriate. The gap risk haircut that would be applied to the second largest non-diversified Net Unsettled Position in the portfolio would be no larger than the gap risk haircut that would be applied to the largest non-diversified Net Unsettled Position and would be subject to a floor of 2.5 percent.

Initially, upon implementation, NSCC would set the concentration threshold at 10%, apply a gap risk haircut on the largest Net Unsettled Position of 10% and a gap risk haircut on the second largest Net Unsettled Position of 5%. NSCC would set the concentration threshold and the gap risk haircuts based on backtesting and impact analysis from time to time in accordance with NSCC's model risk management practices and governance set forth in the Model Risk Management Framework (''Model Risk Management Framework'').[20] NSCC's model risk management governance procedures include daily backtesting of model performance, periodic sensitivity analyses of models and annual validation of models. NSCC would review the concentration threshold and the gap risk haircuts at least annually. NSCC would provide notice to Members by important notice of the concentration threshold and gap risk haircuts that it would be applying and changes to the concentration threshold and to the gap risk haircuts.

Therefore, upon implementation, to determine the Gap Risk Measure for each portfolio, NSCC would determine the two largest non-diversified positions in the portfolio. If the sum of the gross market values of those two positions represent more than the concentration threshold of 10% of the gross market value of the portfolio, NSCC would add (i) an amount equal to 10% of the gross market value of the largest position and (ii) an amount equal to 5% of the gross market value of the second largest position. The sum amount would be included in the volatility component of the Required Fund Deposit for that portfolio.

As described in the Initial Filing, the Gap Risk Measure is designed to measure concentration of positions in a portfolio, which is an important indicator of that portfolio's vulnerability to idiosyncratic risks. By expanding the applicability of the Gap Risk Measure to each time the concentration threshold is met, the proposed changes to enhance the calculation of the Gap Risk Measure, described above, would improve the effectiveness of the VaR Charge in mitigating against those risks.

Proposed Changes To Improve Transparency

Fifth, NSCC would make the following clarification changes to improve transparency in the Rules.

NSCC is proposing to remove the specific references to the concentration threshold as 30 percent in the definition to reflect that NSCC may adjust the concentration threshold from time to time, as determined by NSCC based on the backtesting results and impact analysis over a look-back period of no less than the previous 12 months.[21] The Rules currently define the concentration threshold as more than 30 percent of the value of the entire portfolio.[22] The Rules also provide that the concentration threshold would be no more than 30 percent and would be determined by NSCC from time to time.[23] The proposed changes would clarify that the concentration threshold is not fixed at 30 percent by defining concentration threshold as a percentage designated by the Corporation of the value of the entire portfolio which is determined by NSCC from time to time. The Rules would continue to state that the concentration threshold would be no more than 30 percent. NSCC believes this proposed change will help clarify that the concentration threshold could change from time to time but could not be set to be more than 30 percent.

NSCC would revise language relating to the application of the Gap Risk Measure to Securities Financing Transactions (''SFTs''). Rule 56 governs the SFT Clearing Service.[24] Section 12(c) of Rule 56 (''Section 12(c)'') provides that NSCC shall calculate the amount of each SFT Member's required deposit for SFT Positions by applying the Clearing Fund Formula for CNS

[18] *Id.*

[19] *Id.*

[20] *See* Securities Exchange Act Release Nos. 81485 (August 25, 2017), 82 FR 41433 (August 31, 2017) (File No. SR–NSCC–2017–008); 84458 (October 19, 2018), 83 FR 53925 (October 25, 2018) (File No. SR–NSCC–2018–009), 88911 (May 20, 2020), 85 FR 31828 (May 27, 2020) (File No. SR–NSCC–2020–008), 92381 (July 13, 2021), 86 FR 38163 (July 19, 2021) (File No. SR–NSCC–2021–008), and 94272 (February 17, 2022), 87 FR 10419 (February 24, 2022) (File No. SR–NSCC–2022–001). The Model Risk Management Framework sets forth the model risk management practices adopted by NSCC.

[21] *Id.*

[22] *See* Section I(A)(1)(a)(i)II and I(A)(2)(a)(i)II of Procedure XV of the Rules, *supra* note 6. *See also* Initial Filing, *supra* note 11.

[23] *Id.*

[24] Rule 56, *supra* note 4.

Transactions set forth in certain sections in Procedure XV.[25] Footnote 1 (''Footnote 1'') in Section 12(c) provides that for purposes of applying the VaR Charge with respect to SFT Positions, NSCC shall apply the Gap Risk Measure as an additive component of the VaR Charge, which is consistent with how Net Unsettled Positions would be treated by the proposed changes.[26] Pursuant to Footnote 1, NSCC has been applying the Gap Risk Measure as an additive component of the VaR Charge with respect to SFT Positions but applying the Gap Risk Measure to other Net Unsettled Positions as a substitutive component as currently set forth in Procedure XV of the Rules. If the proposed changes contemplated by this filing were implemented, it would be unnecessary to distinguish how the Gap Risk Measure is calculated for SFT Positions because the Gap Risk Measure would be applied to SFT Positions in the same manner as it would be applied to other Net Unsettled Positions. As a result, NSCC is proposing to remove Footnote 1.

NSCC is also proposing to change the reference from ''positions'' to ''Net Unsettled Positions'' or ''Net Balance Order Unsettled Positions'', as applicable, to clarify that the positions subject to the Gap Risk Measure are Net Unsettled Positions. NSCC would also remove ''the portfolio's'' from the provision relating to how the concentration threshold and gap risk haircuts would be determined and calibrated because the reference is unnecessary. The same concentration threshold and gap risk haircuts would apply to all portfolios and would be calibrated based on backtesting and impact analysis of multiple portfolios. In addition, in accordance with the Model Risk Management Framework,[27] NSCC conducts periodic impact analysis of its models, including impacts on NSCC and impacts on Members. As such, NSCC is proposing to include ''impact analysis'' in addition to backtesting results as a measure of what NSCC would review to determine and calibrate the concentration threshold and gap risk haircuts. NSCC is also proposing to replace ''would'' with ''shall'' in four places to reflect that it is referring to future actions. NSCC would add ''gross market'' in front of ''value'' in two places and replace ''absolute'' with ''gross market'' in two places to clarify that NSCC would be using the gross market value of the positions and the portfolio in the Gap Risk Measure calculations. NSCC would also add a sentence in the Gap Risk Measure sections indicating that NSCC would announce updates of the concentration threshold and gap risk haircuts by Important Notice.

Proposed Changes to NSCC Rules

The proposed changes described above would be implemented by amending the description of the VaR Charge in Sections I(A)(1)(a)(i) and I(A)(2)(a)(i) of Procedure XV of the Rules. The proposed changes would also move the descriptions of the Portfolio Margin Floor and the Gap Risk Measure to Sections I(A)(1)(a)(i)II and I(A)(2)(a)(i)II and Sections I(A)(1)(a)(i)III and I(A)(2)(a)(i)III of Procedure XV, respectively.

The proposed changes would amend the description of the VaR Charge to state that it would be equal to the sum of (1) the highest resultant value among Sections I(A)(1)(a)(i)I and I(A)(2)(a)(i)I (which describe the Core Parametric Estimation) and Sections I(A)(1)(a)(i)II and I(A)(2)(a)(i)II (which would describe the Portfolio Margin Floor); and (2) the resultant value of Sections I(A)(1)(a)(i)III and I(A)(2)(a)(i)III (which would describe the Gap Risk Measure).

The proposed changes would amend the description of the Gap Risk Measure to refer to the two largest non-diversified Net Unsettled Positions in the portfolio, rather than the largest non-index position, as described above, would include a footnote in this description to clarify which positions are excluded from the calculation of the Gap Risk Measure and make the other changes described above in proposed Sections I(A)(1)(a)(i)III and I(A)(2)(a)(i)III.

The proposed changes would also remove Footnote 1 from Rule 56 as described above.

(iv) Implementation Timeframe

NSCC would implement the proposed changes no later than 60 Business Days after the later of the approval of the proposed rule change and the no objection to the advance notice [28] by the Commission. NSCC would announce the effective date of the proposed changes by Important Notice posted to its website.

2. Statutory Basis

NSCC believes that the proposed changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. In particular, NSCC believes the proposed changes are consistent with Section 17A(b)(3)(F) of the Act,[29] and Rules 17Ad–22(e)(4)(i), (e)(6)(i) and (e)(23)(ii), each promulgated under the Act,[30] for the reasons described below.

Section 17A(b)(3)(F) of the Act requires that the rules of NSCC be designed to, among other things, assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible and promote the prompt and accurate clearance and settlement of securities transactions.[31] As discussed above, NSCC is proposing enhancements to the Gap Risk Measure portion of the VaR Charge, one of the components of its Members' Required Deposits—a key tool that NSCC uses to mitigate potential losses to NSCC associated with liquidating a Member's portfolio in the event of Member default. NSCC believes the proposed changes are designed to assure the safeguarding of securities and funds which are in its custody or control or for which it is responsible because they are designed to enable NSCC to better limit its exposure to Members in the event of a Member default. More specifically, the proposal would expand the applicability of the Gap Risk Measure and NSCC's ability to collect amounts calculated through this component, which is designed to mitigate idiosyncratic risks that NSCC may face.

In its review of the Gap Risk Measure, NSCC conducted impact studies adjusting differing parameters and thresholds to determine a model that would provide improved backtesting performance, broader coverage for idiosyncratic risk scenarios and flexibility for model tuning to balance performance and cost considerations to Members. Based on the impact studies, NSCC determined that the following enhancements to the Gap Risk Measure described above would enhance the flexibility of the Gap Risk Measure to

[25] Section 12(c) of Rule 56, *supra* note 4.

[26] *See* Footnote 1, *supra* note 4, which states ''For the purpose of applying Section I.(A)(1)(a)(i) of Procedure XV (Value-at-Risk (VaR) charge), the volatility of an SFT Member's SFT Positions shall be the sum of (a) the highest resultant value between Section I.(A)(1)(a)(i)I. (Core Parametric Estimation) and Section I.(A)(1)(a)(i)III. (Margin Floor) and (b) the resultant value of Section I.(A)(1)(a)(i)II. (Gap Risk Measure).''

[27] *See* Model Risk Management Framework, *supra* note 20.

[28] NSCC filed this proposed rule change as an advance notice (File No. SR–NSCC–2022–802) with the Commission pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010, 12 U.S.C. 5465(e)(1), and Rule 19b–4(n)(1)(i) under the Act, 17 CFR 240.19b–4(n)(1)(i). A copy of the advance notice is *available at https://www.dtcc.com/legal/sec-rule-filings.aspx*.

[29] 15 U.S.C. 78q–1(b)(3)(F).

[30] 17 CFR 240.17Ad–22(e)(4)(i), (e)(6)(i) and (e)(23)(ii).

[31] 15 U.S.C. 78q–1(b)(3)(F).

broaden the scope of gap risk event coverage and to use parameters to allow for coverage of larger gap moves: (1) making the Gap Risk Measure an additive component of the Member's total VaR Charge when it is applicable, rather than being applied as the applicable VaR Charge when it is the largest of three separate calculations, (2) modifying the language relating to which ETF positions are excluded from the Gap Risk Measure, (3) adjusting both the trigger for applying the Gap Risk Measure and the calculation of the Gap Risk Measure to be based on the two largest positions in a portfolio, rather than based on the single largest position and (4)(a) removing the description of the methodology in the Rules for calculating the gap risk haircut, (b) providing that, like the concentration threshold, gap risk haircuts would be calibrated from time to time based on backtesting and impact analysis and (c) changing the floor of the gap risk haircut from 10 percent to 5 percent for the largest position and adding a floor of the gap risk haircut of 2.5 percent for the second largest position subject to the Gap Risk Measure (''Gap Risk Measure Enhancements'').

The Clearing Fund is a key tool that NSCC uses to mitigate potential losses to NSCC associated with liquidating a Member's portfolio in the event of Member default. Therefore, the Gap Risk Measure Enhancements would enable NSCC to better address the potential idiosyncratic risks that it may face when liquidating a portfolio that contains a concentration of positions, such that, in the event of Member default, NSCC's operations would not be disrupted, and non-defaulting Members would not be exposed to losses they cannot anticipate or control. In particular, making the Gap Risk Measure additive would allow NSCC to collect the amount that results from a calculation of the Gap Risk Measure every time the concentration threshold is met which would improve NSCC's ability to mitigate idiosyncratic risks that it could face through the collection of the VaR Charge and better protect against more idiosyncratic risk scenarios than the current methodology. Modifying ETF positions that are subject to the Gap Risk Measure based on whether they are non-diversified rather than whether they are non-index would allow NSCC to more accurately determine which ETFs should be included and excluded from the Gap Risk Measure based on characteristics that indicate that such ETFs are more or less prone to the effects of gap risk events. Adjusting the Gap Risk Measure trigger and calculation to target the largest two non-diversified Net Unsettled Positions in a portfolio would cover concurrent gap moves involving more than one concentrated position providing more coverage of the Gap Risk Measure. Removing specific methodology metrics relating to the gap risk haircuts and adding that gap risk haircuts would be calibrated from time to time based on backtesting and impact analysis, lowering the floor for the gap risk haircut that applies to the largest of the two largest non-diversified Net Unsettled Positions and setting a floor of 2.5 percent for the second largest non-diversified Net Unsettled Positions would allow NSCC to calibrate and set appropriate gap risk haircuts based on the Gap Risk Measure being additive rather than a substitutive component to the VaR Charge. In this way, the proposed rule change to introduce the Gap Risk Measure Enhancements are designed to assure the safeguarding of securities and funds which are in the custody or control of NSCC or for which it is responsible, consistent with Section 17A(b)(3)(F) of the Act.[32]

NSCC also believes the proposed changes to provide transparency to the Rules by (a) removing the references to 30 percent as the concentration threshold to reflect that it is adjusted from time, (b) removing Footnote 1 relating to the application of Gap Risk Measure for SFT Positions from Rule 56, (c) changing the reference from ''positions'' to ''Net Unsettled Positions'' or ''Net Balance Order Unsettled Positions'', as applicable, (d) removing the unnecessary reference to ''the portfolio's'' in reference to backtesting results, (e) including a reference to ''impact analysis'' as a measure of what NSCC would review to determine and calibrate the concentration threshold and gap risk haircuts, (f) replacing ''would'' with ''shall'' in four places, (g) clarifying that the calculations would be referring to the gross market value of the positions and portfolios, and (h) adding a sentence indicating that NSCC would announce updates of the concentration threshold and gap risk haircuts by Important Notice (''Transparency Enhancements'') are consistent with the requirements of Section 17A(b)(3)(F) of the Act.[33] Specifically, by enhancing the transparency of the Rules, the proposed changes would allow Members to more efficiently and effectively conduct their business in accordance with the Rules, which NSCC believes would promote the prompt and accurate clearance and settlement of securities transactions.

Rule 17Ad–22(e)(4)(i) under the Act requires, in part, that NSCC establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence.[34]

As described above, NSCC believes that the proposed changes would enable it to better identify, measure, monitor, and, through the collection of Members' Required Fund Deposits, manage its credit exposures to Members by maintaining sufficient resources to cover those credit exposures fully with a high degree of confidence. Specifically, NSCC believes that the Gap Risk Measure Enhancements would provide improved backtesting performance, broader coverage for idiosyncratic risk scenarios and flexibility for model tuning to balance performance and cost considerations to Members, and would address the potential increased risks NSCC may face related to its ability to liquidate a portfolio that is susceptible to such risks in the event of a Member default. In particular, making the Gap Risk Measure additive would allow NSCC to collect the amount that results from a calculation of the Gap Risk Measure every time the concentration threshold is met which would improve NSCC's ability to mitigate idiosyncratic risks that it could face through the collection of the VaR Charge and better protect against more idiosyncratic risk scenarios than the current methodology. Modifying ETF positions that are subject to the Gap Risk Measure based on whether they are non-diversified rather than whether they are non-index would allow NSCC to more accurately determine which ETFs should be included and excluded from the Gap Risk Measure based on characteristics that indicate that such ETFs are more or less prone to the effects of gap risk events. Adjusting the Gap Risk Measure trigger and calculation to target the largest two non-diversified Net Unsettled Positions in a portfolio would cover concurrent gap moves involving more than one concentrated position providing more coverage of the Gap Risk Measure. Removing specific methodology metrics relating to the gap risk haircuts and adding that gap risk

[32] *Id.*

[33] *Id.*

[34] 17 CFR 240.17Ad–22(e)(4)(i).

haircuts would be calibrated from time to time based on backtesting and impact analysis, lowering the floor for the gap risk haircut that applies to the largest of the two largest non-diversified Net Unsettled Positions and setting a floor of 2.5 percent for the second largest non-diversified Net Unsettled Positions would allow NSCC to calibrate and set appropriate gap risk haircuts based on the Gap Risk Measure being additive rather than a substitutive component to the VaR Charge. NSCC compared a number of different models for the Gap Risk Measure with different parameters and thresholds, including the Gap Risk Measure Enhancements and determined that the Gap Risk Measure Enhancements improved backtesting performance, provided broader coverage for idiosyncratic risk scenarios and flexibility for model tuning to balance performance and cost considerations to Members.

Therefore, NSCC believes that the proposal would enhance NSCC's ability to effectively identify, measure and monitor its credit exposures and would enhance its ability to maintain sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence. As such, NSCC believes the proposed changes are consistent with Rule 17Ad–22(e)(4)(i) under the Act.[35]

Rule 17Ad–22(e)(6)(i) under the Act requires, in part, that NSCC establish, implement, maintain and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market.[36]

The Required Fund Deposits are made up of risk-based components (as margin) that are calculated and assessed daily to limit NSCC's credit exposures to Members, including the VaR Charge. NSCC's proposed Gap Risk Measure Enhancements are designed to more effectively address the risks presented by a portfolio that meets the concentration threshold and, therefore, is more susceptible to the impacts of idiosyncratic risks. NSCC believes the enhanced VaR Charge, as a result of the Gap Risk Measure Enhancements would enable NSCC to assess a more appropriate level of margin that accounts for these risks. In particular, making the Gap Risk Measure additive would allow NSCC to collect the amount that results from a calculation of the Gap Risk Measure every time the concentration threshold is met which would improve NSCC's ability to mitigate idiosyncratic risks that it could face through the collection of the VaR Charge and better protect against more idiosyncratic risk scenarios than the current methodology. Rather than being applied only if the Gap Risk Measure calculation exceeds the Core Parametric Estimation and the Portfolio Margin Floor calculation, the Gap Risk Measure calculation would apply every time the top two positions exceed the concentration threshold. Based on impact studies, NSCC believes this broader application together with the other proposed changes outlined below would better protect against more idiosyncratic risk scenarios than the current methodology Modifying ETF positions that are subject to the Gap Risk Measure based on whether they are non-diversified rather than whether they are non-index would allow NSCC to more accurately determine which ETFs should be included and excluded from the Gap Risk Measure based on characteristics that indicate that such ETFs are more or less prone to the effects of gap risk events. Adjusting the Gap Risk Measure trigger and calculation to target the largest two non-diversified Net Unsettled Positions in a portfolio would cover concurrent gap moves involving more than one concentrated position providing more coverage of the Gap Risk Measure. Removing specific methodology metrics relating to the gap risk haircuts and adding that gap risk haircuts would be calibrated from time to time based on backtesting and impact analysis, lowering the floor for the gap risk haircut that applies to the largest of the two largest non-diversified Net Unsettled Positions and setting a floor of 2.5 percent for the second largest non-diversified Net Unsettled Positions would allow NSCC to calibrate and set appropriate gap risk haircuts based on the Gap Risk Measure being additive rather than a substitutive component to the VaR Charge. These proposed changes are designed to assist NSCC in maintaining a risk-based margin system that considers, and produces margin levels commensurate with, the risks and particular attributes of portfolios that meet the concentration threshold, as applied through the current methodology. Therefore, NSCC believes the proposed change is consistent with Rule 17Ad–22(e)(6)(i) under the Act.[37]

Rule 17A–d22(e)(23)(ii) under the Act requires, in part, that NSCC establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in the covered clearing agency.[38] By making the proposed Transparency Enhancements, the proposed changes would improve the transparency of the Rules. By providing Members with additional information that would enable them to evaluate the risks and material costs they incur by participating in NSCC, NSCC believes the proposed change is consistent with the requirements of Rule 17Ad–e)(23)(ii).[39]

(B) Clearing Agency's Statement on Burden on Competition

NSCC does not believe the proposed Transparency Enhancements would impact competition. These proposed rule changes would merely enhance the transparency of the Rules. Therefore, this proposed changes would not affect NSCC's operations or the rights and obligations of Members. As such, NSCC believes this proposed rule change to improve the transparency of the Rules would not have any impact on competition.

NSCC believes that the Gap Risk Measure Enhancements could have an impact on competition. Specifically, NSCC believes the proposed changes could burden competition because they would result in larger Required Fund Deposit amounts for Members when the additional charges are applicable and result in a Required Fund Deposit that is greater than the amount calculated pursuant to the current formula.

When the proposal results in a larger Required Fund Deposit, the Gap Risk Measure Enhancements could burden competition for Members that have lower operating margins or higher costs of capital compared to other Members. However, the increase in Required Fund Deposit would be in direct relation to the specific risks presented by each Member's Net Unsettled Positions, and each Member's Required Fund Deposit would continue to be calculated with the same parameters and at the same confidence level for each Member. Therefore, Members that present similar Net Unsettled Positions, regardless of the type of Member, would have similar impacts on their Required Fund Deposit amounts. As such NSCC believes that any burden on competition imposed by the proposed changes would not be significant and, further, would be both

[35] *Id.*

[36] 17 CFR 240.17Ad–22(e)(6)(i).

[37] *Id.*

[38] 17 CFR 240.17Ad–22(e)(23)(ii).

[39] *Id.*

necessary and appropriate in furtherance of NSCC's efforts to mitigate risks and meet the requirements of the Act, as described in this filing and further below.

NSCC believes the above described burden on competition that may be created by the proposed enhancement of the VaR Charge through the expansion of the Gap Risk Measure would be necessary in furtherance of the Act, specifically Section 17A(b)(3)(F) of the Act.[40] As stated above, the proposed Gap Risk Measure Enhancements would improve NSCC's ability to mitigate against idiosyncratic risks that are presented by portfolios that meet the concentration threshold, including the risks related to gap risk events that are not driven by issuer events. Therefore, NSCC believes this proposed change is consistent with the requirements of Section 17A(b)(3)(F) of the Act, which requires that the Rules be designed to assure the safeguarding of securities and funds that are in NSCC's custody or control or which it is responsible.[41]

NSCC believes these proposed changes would also support NSCC's compliance with Rules 17Ad–22(e)(4)(i) and Rule 17Ad–22(e)(6)(i) under the Act, which require NSCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to (x) effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence; and (y) cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market.[42]

As described above, NSCC believes the proposed Gap Risk Measure Enhancements would allow NSCC to employ a risk-based methodology to address the increased idiosyncratic risks presented by the occurrence of gap risk events that are presented by portfolios that meet the concentration threshold. Therefore, the proposed changes would better limit NSCC's credit exposures to Members, consistent with the requirements of Rules 17A–d22(e)(4)(i) and Rule 17Ad22–(e)(6)(i) under the Act.[43]

NSCC believes that the above-described burden on competition that could be created by the proposed changes would be appropriate in furtherance of the Act because such changes have been appropriately designed to assure the safeguarding of securities and funds which are in the custody or control of NSCC or for which it is responsible, as described in detail above. The proposed enhancement to the VaR Charge through the expansion of the Gap Risk Measure would enable NSCC to produce margin levels more commensurate with the risks and particular attributes of each Member's portfolio.

The proposed changes would do this by continuing to apply the Gap Risk Measure only when the concentration threshold is met. The proposed change to expand the sensitivity of the charge to refer to the two largest non-diversified Net Unsettled Positions in the portfolio would provide NSCC with a better measure of the various and unexpected idiosyncratic risks it may face, in light of the recent gap risk events that did not derive from issuer events. Therefore, because the proposed changes are designed to provide NSCC with an appropriate measure of the risks (*i.e.,* risks related to gap risk events) presented by Members' portfolios, NSCC believes the proposal is appropriately designed to meet its risk management goals and its regulatory obligations.

NSCC believes that it has designed the proposed changes in an appropriate way in order to meet compliance with its obligations under the Act. Specifically, the proposals would improve the risk-based margining methodology that NSCC employs to set margin requirements and better limit NSCC's credit exposures to its Members. Therefore, as described above, NSCC believes the proposed changes are necessary and appropriate in furtherance of NSCC's obligations under the Act, specifically Section 17A(b)(3)(F) of the Act[44] and Rule 17Ad–22(e)(4)(i) and Rule 17Ad–22(e)(6)(i) under the Act.[45]

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

NSCC has not received or solicited any written comments relating to this proposal. If any written comments are received, they will be publicly filed as an Exhibit 2 to this filing, as required by Form 19b–4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b–4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, available at *https://www.sec.gov/regulatory-actions/how-to-submit-comments.* General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at *tradingandmarkets@sec.gov* or 202–551–5777.

NSCC reserves the right not to respond to any comments 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 such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

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–NSCC–2022–015 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

[40] 15 U.S.C. 78q–1(b)(3)(F).

[41] *Id.*

[42] 17 CFR 240.17Ad–22(e)(4)(i), (e)(6)(i).

[43] *Id.*

[44] 15 U.S.C. 78q–1(b)(3)(F).

[45] 17 CFR 240.17Ad–22(e)(4)(i), (e)(6)(i).

Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–NSCC–2022–015. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of NSCC and on DTCC's website (*https://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–NSCC–2022–015 and should be submitted on or before January 11, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[46]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–27657 Filed 12–20–22; 8:45 am]

BILLING CODE 8011–01–P

[46] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96509; File No. SR–NASDAQ–2022–057]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Adopt Listing Rule 5732 To Provide Listing Standards for Contingent Value Rights on Nasdaq Global Market

December 15, 2022.

On October 17, 2022, The Nasdaq Stock Market LLC (''Nasdaq'' 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 adopt Listing Rule 5732 to provide listing standards for Contingent Value Rights on Nasdaq Global Market. The proposed rule change was published for comment in the **Federal Register** on November 3, 2022.[3] The Commission has 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 December 18, 2022. 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 February 1, 2023 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–NASDAQ–2022–057).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–27655 Filed 12–20–22; 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. 96176 (October 28, 2022), 87 FR 66337 (November 3, 2022).

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96504; File No. SR–NYSEARCA–2022–82]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 6.40P–O

December 15, 2022.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on December 14, 2022, 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 amend Rule 6.40P–O (Pre-Trade and Activity-Based Risk Controls) pertaining to pre-trade risk controls to make additional pre-trade risk controls available to Entering Firms. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 6.40P–O (Pre-Trade and Activity-Based Risk Controls) pertaining to pre-trade risk controls to make additional pre-trade risk controls available to entering Firms.[4]

Background and Purpose

In 2022, in connection with the Exchange's migration to Pillar and to better assist OTP Holders and OTP Firms in managing their risk, the Exchange adopted Rule 6.40P–O, which included pre-trade risk controls, among other activity-based controls, wherein an Entering Firm had the option of establishing limits or restrictions on certain of its trading behavior on the Exchange and authorizing the Exchange to take action if those limits or restrictions were exceeded.[5] Specifically, the Exchange added a Single Order Maximum Notional Value Risk Limit, and a Single Order Maximum Quantity Risk Limit [6] (collectively, the ''Initial Pre-Trade Risk Controls'').

The Exchange now proposes to expand the list of the optional pre-trade risk controls available to Entering Firms by adding several additional pre-trade risk controls that would provide Entering Firms with enhanced abilities to manage their risk with respect to orders on the Exchange. Like the Initial Pre-Trade Risk Controls, use of the pre-trade risk controls proposed herein is optional, but all orders on the Exchange would pass through these risk checks. As such, an Entering Firm that does not choose to set limits pursuant to the new proposed pre-trade risk controls would not achieve any latency advantage with respect to its trading activity on the Exchange. In addition, the Exchange expects that any latency added by the pre-trade risk controls would be *de minimis.*

Proposed Amendment to Rule 6.40P–O

To accomplish this rule change, the Exchange proposes to amend the definition of the term ''Pre-Trade Risk Controls'' set forth in Rule 6.40P–O(a)(2) to adopt the definition of ''Single-Order Risk Controls,'' which controls would be listed in proposed paragraph (A) to Rule 6.40P–O(a)(2). As proposed, the ''Single-Order Risk Controls'' would include the already-defined risk controls of the Single Order Maximum Notional Value Risk Limit and Single Order Maximum Quantity Risk Limit (collectively referred to herein as the ''existing Single-Order Risk Checks''), with non-substantive changes to streamline the descriptions of these controls into new paragraph (i) of proposed Rule 6.40P–O(a)(2)(A).[7] However, because of a lack of demand for the option to apply the existing Single-Order Risk Checks to Market Maker quotes, the Exchange proposes to discontinue functionality supporting this optional feature.

In the addition, the Exchange proposes to add paragraphs (a)(2)(A)(ii) through (v) to enumerate the proposed new Single-Order Risk Controls, as follows:

(ii) controls related to the price of an order or quote (including percentage-based and dollar-based controls);

(iii) controls related to the order types or modifiers that can be utilized;

(iv) controls to restrict the options class transacted; and

(v) controls to prohibit duplicative orders.

Each of the new Single-Order Risk Controls in proposed paragraph (a)(2)(A)(ii)–(v) is substantively identical to risk settings already in place on the Exchange's affiliate equities exchange NYSE American LLC (''NYSE American''),[8] as well as those on the Cboe and MEMX equities exchanges,[9] except that the proposed controls account for options trading, such as including reference to ''an order or quote'' versus ''an order'' and reference to restrictions on trading in an ''options class'' versus on ''the types of securities transacted (including but not limited to restricted securities).'' [10] As such, the proposed new optional Pre-Trade Risk Controls are familiar to market participants and are not novel.

The Exchange proposes to modify current paragraph (b)(2) regarding the setting and adjusting of the Pre-Trade Risk Controls to state that, in addition to Pre-Trade Risk Controls being available to be set at the MPID level or at one or more sub-IDs associated with that MPID, or both, that Pre-Trade Risk Controls to restrict the options class(es) transacted must be set per option class.[11]

The Exchange proposes to modify paragraph (c)(1) regarding ''Breach Action for Pre-Trade Risk Controls.'' First, the Exchange proposes to specify that ''[a] Limit Order that breaches any Single-Order Risk Control will be rejected.'' [12] The proposed functionality is consistent with the treatment of Limit Orders that breach the existing Single Order Risk Checks and simply extends the application of the breach action to the newly proposed Single-Order Risk Controls. Next, proposed Rule 6.40P–O(c)(1)(A)(ii) specifies that ''[a] Market Order that arrives during a pre-open state will be cancelled if the quantity remaining to trade after an Auction breaches the Single Order Maximum Notional Value Risk Limit,'' which functionality is identical to treatment of such interest under the current Rule.[13] Proposed Rule 6.40P–O(c)(1)(A)(ii) further specifies that ''[a]t all other times, a Market Order that triggers or breaches any Single-Order Risk Control will be rejected.'' [14] The proposed functionality is consistent with the treatment of Market Orders (that arrive other than during a pre-open state) that breach the existing Single Order Risk Checks and simply extends the

[4] The term ''Entering Firm'' refers to an OTP Holder or OTP Firm (including those acting as Market Makers). *See* Rule 6.40P–O(a)(1).

[5] *See* Securities Exchange Act Release No. 94072 (January 26, 2022), 87 FR 5592 (February 1, 2022) (Notice of filing Notice of Filing of Amendment No. 4 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 4) (SR–NYSEArca–2021–47).

[6] The terms ''Single Order Maximum Notional Value Risk Limit, and ''Single Order Maximum Quantity Risk Limit'' are defined in Rule 6.40P–O(a)(2).

[7] *See* proposed Rule 6.40P–O(a)(2)(A)(i) (setting forth ''controls related to the maximum dollar amount for a single order to be applied one time ('Single Order Maximum Notional Value Risk Limit') and the maximum number of contracts that may be included in a single order before it can be traded ('Single Order Maximum Quantity Risk Limit'). Orders designated GTC will be subject to these checks only once.'') Consistent with the foregoing changes, the Exchange proposes to delete current paragraph (B) to Rule 6.40P–O(a)(2)(B). *See id.*

[8] *See* NYSE American Rule 7.19E; *see also* Securities Exchange Act Release No. 96403 (November 29, 2022) (SR–NYSEAMER–2022–53).

[9] *See* Cboe BZX Exchange, Inc. (''Cboe BZX'') Rule 11.13, Interpretations and Policies .01; Cboe BYX Exchange, Inc. (''Cboe BYX'') Rule 11.13, Interpretations and Policies .01; Cboe EDGA Exchange, Inc. (''Cboe EDGA'') Rule 11.10, Interpretations and Policies .01; Cboe EDGX Exchange, Inc. (''Cboe EDGX'') Rule 11.10, Interpretations and Policies .01; and MEMX LLC (''MEMX'') Rule 11.10, Interpretations and Policies .01.

[10] *See* proposed Rule 6.40P(a)(2)(A)(ii) and (a)(2)(A)(iv) as compared to NYSE American Rule 7.19E(b)(2)(B) and (b)(2)(F), respectively.

[11] *See, e.g.,*. Rule 7.19E(d)(2) (specifying that pre-trade risk controls related to transacting in restricted securities must be set per symbol).

[12] *See* proposed Rule 6.40P(c)(1)(A)(i).

[13] *See* Rule 6.40P(c)(1)(A)(i) (providing, in relevant part, that ''[a] Market Order that breaches the designated limit of a Single Order Maximum Quantity Risk Limit'' will be ''canceled if the order was received during a pre-open state and the quantity remaining to trade after an Auction concludes breaches the designated limit.'').

[14] *See* proposed Rule 6.40P(c)(1)(A)(ii).

application of the breach action to the newly proposed Single-Order Risk Controls. Further, proposed Rule 6.40P–O(c)(1)(A)(iii) addresses the breach action relevant to the new Single-Order Risk Control set forth in proposed Rule 6.40P–O(a)(2)(A)(ii) (*i.e.,* a breach of controls related to the price of an order or quote including percentage-based and dollar-based controls). As proposed, a Limit Order or quote that would breach a price control under paragraph (a)(2)((A)(ii) would be rejected or cancelled as specified in Rule 6.62P–O (a)(3)(A) (Limit Order Price Protection).[15]

Finally, the Exchange proposes to add new Commentary .02 to specify the interplay between the Exchange's Limit Order Price Protection (''LOPP'') functionality and the price controls that may be set by an Entering Firm pursuant to proposed paragraph (a)(2)(A)(ii). Proposed Commentary .02 specifies that an Entering Firm may set price controls under paragraph (a)(2)(A)(ii) that are equal to or more restrictive than levels set by the Exchange LOPP functionality.

Continuing Obligations of OTP Holders Under Rule 15c3–5

The proposed Pre-Trade Risk Controls described here are meant to supplement, and not replace, the OTP Holders' own internal systems, monitoring, and procedures related to risk management. The Exchange does not guarantee that these controls will be sufficiently comprehensive to meet all of an OTP Holder's needs, the controls are not designed to be the sole means of risk management, and using these controls will not necessarily meet an OTP Holder's obligations required by Exchange or federal rules (including, without limitation, the Rule 15c3–5 under the Act[16] (''Rule 15c3–5'')). Use of the Exchange's Pre-Trade Risk Controls will not automatically constitute compliance with Exchange or federal rules and responsibility for compliance with all Exchange and SEC rules remains with the OTP Holder.[17]

Timing and Implementation

The Exchange anticipates completing the technological changes necessary to implement the proposed rule change in the second quarter of 2023, but in any event no later than June 30, 2023. The Exchange anticipates announcing the availability of the Pre-Trade Risk Controls introduced in this filing by Trader Update in the first quarter of 2023.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[18] in general, and furthers the objectives of Section 6(b)(5) of the Act,[19] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Specifically, the Exchange believes that the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed optional additional Pre-Trade Risk Controls would provide Entering Firms enhanced abilities to manage their risk with respect to orders or quotes on the Exchange. The proposed additional Pre-Trade Risk Controls are not novel; they are based on existing risk settings already in place on NYSE American,[20] as well as those on the Cboe and MEMX equities exchanges,[21] and market participants are already familiar with the types of protections that the proposed risk controls afford. Moreover, the proposed new Single-Order Risk Controls (like the existing Single-Order Risk Checks) are options and, as such, Entering Firms are free to utilize or not at their discretion. Thus, the Exchange believes that the proposed additional Pre-Trade Risk Controls would provide a means to address potentially market-impacting events, helping to ensure the proper functioning of the market.

In addition, the Exchange believes that the proposed rule change will protect investors and the public interest because the proposed additional Pre-Trade Risk Controls are a form of impact mitigation that will aid Entering Firms in minimizing their risk exposure and reduce the potential for disruptive, market-wide events. The Exchange understands that OTP Holders implement a number of different risk-based controls, including those required by Rule 15c3–5. The controls proposed here will serve as an additional tool for Entering Firms to assist them in identifying any risk exposure. The Exchange believes the proposed additional Pre-Trade Risk Controls will assist Entering Firms in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system.

The Exchange believes that the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system by permitting Entering Firms to set price controls under paragraph (a)(2)(A)(ii) that are equal to or more restrictive than the levels established in the Exchange's LOPP functionality, which protects from aberrant trades, thus improving continuous trading and price discovery. To the extent that Entering Firms would like to further manage their exposure to aberrant trades, this proposed functionality affords such Firms the ability to set price controls at levels that are more restrictive than the LOPP levels. Additionally, because price controls set by an Entering Firm under paragraph (a)(2)(A)(ii) would function as a form of limit order price protection, the Exchange believes that it would remove impediments to and perfect the mechanism of a free and open market and a national market system for an order that would breach such a price control to be rejected or cancelled as specified per Rule 6.62P–O(a)(3)(A) regarding the LOPP.

Finally, the Exchange believes that the proposed rule change does not unfairly discriminate among the Exchange's OTP Holders because use of the proposed additional Pre-Trade Risk Controls is optional and is not a prerequisite for participation on the Exchange. In addition, because all orders on the Exchange would pass through the risk checks, there would be no difference in the latency experienced by OTP Holders who have opted to use the proposed additional Pre-Trade Risk Controls versus those who have not opted to use them.

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

[15] *See* proposed Rule 6.40P(c)(1)(A)(iii).

[16] *See* 17 CFR 240.15c3–5.

[17] *See also* Commentary .01 to Rule 6.40P–O, which provides that the Pre-Trade Risk Controls set forth in Rule 6.40P–O ''are meant to supplement, and not replace, the OTP Holder's or OTP Firm's own internal systems, monitoring, and procedures related to risk management and are not designed for compliance with Rule 15c3–5 under the Exchange Act. Responsibility for compliance with all Exchange and SEC rules remains with the OTP Holder or OTP Firm.'').

[18] 15 U.S.C. 78f(b).

[19] 15 U.S.C. 78f(b)(5).

[20] *See supra* note 8.

[21] *See supra* note 9.

necessary or appropriate in furtherance of the purposes of the Act. In fact, the Exchange believes that the proposal will have a positive effect on competition because, by providing Entering Firms additional means to monitor and control risk, the proposed rule will increase confidence in the proper functioning of the markets. The Exchange believes the proposed additional Pre-Trade Risk Controls will assist Entering Firms in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system. As a result, the level of competition should increase as public confidence in the markets is solidified.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [22] and Rule 19b–4(f)(6) thereunder.[23] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[24]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [25] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. 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–2022–82 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–2022–82. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2022–82 and should be submitted on or before January 11, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–27651 Filed 12–20–22; 8:45 am]

BILLING CODE 8011–01–P

[22] 15 U.S.C. 78s(b)(3)(A)(iii).

[23] 17 CFR 240.19b–4(f)(6).

[24] 17 CFR 240.19b–4(f)(6)(iii). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[25] 15 U.S.C. 78s(b)(2)(B).

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96503; File No. SR–ICEEU–2022–026]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Amendments to the Finance Procedures

December 15, 2022.

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 December 6, 2022, ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II, and III below, which Items have been prepared primarily by ICE Clear Europe. ICE Clear Europe filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(4) thereunder,[4] such that the proposed rule change was immediately effective upon filing with the Commission. 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

ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') proposes to amend its Finance Procedures in order to align the timing at which monthly interest payments and monthly transaction fees are processed.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe included statements concerning the purpose of and basis for the proposed rule change and discussed

[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).

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. ICE Clear Europe 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

(a) Purpose

ICE Clear Europe is proposing to amend its Finance Procedures to align the timing for payment of the return on cash margin and Guaranty Fund deposits of Clearing Members with that for payment of monthly transaction fees. Under existing Finance Procedures paragraph 6.1(i)(vi), transaction fees are payable through the overnight payment call or return by the fifth Business Day after the end of each month. ICE Clear Europe is proposing to amend Finance Procedures paragraph 6.1(i)(iv) to provide that interest on margin and Guaranty Fund contributions will be credited by the fifth Business Day after the end of each month, rather than the fourth Business Day after the end of each month. ICE Clear Europe proposes to implement the change on or about December 14, 2022.

ICE Clear Europe believes that processing interest and transaction fees on the same day as part of the same net overnight payment calculation will reduce the number and size of overall cash flows and thus improve overall payment efficiency. The change will also reduce unnecessary potential liquidity demands on the Clearing House and Clearing Members to the extent of offsetting interest and transaction fees and reduce the risk to the Clearing House of a failure or default in payment of transaction fees by a Clearing Member after payment by the Clearing House of interest. ICE Clear Europe believes that the benefits of improving payment efficiency in this manner will be more significant in the current rising interest rate environment, as increases in ICE Clear Europe's ICE Deposit Rate have resulted in an increase in monthly interest payments due from ICE Clear Europe to Clearing Members.

(b) Statutory Basis

ICE Clear Europe believes that the proposed amendments to the Finance Procedures are consistent with the requirements of Section 17A [5] of the Act and the regulations thereunder applicable to it. In particular, Section 17A(b)(3)(D) of the Act [6] requires that ''[t]he rules of the clearing agency provide for the equitable allocation of reasonable dues, fees and other charges among its participants.'' ICE Clear Europe believes that the proposal is a reasonable and appropriate change to the timing of payment of return on cash margin and Guaranty Fund contributions, in order to enhance overall settlement efficiency. This is particularly so, in ICE Clear Europe's view, in light of the current interest rate environment which has led to increases in the ICE Deposit Rate. The amendment also reduces liquidity demands and reduces the risk of a payment failure or default with respect to the payment of transaction fees. As such, in ICE Clear Europe's view, the amendments are consistent with the equitable allocation of reasonable dues, fees and other charges among its Clearing Members and other market participants, within the meaning of Section 17A(b)(3)(D) of the Act.[7]

The proposed amendments are also consistent with the requirements of Section 17A(b)(3)(F) of the Act which requires, among other things, that ''[t]he rules of a clearing agency [. . .] are not designed to permit unfair discrimination in the admission of participants or among participants in the use of the clearing agency.'' [8] As noted above, the Finance Procedures, as proposed to be amended, would apply to all Clearing Members and the amendments would not otherwise the rights or obligations of the Clearing House or Clearing Members with respect to the payment of transaction fees or the payment of interest on cash margin and Guaranty Fund contributions. Section 17A(b)(3)(F) also requires that the ''[t]he rules of a clearing agency [. . .] are designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts and transactions, to assure the safeguarding of securities or funds which are in the custody or control of the clearing agency or for which it is responsible . . . and, in general, to protect investors and the public interest.'' [9] As set forth above, ICE Clear Europe believes the amendments will enhance payment efficiency and reduce payment risks. As such, the amendments, in ICE Clear Europe's view, would be consistent with prompt and accurate clearance and settlement, would not adversely affect the safeguarding of securities and funds which are in the custody or control of ICE Clear Europe or for which it is responsible, and generally would be consistent with the public interest in the sound operation of the Clearing House. As a result, the amendments are consistent with the requirements of Section 17A(b)(3)(F) of the Act.[10]

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed amendments would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed amendments to the Finance Procedures are intended to reduce the number of cash flows, improve payment efficiency and to reduce the (low) risk of payment failure with respect to transaction fees, by changing the interest payment date to be consistent to that of the transaction fee payment date. The amendments would not otherwise change the rights or obligations of market participants. ICE Clear Europe does not believe the amendments would adversely affect competition among Clearing Members, materially affect the cost of clearing, adversely affect access to clearing in the new contracts for Clearing Members or their customers, or otherwise adversely affect competition in clearing services. Accordingly, ICE Clear Europe does not believe that the amendments would impose any impact or burden on competition that is not appropriate in furtherance of the purpose of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any comments received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and paragraph (f) of Rule 19b–4 [12] 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

[5] 15 U.S.C. 78q–1.

[6] 15 U.S.C. 78q–1(b)(3)(D).

[7] 15 U.S.C. 78q–1(b)(3)(D).

[8] 15 U.S.C. 78q–1(b)(3)(F).

[9] 15 U.S.C. 78q–1(b)(3)(F).

[10] 15 U.S.C. 78q–1(b)(3)(F).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f).

it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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–ICEEU–2022–026 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–ICEEU–2022–026. 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 filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/regulation.*

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–ICEEU–2022–026 and should be submitted on or before January 11, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Sherry R. Haywood,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96502; File No. SR–BOX–2022–31]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend IM–8050–3 To Establish Functionality That Will Reject Market Maker Quotes When Those Quotes Would Otherwise Lock or Cross the National Best Bid or Offer

December 15, 2022.

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 December 6, 2022, BOX Exchange LLC (''BOX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II, below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend IM–8050–3 to establish functionality that will reject Market Maker [3] quotes when those quotes would otherwise lock or cross the National Best Bid or Offer (''NBBO'').[4] The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at *https://rules.boxexchange.com/rulefilings.*

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 these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend Rule IM–8050–3 to establish functionality that will automatically reject a Market Maker quote that would otherwise lock or cross the NBBO.

Background

Currently, all Market Maker quotes received on BOX after the opening of the market will not execute against a resting order or quote on the BOX Book.[5] However, if there is no BOX Book for a particular option or if the BOX Book is inferior to the NBBO, a Market Maker quote could display at a price that locks or crosses the NBBO.[6] This proposal is designed to prevent such occurrences. The following examples demonstrate the current functionality and interaction of Market Maker quotes, defined as a bid and offer, with the BOX Book depending on whether the BOX Book is on the NBBO:

Example 1: Assume that the BOX Book in an option is $1.00 bid and offered at $1.10, hereinafter expressed as 1.00/1.10, and the NBBO is 1.00/1.10. A Market Maker quote of 1.10/1.20 would remove liquidity from the BOX

[13] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Market Makers make markets in options contracts traded on the Exchange and are vested with the rights and responsibilities specified in the BOX Rule 8000 Series. *See* BOX Rule 100(a)(31).

[4] NBBO is defined as the national best bid or offer. *See* BOX Rule 100(a)(34).

[5] *See* BOX Rule IM–8050–3(a).

[6] BOX Exchange has policies and procedures in place to ensure Participant compliance with Rule 15020 (Locked and Crossed Markets). Rule 15020 provides that, absent an exception, Participants shall reasonably avoid displaying, and shall not engage in a pattern or practice of displaying, any Quotations that lock or cross a Protected Quotation. BOX Exchange surveils for instances where a BOX Participant, including a Market Maker, displays a quotation which locks or crosses the NBBO without taking corrective action in a timely manner. Additionally, violations of Rule 15020 are subject to disciplinary action as detailed in the Exchange's minor rule violation plan (''MRVP''). *See* Rule 12140(d)(12).

Book [7] because the Market Maker's 1.10 bid equals the BOX Book offer at 1.10. Each side of the quote is evaluated separately to determine whether it will be accepted or rejected. As a result, the 1.10 bid will be rejected and a message will be sent to the Market Maker indicating that their bid was rejected. The Market Maker's offer will be accepted.

Example 2: Assume the BOX Book in an option is 1.00/1.20, the NBBO is 1.00/1.10, and a Market Maker sends a quote of 1.10/1.20. In this case, the BOX Book is inferior to NBBO on the offer. The Market Maker's bid of 1.10 would not execute against the BOX Book, therefore it would be displayed in the BOX Book and would be disseminated to the Options Price Reporting Authority (''OPRA''). In this example, the Market Maker's bid and offer will be accepted even though the bid of 1.10 would lock the NBO [8] of 1.10.

Proposal

The Exchange proposes to add functionality that will reject a Market Maker quote that would otherwise lock or cross the NBBO. Referring to Example 2 above, under the current functionality, a Market Maker quote of 1.10/1.20, when displayed in the BOX Book and disseminated to OPRA, would lock the NBO because the Market Maker's bid of 1.10 equals the NBO of 1.10. Under this proposal, the 1.10 bid will be instead rejected and a message will be sent to the Market Maker indicating that their bid was rejected. Illustrated further, assume that the BOX Book in an option is 1.00/1.20 and the NBBO is 1.10/1.20. A Market Maker quote of 1.00/1.10 would lock the NBB [9] because the Market Maker's offer of 1.10 equals the NBB of 1.10. Under this proposal, the 1.10 offer will be rejected and a message will be sent to the Market Maker indicating that their offer was rejected.

The Exchange notes that BOX Market Makers requested this functionality to: (1) avoid inadvertently locking or crossing the NBBO; [10] and (2) to give themselves the opportunity to re-evaluate their quoting in the event they are submitting quotes to BOX that are locking or crossing the NBBO. Additionally, the Exchange is seeking to address an inconsistency between quote and order handling when the quote or order would lock or cross the NBBO. Currently, pursuant to Rule 7130(b) *Filtering of BOX In-Bound Orders,* orders will not, in the case of a sell order, execute at a price below the NBB or, in the case of a buy order, execute at a price above the NBO.[11] The proposal discussed herein will produce the same result for quotes on BOX. The Exchange believes that rejecting quotes that would otherwise lock or cross the NBBO is beneficial because it will avoid the display of any quotations that would lock or cross a Protected Quotation.[12]

The Exchange notes that it is not proposing to change the interaction of an incoming quote with a PIP Order [13] as incoming quotes may interact with the PIP before being rejected.[14] Under the proposal, the incoming quote will continue to cause the PIP to end early if the conditions of Rule 7150(i) [15] exist. Specifically, under the current functionality, after the PIP is concluded, if the incoming quote would execute against resting orders or quotes on the BOX Book, the relevant side will continue to be rejected.[16] Further, under the proposed functionality, if the incoming quote would lock or cross the BOX Book or the NBBO,[17] the relevant side will be rejected. Additionally, when an incoming quote on the opposite side of the PIP Order is received such that it would cause an execution to occur prior to the end of the PIP, the incoming quote shall be immediately executed pursuant to Rule 7150(j). In order for the incoming quote on the opposite side of the PIP Order to execute against the PIP Order, the conditions of Rule 7150(j) must be met.[18] Under this proposal, any remaining balance of the incoming quote that did not execute against the PIP Order, and that would execute against a resting order or quote on the BOX Book or that would lock or cross the NBBO, will be rejected. The following examples demonstrate interaction between incoming quotes and a PIP Order both currently and under the proposal:

Example 1: Incoming Quote Trades against PIP Order

[7] However, such a quote may execute in a PIP auction before rejection. *See* BOX Rule IM–8050–3(b)(2). Pursuant to current Rule 7150(j), when an incoming quote on the opposite side of the PIP Order is received such that it would cause an execution to occur prior to the end of the PIP, the incoming quote shall be immediately executed.

[8] NBO is the national best offer. *See* BOX Rule 100(a)(34).

[9] NBB is the national best bid. *See* BOX Rule 100(a)(34).

[10] BOX Rule 15020(a) Locked and Crossed Markets provides that Options Participants shall reasonably avoid displaying, and shall not engage in a pattern or practice of displaying, any Quotations that lock or cross a Protected Quotation with some exceptions noted in BOX Rule 15020(b).

[11] *See* BOX Rule 7130(b)(1). The filter will determine if the order is executable against the NBBO (an order is deemed ''executable against the NBBO'' when, in the case of an order to sell(buy), its limit price is equal to or lower(higher) than the best bid(offer) across all options exchanges. By definition, a Market Order is executable against the NBBO). If the order is not executable against the NBBO, the order will be placed on the BOX Book. If the order is executable against the NBBO, the filter will determine whether there is a quote on BOX that is equal to the NBBO. If there is a quote on BOX that is equal to the NBBO, then the order will be executed against the relevant quote. Any remaining quantity of the order is exposed on the BOX Book at the NBBO for a time period established by the Exchange, not to exceed one second. At the end of the exposure period, any unexecuted quantity will be handled by the Trading Host in the following manner: (i) If the best BOX price is now equal to the NBBO, the remaining unexecuted quantity will be placed on the BOX Book and immediately executed against that quote. Any remaining quantity will be (i) in the case of Public Customer Eligible Orders, routed to one or more Away Exchanges displaying the NBBO, or (ii) in the case of market maker or proprietary broker-dealer orders, returned to the submitting Options Participant. *See* BOX Rule 7130(b)(3).

[12] A Protected Bid or Protected Offer means a Bid or Offer in an option series, respectively, that is disseminated pursuant to the OPRA Plan; and is the Best Bid or Best Offer, respectively, displayed by an Eligible Exchange. *See* BOX Rule 15000(o). A Quotation means a Bid or Offer. *See* BOX Rule 15000(q).

[13] PIP Orders are customer orders designated for the PIP. *See* BOX Rule 7150(f).

[14] *See* BOX Rule IM–8050–3(b).

[15] Specifically, Rule 7150(i) provides that in cases where an Unrelated Order is submitted to BOX on the same side as the PIP Order, or a Legging Order is generated during the PIP on the BOX Book on the same side as the PIP Order, such that either would cause an execution to occur prior to the end of the PIP, the PIP shall be deemed concluded and the PIP Order shall be matched pursuant to 7150(g). Specifically, the submission to BOX of a Market Order on the same side as a PIP Order will prematurely terminate the PIP when, at the time of the submission of the Market Order, the best Improvement Order is equal to or better than the NBBO on the same side of the market as the best Improvement Order. The submission to BOX of an executable Limit Order or generation of an executable Legging Order on the same side as a PIP Order will prematurely terminate the PIP if at the time of submission: (1) the Buy (Sell) Limit Order or Legging Order price is equal to or higher (lower) than the National Best Offer (Bid) and either: (i) the BOX Best Offer (Bid) is equal to the National Best Offer (Bid); or (ii) the BOX Best Offer (Bid) is higher (lower) than the National Best Offer (Bid) and the price of the best Improvement Order is equal to or lower (higher) than the National Best Offer (Bid); or (2) the Buy (Sell) Limit Order or Legging Order price is lower (higher) than the National Best Offer (Bid) and its limit price equals or crosses the price of the best Improvement Order. Following the execution of the PIP Order, any remaining Improvement Orders are cancelled and the Market Order or Limit Order is filtered pursuant to Rule 7130(b).

[16] *See* BOX Rule IM–8050–3(a).

[17] *See* proposed Rule IM–8050–3(a)(1).

[18] Specifically, Rule 7150(j) states that a Market Order on the opposite side of a PIP Order will immediately execute against the PIP Order when, at the time of the submission of the Market Order, the best Improvement Order does not cross the NBBO on the same side of the market as the PIP Order. The submission of an executable Limit Order or generation of an executable Legging Order on the opposite side of a PIP Order will immediately execute against a PIP Order when the Sell (Buy) Limit Order price is equal to or crosses the National Best Bid (Offer), and: (1) the BOX Best Bid (Offer) is equal to the National Best Bid (Offer); or (2) the BOX Best Bid (Offer) is lower (higher) than the National Best Bid (Offer) and neither the best Improvement Order nor BOX Best Offer (Bid) is equal to or crosses the National Best Bid (Offer).

BOX BBO: 2.03 bid and 2.10 offer
NBBO: 2.03 bid and 2.10 offer
PIP Order: Buy 5 contracts for 2.05
Incoming Quote: Sell 10 contracts at 2.03

The incoming quote will execute 5 contracts against the PIP Order. In this case, the best BOX price on the opposite side of the market from the quote is 2.03, the NBB is 2.03, and the order will execute one penny better than the NBBO at 2.04 because the best BOX price on the opposite side of the market from the quote is equal to the NBBO.[19] The PIP will then be terminated because the PIP Order was filled and the remaining 5 contracts of the incoming quote that would lock the NBB will be rejected. The Exchange notes that this quote would also be rejected because it would remove liquidity from the BOX Book.[20]

Example 2: Incoming Quote Terminates PIP
BOX BBO: 2.00 bid and 2.06 offer
NBBO: 2.00 bid and 2.06 offer
PIP Order: Buy 5 contracts for 2.05
Incoming Quote: Buy 10 contracts for 2.06

The incoming quote would lock the NBO and will be rejected. The quote submitted to BOX will not interact with the PIP Order because it is on the same side as the PIP Order, such that it would cause an execution to occur prior to the end of the PIP, in which case the PIP will terminate and the PIP Order will be matched.[21] The Exchange notes that this quote would also be rejected because it would remove liquidity from the BOX Book.[22]

Lastly, the Exchange notes that as is the case today, rejected quotes will not be considered when determining a Market Maker's quoting obligations.[23]

Other options exchanges provide functionality similar to the proposed changes discussed herein. Specifically, in the situation where an incoming quote would lock or cross the NBBO, other exchanges adjust quote prices to one minimum price variation (''MPV'') below the NBO for bids and one MPV above the NBB for offers.[24] Similar to this proposal, other exchanges offer market makers a choice between having their quote rejected or repriced.[25] For simplicity, the Exchange is proposing to reject quotes that would otherwise lock or cross the NBBO, which would allow Market Makers the opportunity to reevaluate, reprice, and resend quotes to BOX. The Exchange believes that rejecting Market Maker quotes is simpler for both BOX and BOX Market Makers because a quote sent to BOX is either added to the BOX Book or rejected. This results in no uncertainty regarding the price. Further, the Exchange chose not to add functionality that would reprice a quote that would otherwise lock or cross the NBBO so the respective Market Makers have the opportunity to resubmit their quote to BOX at a price of their choosing. Thus, the Exchange believes that the proposed change may provide Market Makers with greater control over their quotes and may encourage Market Makers to provide greater liquidity to BOX given this flexibility.

BOX plans to provide this functionality during the fourth calendar quarter of 2022. The Exchange will distribute an Informational Circular to Participants prior to implementation of this functionality.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act,[26] in general, and Section 6(b)(5) of the Act,[27] in particular, in that it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general protect investors and the public interest. The Exchange believes that rejecting Market Maker quotes that would otherwise lock or cross the NBBO may provide Maker Makers with greater control over their quotes on BOX because a quote sent to BOX is either added to the BOX Book or rejected. As discussed above, this results in no uncertainty regarding the price. Further, the Exchange chose not to add functionality that would reprice a quote that would otherwise lock or cross the NBBO so the respective Market Maker has the opportunity to resubmit their quote to BOX at a price of their choosing. The Exchange believes this change will assist Market Makers in reducing their regulatory risk, maintaining a fair and orderly market, and in quoting with greater confidence which may lead Market Makers to quote with larger sizes or tighter bid to offer spreads on BOX, that could then benefit all BOX Participants, increasing price discovery, and potentially increasing trading activity.

The Exchange also believes the proposed functionality will also provide Market Makers with protection from inadvertently submitting quotes that lock or cross the NBBO[28] and from trading on those quotes, thus promoting the policy goals of the Commission that has encouraged execution venues, exchanges, and non-exchanges alike, to enhance risk protection tools and other mechanisms to decrease regulatory risk and increase stability. Additionally, the benefits of enhanced risk protections and other mechanisms to decrease risk may flow downstream to counterparties both within and away from the Exchange, thereby increasing systemic protections as well.

The Exchange notes further, a Market Maker that produces erroneous quotes causing displayed markets to lock or cross the NBBO may cause erroneous trading activity and disrupt markets. The Exchange believes that rejecting Market Maker quotes that would otherwise lock or cross the NBBO will reduce the likelihood of BOX displaying quotes that lock or cross the NBBO, which is consistent with the Options Order Protection and Locked/Crossed Market Plan (''the Plan'').[29] The Exchange notes that as a party to the Plan, the Exchange has agreed to comply with, and enforce compliance by BOX Options Participants, which includes avoidance of Trade-Throughs and prohibition against a pattern or practice of displaying any quotations that lock or cross a Protected Quotation.[30] This proposal is designed

[19] *See* BOX Rule 7150(j).

[20] *See* BOX Rule IM–8050–3(a).

[21] The PIP shall be deemed concluded pursuant to BOX Rule 7150(i) and the PIP Order will be matched pursuant to Rule 7150(g).

[22] *See* BOX Rule IM–8050–3(a).

[23] On a daily basis, a Market Maker must, during regular market hours, make markets and enter into any resulting transactions consistent with the applicable quoting requirements, such that on a daily basis a Market Maker must post valid quotes at least sixty percent (60%) of the time that the classes are open for trading. These obligations apply to all of the Market Maker's appointed classes collectively, rather than on a class-by-class basis. *See* Rule 8050(e). *See also* Rule 8040.

[24] *See* Miami International Securities Exchange, LLC Rules 514(f)(1)(i) and 515(d) *and* MIAX Emerald, LLC Rules 514(f)(1)(i) and 515(d) (repricing quotes continuously until the Market Maker quote reaches its original limit price, is fully executed or cancelled). *See also* Nasdaq Stock Market LLC Rules Options 3, Section 4(b)(6) and Section 15(c)(3) *and* Nasdaq BX, Inc. Rules Options 3, Section 4(b)(6) and Section 15(c)(3).

[25] *See* Nasdaq ISE, LLC Rule Options 3, Section 4(b)(6) *and* Nasdaq GEMX, LLC Rule Options 3, Section 4(b)(6) *and* Nasdaq MRX, LLC Rule Options 3, Section 4(b)(6) *and* Cboe EDGX Exchange, Inc. Rule 21.1(l) *and* Cboe C2 Exchange, Inc. Rules 5.32(b)–(c) *and* Cboe Exchange, Inc. Rules 5.32(b)–(c).

[26] 15 U.S.C. 78f(b).

[27] 15 U.S.C. 78f(b)(5).

[28] Except for quotations that fall within the provisions of 15020(b), Options Participants shall reasonably avoid displaying, and shall not engage in a pattern or practice of displaying, any Quotations that lock or cross a Protected Quotation. *See* BOX Rule 15020(a).

[29] *See* BOX Rule 15020.

[30] *See* BOX Rule 15010.

to aid the Exchange in enforcing such compliance.

Lastly, the Exchange again notes that the proposed changes have no impact on the interaction of an incoming quote with a PIP Order and have no impact on a Market Maker's obligations pursuant to current BOX Rules 8040 and 8050. Market Makers will continue to be subject to the obligations detailed in these rules.

As such, the Exchange believes the proposed rule change is in the public interest, and therefore, consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Market Makers are required to provide continuous two-sided quotes on a daily basis and are subject to various obligations associated with providing liquidity on BOX. BOX Participants' orders are already provided NBBO protection and either routed (if eligible) or rejected immediately.[31] The proposed change would afford quotes a similar level of protection to assist Market Makers in managing their unique risks and obligations. Further, the proposed change will not impose any burden on intramarket competition as the proposed change will apply to all Market Makers on BOX. Lastly, the Exchange again notes that Market Makers have requested that BOX implement the proposed protections.

The Exchange believes that the proposed change will not impose any burden on intermarket competition as other exchanges offer similar functionality.[32] Further, the proposed change may encourage intermarket competition by improving compliance with the Plan, which includes avoidance of Trade-Throughs and prohibition against a pattern or practice of displaying any quotations that lock or cross a Protected Quotation. As such, the Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[33] and Rule 19b–4(f)(6) thereunder.[34]

A proposed rule change filed under Rule 19b–4(f)(6)[35] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[36] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Waiver of the operative delay would allow the Exchange to immediately offer the functionality that will reject Market Maker quotes when those quotes would otherwise lock or cross the NBBO, which is consistent with the Options Order Protection and Locked/Crossed Market Plan. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[37]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–BOX–2022–31 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–BOX–2022–31. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All

[31] *See* BOX Rule 7130(b).

[32] *See supra,* notes 24, 25.

[33] 15 U.S.C. 78s(b)(3)(A).

[34] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[35] 17 CFR 240.19b–4(f)(6).

[36] 17 CFR 240.19b–4(f)(6)(iii).

[37] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

submissions should refer to File Number SR–BOX–2022–31 and should be submitted on or before January 11, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[38]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–27649 Filed 12–20–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96505; File No. SR–PEARL–2022–47]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Withdrawal of Proposed Rule Change To Amend the MIAX PEARL Options Fee Schedule To Remove a Monthly Credit Associated With Trading Permit Fees

December 15, 2022.

On November 2, 2022, MIAX PEARL, LLC (''MIAX Pearl'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 [1] and Rule 19b–4 thereunder,[2] a proposed rule change to remove a monthly credit associated with trading permit fees. The proposed rule change was published for comment in the **Federal Register** on November 14, 2022.[3]

On December 14, 2022, MIAX Pearl withdrew the proposed rule change (SR–PEARL–2022–47).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[4]

Sherry R. Haywood,

Assistant Secretary.

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[38] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 96249 (November 7, 2022), 87 FR 68217.

[4] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96513; File No. SR–NSCC–2022–802]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing of Advance Notice Related to Certain Enhancements to the Gap Risk Measure and the VaR Charge

December 15, 2022.

Pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 (''Clearing Supervision Act'') [1] and Rule 19b–4(n)(1)(i) under the Securities Exchange Act of 1934 (''Act''),[2] notice is hereby given that on December 2, 2022, National Securities Clearing Corporation (''NSCC'') filed with the Securities and Exchange Commission (''Commission'') the advance notice as described in Items I, II and III below, which Items have been prepared by the clearing agency.[3] The Commission is publishing this notice to solicit comments on the advance notice from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Advance Notice

This advance notice consists of modifications to NSCC's Rules & Procedures (''Rules'') [4] in order to enhance the calculation of the volatility component of the Clearing Fund formula that utilizes a parametric Value-at-Risk (''VaR'') model (''VaR Charge'') by (1) making the result of the gap risk measure (''Gap Risk Measure'') calculation an additive component of the VaR Charge when it is applicable, rather than being applied as the applicable VaR Charge when it is the largest of three separate calculations, (2) modifying the language relating to which ETF (as defined below) positions are excluded from the Gap Risk Measure, (3) adjusting both the trigger for applying the Gap Risk Measure and the calculation of the Gap Risk Measure to be based on the two largest positions in a portfolio, rather than based on the single largest position, (4)(a) removing the description of the methodology in the Rules for calculating the gap risk haircut, (b) providing that, like the concentration threshold, gap risk haircuts would be calibrated from time to time based on backtesting and impact analysis and (c) changing the floor of the gap risk haircut from 10 percent to 5 percent for the largest position and adding a floor of the gap risk haircut of 2.5 percent for the second largest position subject to the Gap Risk Measure and (5) making certain clarifications to the description of Gap Risk Measure, as described in greater detail below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Advance Notice

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the advance notice and discussed any comments it received on the advance notice. 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 and B below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement on Comments on the Advance Notice Received From Members, Participants, or Others

NSCC has not received or solicited any written comments relating to this proposal. NSCC will notify the Securities and Exchange Commission (''Commission'') of any written comments received by NSCC.

(B) Advance Notice Filed Pursuant to Section 806(e) of the Clearing Supervision Act

Description of Proposed Changes

NSCC is proposing to enhance the calculation of the VaR Charge by (1) making the result of the Gap Risk Measure calculation an additive component of the VaR Charge when it is applicable, rather than being applied as the applicable VaR Charge when it is the largest of three separate calculations, (2) modifying the language relating to which ETF positions are excluded from the Gap Risk Measure, (3) adjusting both the trigger for applying the Gap Risk Measure and the calculation of the Gap Risk Measure to be based on the two largest positions in a portfolio, rather than based on the single largest position, (4)(a) removing the description of the methodology in the Rules for calculating the gap risk haircut, (b) providing that, like the concentration threshold, gap risk haircuts would be

[1] 12 U.S.C. 5465(e)(1).

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] NSCC filed this advance notice as a proposed rule change (SR–NSCC–2022–015) with the Commission pursuant to Section 19(b)(1) of the Act, 15 U.S.C. 78s(b)(1), and Rule 19b–4 thereunder, 17 CFR 240.19b–4. A copy of the proposed rule change is *available at https://www.dtcc.com/legal/sec-rule-filings.aspx.*

[4] Capitalized terms not defined herein are defined in the Rules, *available at https://dtcc.com/~/media/Files/Downloads/legal/rules/nscc_rules.pdf.*

calibrated from time to time based on backtesting and impact analysis and (c) changing the floor of the gap risk haircut from 10 percent to 5 percent for the largest position and adding a floor of the gap risk haircut of 2.5 percent for the second largest position subject to the Gap Risk Measure and (5) making certain clarifications to the description of Gap Risk Measure, as described in greater detail below.

The proposed changes would enhance the flexibility of the Gap Risk Measure to broaden the scope of gap risk event coverage and result in more frequent gap risk charges. NSCC conducted an impact study for the period January 1, 2021 through December 31, 2021 (''Impact Study'') which reviewed the overall impact of the proposed changes on the VaR Charge amounts, the Clearing Fund amounts (at the NSCC level and Member level) and the effect on the Members during the Impact Study period. The Impact Study looked at the impacts during the Impact Study period as if all of the proposed changes had been made and did not look at the impacts of each of the proposed changes individually. The Impact Study indicated that the proposed changes would have resulted in a 10.66% increase for the daily total VaR Charge on average and would have resulted in a 4.04% increase in the daily total Clearing Fund on average during that period.

The three Members with the largest average daily VaR Charge increases in dollar amount during the Impact Study period would have had increases of $60,113,514, $30,054,385 and $22,237,892 representing an average daily increase for such Members of 31.68%, 14.97% and 28.11%, respectively. The three Members with the largest average daily VaR Charge increases as a percentage of production Clearing Fund paid by such Members during the Impact Study period would have had an average daily increase of 31.78%, 29.07% and 28.99%, respectively, had the proposed changes been in place. Approximately 14% of Members would have had either a decrease or an increase of less than 1% in their average daily VaR Charge had the proposed changes been in place.

Prior to implementation of the proposed changes, NSCC would conduct Member outreach to discuss the proposed changes and the impact of the proposed changes on the Members. Following implementation, NSCC would also incorporate the proposed changes into the NSCC Risk Client Portal and VaR Calculator.

(i) Overview of the Required Fund Deposit and NSCC's Clearing Fund

As part of its market risk management strategy, NSCC manages its credit exposure to Members by determining the appropriate Required Fund Deposits to the Clearing Fund and monitoring its sufficiency, as provided for in the Rules.[5] The Required Fund Deposit serves as each Member's margin.

The objective of a Member's Required Fund Deposit is to mitigate potential losses to NSCC associated with liquidating a Member's portfolio in the event NSCC ceases to act for that Member (hereinafter referred to as a ''default'').[6] The aggregate of all Members' Required Fund Deposits constitutes the Clearing Fund of NSCC. NSCC would access its Clearing Fund should a defaulting Member's own Required Fund Deposit be insufficient to satisfy losses to NSCC caused by the liquidation of that Member's portfolio.

The volatility component of each Member's Required Fund Deposit is designed to measure market price volatility of the start of day portfolio and is calculated for Members' Net Unsettled Positions and Net Unsettled Balance Order Positions (hereinafter collectively referred to as ''Net Unsettled Positions'').[7] The volatility component is designed to capture the market price risk[8] associated with each Member's portfolio at a 99th percentile level of confidence. NSCC has two methodologies for calculating the volatility component—a ''VaR Charge'' and a haircut-based calculation. The VaR Charge applies to the majority of Net Unsettled Positions and is calculated as the greater of: (1) the larger of two separate calculations that utilize a parametric Value at Risk (''VaR'') model (''Core Parametric Estimation''); (2) the calculation of the Gap Risk Measure, which is based on the concentration threshold of the largest non-index position in a portfolio, as described in greater detail below; and (3) a portfolio margin floor calculation based on the market values of the long and short positions in the portfolio (''Portfolio Margin Floor'').[9] The VaR Charge usually comprises the largest portion of a Member's Required Fund Deposit.

Certain Net Unsettled Positions are excluded from the calculation of the VaR Charge pursuant to Sections I(A)(1)(a)(ii) and I(A)(2)(a)(ii) of Procedure XV and are instead subject to a haircut-based calculation.[10] The charge that is applied to a Member's Required Fund Deposit with respect to the volatility component is referred to as the volatility charge and is the sum of the applicable VaR Charge and the haircut-based calculation.

NSCC regularly assesses the risks it may face as a central counterparty as such risks relate to its margining methodologies to evaluate whether margin levels are commensurate with the particular risk attributes of each relevant product, portfolio and market. In connection with this assessment, NSCC is proposing to enhance the Gap Risk Measure calculation. These proposed enhancements have been developed in response to regulatory feedback and in light of recent market events that led to a reconsideration of the idiosyncratic risks that the Gap Risk Measure is designed to mitigate, as described in greater detail below.

The proposed changes would enhance the calculation of the VaR Charge by making the result of the Gap Risk Measure calculation an additive component of the VaR Charge, rather than being applied as the VaR Charge only when it is the largest of three separate calculations. The proposed changes would modify the language relating to which positions are excluded from the Gap Risk Measure. The proposed changes would also adjust both the trigger for applying the Gap Risk Measure and the calculation of the Gap Risk Measure, when applicable, to be based on the two largest positions in a portfolio, rather than based on the single largest position. The proposed changes would also adjust the calculation and description of the gap risk haircut and make certain other clarifications discussed below.

[5] *See* Rule 4 (Clearing Fund) and Procedure XV (Clearing Fund Formula and Other Matters), *supra* note 4. NSCC's market risk management strategy is designed to comply with Rule 17Ad–22(e)(4) under the Act, where these risks are referred to as ''credit risks.'' 17 CFR 240.17Ad–22(e)(4).

[6] The Rules identify when NSCC may cease to act for a Member and the types of actions NSCC may take. For example, NSCC may suspend a firm's membership with NSCC or prohibit or limit a Member's access to NSCC's services in the event that Member defaults on a financial or other obligation to NSCC. *See* Rule 46 (Restrictions on Access to Services) of the Rules, *supra* note 4.

[7] Net Unsettled Positions refer to net positions that have not yet passed their settlement date or did not settle on their settlement date. *See* Procedure XV (Clearing Fund Formula and Other Matters) of the Rules, *supra* note 4.

[8] Market price risk refers to the risk that volatility in the market causes the price of a security to change between the execution of a trade and settlement of that trade. This risk is also referred to herein as market risk and volatility risk.

[9] Procedure XV, Sections I(A)(1)(a)(i) and I(A)(2)(a)(i) of the Rules, *supra* note 4.

[10] Procedure XV, Sections I(A)(1)(a)(ii) and I(A)(2)(a)(ii) of the Rules, *supra* note 4.

(ii) Overview of Idiosyncratic Risks and the Gap Risk Measure

The Gap Risk Measure was designed to address the risks presented by a portfolio that is more susceptible to the effects of gap risk events due to the idiosyncratic nature of the Net Unsettled Positions in that portfolio (such risks may be referred to as idiosyncratic risks).[11] Gap risk events have been generally understood as idiosyncratic issuer events (for example, earning reports, management changes, merger announcements, insolvency, or other unexpected, issuer-specific events) that cause a rapid shift in general market price volatility levels. The Gap Risk Measure is designed to address the risk that a gap risk event affects the price of a security in which a portfolio holds a Net Unsettled Position that represents more than a certain percent of the entire portfolio's value, such that the event could impact the entire portfolio's value. Currently, the Gap Risk Measure serves as a substitution to the calculation of the Core Parametric Estimation in case the Gap Risk Measure is greater in magnitude.

The risk of large, unexpected price movements, particularly those caused by a gap risk event, are more likely to have a greater impact on portfolios with large Net Unsettled Positions in securities that are susceptible to those events. Generally, index-based exchange-traded funds (''ETFs'') that track closely to diversified indices are less prone to the effects of gap risk events. As such, if the concentration threshold is met, NSCC currently calculates the Gap Risk Measure for Net Unsettled Positions in the portfolio other than positions in ETFs that track diversified indices, as determined by NSCC from time to time (''non-index Net Unsettled Positions'').

The Gap Risk Measure is only applied for a Member if the non-index Net Unsettled Position with the largest absolute market value in the portfolio represents more than a certain percent of the entire portfolio's value (''concentration threshold''). The concentration threshold was initially set at 30 percent of a Member's entire portfolio value.[12] The concentration threshold can be set no higher than 30 percent and is evaluated periodically based on Members' backtesting results over a twelve month look-back period to determine if it may be appropriate to lower the threshold.[13] Currently, the concentration threshold is set at 5%.[14]

When applicable, NSCC calculates the Gap Risk Measure by multiplying the gross market value of the largest non-index Net Unsettled Position in the portfolio by a percent of not less than 10 percent (''gap risk haircut'').[15] Currently, NSCC determines the gap risk haircut empirically as no less than the larger of the 1st and 99th percentiles of three-day returns of a set of CUSIPs that are subject to the VaR Charge pursuant to the Rules, giving equal rank to each to determine which has the highest movement over that three-day period. NSCC uses a look-back period of not less than ten years that includes a one-year stress period. If the one-year stress period overlaps with the look-back period, only the non-overlapping period would be combined with the look-back period. The result is then rounded up to the nearest whole percentage.

NSCC is proposing changes to the calculation of the Gap Risk Measure that are designed to allow NSCC to apply this charge based on more than one position and more frequently. Recent extreme market events, including both the impacts of the COVID–19 pandemic and volatility caused by social media sentiments (referred to as the ''meme stock events''), have led NSCC to reconsider the causes and characteristics of idiosyncratic risks that the Gap Risk Measure was designed to mitigate. More specifically, these events have indicated that price changes due to gap risk events seem to occur more frequently and in higher severity; and may not be isolated to issuer events but driven by new mechanisms that drive concurrent market price moves involving unconventionally correlated securities. The Gap Risk Measure provides an insurance against various permutations of idiosyncratic risk moves, however, it is not targeted to capture and cover all such instances, especially when they are extreme, including certain meme stock events. NSCC believes the proposed enhancements to the Gap Risk Measure calculation, described below, would improve its ability to measure and mitigate against these idiosyncratic risks.

(iii) Proposed Changes To Enhance the Gap Risk Measure and Enhance Transparency

With a goal of enhancing the Gap Risk Measure to broaden the scope of gap risk event coverage, NSCC explored a number of alternatives in particular by (1) using the Gap Risk Measure as an additive component rather than a substitutive component of the VaR Charge and (2) applying the Gap Risk Measure to one or more positions in a portfolio. NSCC also conducted impact studies based on various permutations of the parameters and NSCC is proposing enhancements to the Gap Risk Measure that would improve NSCC's ability to mitigate against idiosyncratic risks as described below. NSCC is also proposing enhancements to the transparency of the Rules by making certain clarifications to the description of the Gap Risk Measure.

NSCC is proposing to make the following enhancements to the Gap Risk Measure: (1) make the Gap Risk Measure an additive component of the Member's total VaR Charge when it is applicable, rather than being applied as the applicable VaR Charge when it is the largest of three separate calculations, (2) modify the language relating to which ETF positions are excluded from the Gap Risk Measure, (3) adjust both the trigger for applying the Gap Risk Measure and the calculation of the Gap Risk Measure to be based on the two largest positions in a portfolio, rather than based on the single largest position, (4)(a) remove the description of the methodology in the Rules for calculating the gap risk haircut, (b) provide that, like the concentration threshold, gap risk haircuts would be calibrated from time to time based on backtesting and impact analysis and (c) change the floor of the gap risk haircut from 10 percent to 5 percent for the largest position and add a floor of the gap risk haircut of 2.5 percent for the second largest position subject to the Gap Risk Measure, and (5) make certain clarifications to the description of the Gap Risk Measure.

Proposed Changes to Application and Calculation of the Gap Risk Measure

First, NSCC is proposing to make the result of the Gap Risk Measure calculation an additive component of Members' total VaR Charge, rather than applicable as the VaR Charge only when it is the highest result of three calculations. Following implementation of this proposed change, the total VaR Charge would be equal to the sum of (1) the greater of (a) the Core Parametric Estimation and (b) the Portfolio Margin

[11] *See* Section I(A)(1)(a)(i)II and I(A)(2)(a)(i)II of Procedure XV of the Rules, *supra* note 4. *See also* Securities Exchange Act Release Nos. 82780 (February 26, 2018), 83 FR 9035 (March 2, 2018) (SR–NSCC–2017–808); 82781 (February 26, 2018), 83 FR 9042 (March 2, 2018) (SR–NSCC–2017–020) (''Initial Filing'').

[12] *See Id.*

[13] *Id.*

[14] See Important Notice a9055, dated September 27, 2021, at *https://www.dtcc.com/-/media/Files/pdf/2021/9/27/a9055.pdf* (notifying Members that the concentration threshold had been changed from 10% to 5%).

[15] *See* Section I(A)(1)(a)(i)II and I(A)(2)(a)(i)II of Procedure XV, *supra* note 4.

Floor calculation; and (2) the Gap Risk Measure calculation. This proposed change would allow NSCC to collect the amount that results from a calculation of the Gap Risk Measure every time the concentration threshold is met which could improve NSCC's ability to mitigate idiosyncratic risks that it could face through the collection of the VaR Charge. Rather than being applied only if the Gap Risk Measure calculation exceeds the Core Parametric Estimation and the Portfolio Margin Floor calculation, the Gap Risk Measure calculation would apply every time the top two positions exceed the concentration threshold. Based on impact studies, NSCC believes this broader application together with the other proposed changes outlined below would better protect against more idiosyncratic risk scenarios than the current methodology.

Second, NSCC is proposing to modify the Rules regarding the ETF positions that are excluded from the Gap Risk Measure calculation. The Rules currently state that only ''non-index'' positions are included in the Gap Risk Measure.[16] NSCC is proposing to replace the reference to ''non-index'' positions with a reference to ''non-diversified'' positions and add a footnote to Sections I(A)(1)(a)(i) and I(A)(2)(a)(i) of Procedure XV of the Rules to state that NSCC would exclude ETF positions from the calculation if the ETFs have characteristics that indicate that such positions are less prone to the effects of gap risk events, as determined by NSCC from time to time. NSCC has determined that certain ETFs, both index based and non-index based, are less prone to the effects of gap risk events as a result of having certain characteristics and, therefore, are less likely to pose idiosyncratic risks that the Gap Risk Measure is designed to mitigate. Such characteristics include whether the ETF tracks to an index that is linked to a broad based market index, contains a diversified underlying basket, is unleveraged or tracks an asset class that is less prone to gap risk. For instance, NSCC has determined to include certain commodity ETFs from the Gap Risk Measure that track to an index but that are not linked to a broad-based diversified commodity index. The proposed change would result in these commodity ETFs that track to an index but that are not linked to a broad-based diversified commodity index to be subject to the Gap Risk Measure whereas they are currently excluded. NSCC has determined to exclude certain non-index based ETFs from the Gap Risk Measure that track to an asset that are less prone to gap risk, such as unleveraged U.S. dollar based ETFs. The proposed change would result in certain non-index based ETFs being excluded from the Gap Risk Measure whereas they are currently included.

NSCC currently identifies those positions that are less likely to pose idiosyncratic risks and excludes those positions from the calculation of the Gap Risk Measure.[17] The proposed change would provide Members with further transparency regarding which positions are excluded from this calculation by reflecting that certain non-index ETFs that have characteristics that indicate that such positions are less prone to the effects of gap risk events would be excluded and by reflecting that index based ETFs would only be excluded if they have characteristics that indicate that such positions are less prone to the effects of gap risk events. NSCC would also indicate in the Rules that such characteristics include whether the ETF tracks to an index that is linked to a broad based market index, contains a diversified underlying basket, is unleveraged or tracks an asset class that is less prone to gap risk.

Third, NSCC is proposing to adjust the trigger of the Gap Risk Measure to be based on the sum of the absolute values of the two largest non-diversified Net Unsettled Positions in a portfolio, rather than based on the absolute value of the single largest non-diversified Net Unsettled Position. More specifically, the Gap Risk Measure would be applicable if the sum of the absolute values of the two largest non-diversified Net Unsettled Positions in the portfolio represents more than the concentration threshold determined by NSCC from time to time.

In addition, the Gap Risk Measure would be calculated using the two largest non-diversified Net Unsettled Positions by multiplying each of the positions with a gap risk haircut and adding the sum of the resulting products. By applying the Gap Risk Measure to the two largest non-diversified positions in the portfolio, the Gap Risk Measure calculation would cover concurrent gap moves involving more than one concentrated position adding more flexibility and coverage to the Gap Risk Measure. The Gap Risk Measure charge for the two largest positions would also provide coverage for gap events for smaller positions in the portfolio.

Fourth, NSCC would be adjusting the calculation of the gap risk haircut and replacing the current description with a description like the description of the calculation for the concentration threshold. Currently, the gap risk haircut is determined by selecting the largest of the 1st and 99th percentiles of three day returns of a composite set of equities, using a look-back period of not less than 10 years that includes a one year stress period.[18] With the current methodology, there is implicit overlapping of the risk covered by the core Parametric VaR and the Gap Risk Measure. Because NSCC would be using the Gap Risk Measure as an additive component to the VaR Charge rather than a substitutive component, NSCC does not believe that the current methodology for the gap risk haircut would result in an appropriate level. Instead of using the current methodology to calculate the gap risk haircut, NSCC would determine and calibrate the concentration threshold and the gap risk haircut from time to time based on backtesting and impact analysis. More specifically, the concentration threshold and the gap risk haircuts would be selected from various combinations of concentration thresholds and gap risk haircuts based on backtesting and impact analysis across all member portfolios initially over a five year look-back period. This would provide more flexibility to set the parameters from time to time to provide improved backtesting performance, broader coverage for idiosyncratic risk scenarios and flexibility for model tuning to balance performance and cost considerations.

In connection with the proposed expansion of the calculation of the Gap Risk Measure to be based on the two largest non-diversified Net Unsettled Positions in the portfolio, NSCC is also proposing to lower the gap risk haircut that would be applied to the largest non-diversified Net Unsettled Position to be a percent that is no less than 5 percent. Currently, the percent that is applied to the largest non-index Net Unsettled Positions in the portfolio is no less than 10 percent.[19] Given the proposed expansion of the calculation of the Gap Risk Measure to cover the two largest non-diversified Net Unsettled Positions, rather than only the single largest non-diversified Net Unsettled Position, NSCC believes it is appropriate to set a lower floor for the gap risk haircut that

[16] *See* Section I(A)(1)(a)(i)II and I(A)(2)(a)(i)II of Procedure XV of the Rules, *supra* note 4. *See also* Initial Filing, *supra* note 11.

[17] NSCC uses a third-party market provider to identify ETFs that meet its defined criteria of being diversified. ETFs that do not meet the criteria specified by NSCC are not included the Gap Risk Measure calculation.

[18] *Id.*

[19] *Id.*

applies to the largest of those two positions. Given that the Gap Risk Measure would be additive rather than a substitutive component of the VaR Charge and would be triggered more frequently, NSCC believes that the flexibility to set a lower floor for the largest position would be appropriate. The gap risk haircut that would be applied to the second largest non-diversified Net Unsettled Position in the portfolio would be no larger than the gap risk haircut that would be applied to the largest non-diversified Net Unsettled Position and would be subject to a floor of 2.5 percent.

Initially, upon implementation, NSCC would set the concentration threshold at 10%, apply a gap risk haircut on the largest Net Unsettled Position of 10% and a gap risk haircut on the second largest Net Unsettled Position of 5%. NSCC would set the concentration threshold and the gap risk haircuts based on backtesting and impact analysis from time to time in accordance with NSCC's model risk management practices and governance set forth in the Model Risk Management Framework (''Model Risk Management Framework'').[20] NSCC's model risk management governance procedures include daily backtesting of model performance, periodic sensitivity analyses of models and annual validation of models. NSCC would review the concentration threshold and the gap risk haircuts at least annually. NSCC would provide notice to Members by important notice of the concentration threshold and gap risk haircuts that it would be applying and changes to the concentration threshold and to the gap risk haircuts.

Therefore, upon implementation, to determine the Gap Risk Measure for each portfolio, NSCC would determine the two largest non-diversified positions in the portfolio. If the sum of the gross market values of those two positions represent more than the concentration threshold of 10% of the gross market value of the portfolio, NSCC would add (i) an amount equal to 10% of the gross market value of the largest position and (ii) an amount equal to 5% of the gross market value of the second largest position. The sum amount would be included in the volatility component of the Required Fund Deposit for that portfolio.

As described in the Initial Filing, the Gap Risk Measure is designed to measure concentration of positions in a portfolio, which is an important indicator of that portfolio's vulnerability to idiosyncratic risks. By expanding the applicability of the Gap Risk Measure to each time the concentration threshold is met, the proposed changes to enhance the calculation of the Gap Risk Measure, described above, would improve the effectiveness of the VaR Charge in mitigating against those risks.

Proposed Changes To Improve Transparency

Fifth, NSCC would make the following clarification changes to improve transparency in the Rules.

NSCC is proposing to remove the specific references to the concentration threshold as 30 percent in the definition to reflect that NSCC may adjust the concentration threshold from time to time, as determined by NSCC based on the backtesting results and impact analysis over a look-back period of no less than the previous 12 months.[21] The Rules currently define the concentration threshold as more than 30 percent of the value of the entire portfolio.[22] The Rules also provide that the concentration threshold would be no more than 30 percent and would be determined by NSCC from time to time.[23] The proposed changes would clarify that the concentration threshold is not fixed at 30 percent by defining concentration threshold as a percentage designated by the Corporation of the value of the entire portfolio which is determined by NSCC from time to time. The Rules would continue to state that the concentration threshold would be no more than 30 percent. NSCC believes this proposed change will help clarify that the concentration threshold could change from time to time but could not be set to be more than 30 percent.

NSCC would revise language relating to the application of the Gap Risk Measure to Securities Financing Transactions (''SFTs''). Rule 56 governs the SFT Clearing Service.[24] Section 12(c) of Rule 56 (''Section 12(c)'') provides that NSCC shall calculate the amount of each SFT Member's required deposit for SFT Positions by applying the Clearing Fund Formula for CNS Transactions set forth in certain sections in Procedure XV.[25] Footnote 1 (''Footnote 1'') in Section 12(c) provides that for purposes of applying the VaR Charge with respect to SFT Positions, NSCC shall apply the Gap Risk Measure as an additive component of the VaR Charge, which is consistent with how Net Unsettled Positions would be treated by the proposed changes.[26] Pursuant to Footnote 1, NSCC has been applying the Gap Risk Measure as an additive component of the VaR Charge with respect to SFT Positions but applying the Gap Risk Measure to other Net Unsettled Positions as a substitutive component as currently set forth in Procedure XV of the Rules. If the proposed changes contemplated by this filing were implemented, it would be unnecessary to distinguish how the Gap Risk Measure is calculated for SFT Positions because the Gap Risk Measure would be applied to SFT Positions in the same manner as it would be applied to other Net Unsettled Positions. As a result, NSCC is proposing to remove Footnote 1.

NSCC is also proposing to change the reference from ''positions'' to ''Net Unsettled Positions'' or ''Net Balance Order Unsettled Positions'', as applicable, to clarify that the positions subject to the Gap Risk Measure are Net Unsettled Positions. NSCC would also remove ''the portfolio's'' from the provision relating to how the concentration threshold and gap risk haircuts would be determined and calibrated because the reference is unnecessary. The same concentration threshold and gap risk haircuts would apply to all portfolios and would be calibrated based on backtesting and impact analysis of multiple portfolios. In addition, in accordance with the Model Risk Management Framework,[27] NSCC conducts periodic impact analysis of its models, including impacts on NSCC and impacts on Members. As such, NSCC is proposing to include ''impact analysis'' in addition to backtesting results as a measure of what NSCC would review to determine and calibrate the concentration threshold and gap risk haircuts. NSCC is also proposing to replace ''would'' with ''shall'' in four places to reflect that it

[20] *See* Securities Exchange Act Release Nos. 81485 (August 25, 2017), 82 FR 41433 (August 31, 2017) (File No. SR–NSCC–2017–008); 84458 (October 19, 2018), 83 FR 53925 (October 25, 2018) (File No. SR–NSCC–2018–009), 88911 (May 20, 2020), 85 FR 31828 (May 27, 2020) (File No. SR–NSCC–2020–008), 92381 (July 13, 2021), 86 FR 38163 (July 19, 2021) (File No. SR–NSCC–2021–008), and 94272 (February 17, 2022), 87 FR 10419 (February 24, 2022) (File No. SR–NSCC–2022–001). The Model Risk Management Framework sets forth the model risk management practices adopted by NSCC.

[21] *Id.*

[22] *See* Section I(A)(1)(a)(i)II and I(A)(2)(a)(i)II of Procedure XV of the Rules, *supra* note 4. *See also* Initial Filing, *supra* note 11.

[23] *Id.*

[24] Rule 56, *supra* note 4.

[25] Section 12(c) of Rule 56, *supra* note 4.

[26] *See* Footnote 1, *supra* note 4, which states ''For the purpose of applying Section I.(A)(1)(a)(i) of Procedure XV (Value-at-Risk (VaR) charge), the volatility of an SFT Member's SFT Positions shall be the sum of (a) the highest resultant value between Section I.(A)(1)(a)(i)I. (Core Parametric Estimation) and Section I.(A)(1)(a)(i)III. (Margin Floor) and (b) the resultant value of Section I.(A)(1)(a)(i)II. (Gap Risk Measure).''

[27] *See* Model Risk Management Framework, *supra* note 20.

is referring to future actions. NSCC would add ''gross market'' in front of ''value'' in two places and replace ''absolute'' with ''gross market'' in two places to clarify that NSCC would be using the gross market value of the positions and the portfolio in the Gap Risk Measure calculations. NSCC would also add a sentence in the Gap Risk Measure sections indicating that NSCC would announce updates of the concentration threshold and gap risk haircuts by Important Notice.

Proposed Changes to NSCC Rules

The proposed changes described above would be implemented by amending the description of the VaR Charge in Sections I(A)(1)(a)(i) and I(A)(2)(a)(i) of Procedure XV of the Rules. The proposed changes would also move the descriptions of the Portfolio Margin Floor and the Gap Risk Measure to Sections I(A)(1)(a)(i)II and I(A)(2)(a)(i)II and Sections I(A)(1)(a)(i)III and I(A)(2)(a)(i)III of Procedure XV, respectively.

The proposed changes would amend the description of the VaR Charge to state that it would be equal to the sum of (1) the highest resultant value among Sections I(A)(1)(a)(i)I and I(A)(2)(a)(i)I (which describe the Core Parametric Estimation) and Sections I(A)(1)(a)(i)II and I(A)(2)(a)(i)II (which would describe the Portfolio Margin Floor); and (2) the resultant value of Sections I(A)(1)(a)(i)III and I(A)(2)(a)(i)III (which would describe the Gap Risk Measure).

The proposed changes would amend the description of the Gap Risk Measure to refer to the two largest non-diversified Net Unsettled Positions in the portfolio, rather than the largest non-index position, as described above, would include a footnote in this description to clarify which positions are excluded from the calculation of the Gap Risk Measure and make the other changes described above in proposed Sections I(A)(1)(a)(i)III and I(A)(2)(a)(i)III.

The proposed changes would also remove Footnote 1 from Rule 56 as described above.

(iv) Implementation Timeframe

NSCC would implement the proposed changes no later than 60 Business Days after the later of the no objection to the advance notice and approval of the proposed rule change [28] by the Commission. NSCC would announce the effective date of the proposed changes by Important Notice posted to its website.

Expected Effect on and Management of Risk

NSCC believes that the proposed changes to enhance the Gap Risk Measure as described above would enable NSCC to better limit its risk exposures to Members arising out of their Net Unsettled Positions.

As stated above, the Gap Risk Measure is designed to limit NSCC's exposures to the risks presented by a portfolios that are more susceptible to the effects of gap risk events due to the idiosyncratic nature of the Net Unsettled Positions in those portfolios. The proposal to enhance the Gap Risk Measure would improve NSCC's ability to measure and mitigate such risks by allowing it to (1) collect the amount that results from a calculation of the Gap Risk Measure every time the concentration threshold is met by making the Gap Risk Measure additive, (2) more accurately determine which ETFs should be included and excluded from the Gap Risk Measure based on characteristics that indicate that such ETFs are more or less prone to the effects of gap risk events, (3) provide more coverage of the Gap Risk Measure by adjusting the Gap Risk Measure trigger and calculation to target the largest two non-diversified Net Unsettled Positions in a portfolio and (4) better calibrate and set appropriate gap risk haircuts and concentration thresholds. The proposed changes would allow NSCC to improve its ability to collect sufficient financial resources to cover the exposure that it may face increased market impact costs in liquidating portfolios that are more susceptible to the effects of gap risk events.

By providing NSCC with a more effective measurement of its exposures, as described above, the proposed change would also mitigate risk for Members because lowering the risk profile for NSCC would in turn lower the risk exposure that Members may have with respect to NSCC in its role as a central counterparty.

Consistency With the Clearing Supervision Act

Although the Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 (''Clearing Supervision Act'') does not specify a standard of review for an advance notice, its stated purpose is instructive: to mitigate systemic risk in the financial system and promote financial stability by, among other things, promoting uniform risk management standards for systemically important financial market utilities and strengthening the liquidity of systemically important financial market utilities.[29]

NSCC believes that the proposal is consistent with the Clearing Supervision Act, specifically with the risk management objectives and principles of Section 805(b), and with certain of the risk management standards adopted by the Commission pursuant to Section 805(a)(2), for the reasons described below.[30]

(i) Consistency With Section 805(b) of the Clearing Supervision Act

For the reasons described below, NSCC believes that the proposed changes in this advance notice are consistent with the objectives and principles of these risk management standards as described in Section 805(b) of the Clearing Supervision Act.[31]

As discussed above, NSCC is proposing to enhance the calculation of the VaR Charge by (1) making the result of the Gap Risk Measure calculation an additive component of the VaR Charge when it is applicable, rather than being applied as the applicable VaR Charge when it is the largest of three separate calculations, (2) modifying the language relating to which ETF positions are excluded from the Gap Risk Measure, (3) adjusting both the trigger for applying the Gap Risk Measure and the calculation of the Gap Risk Measure to be based on the two largest positions in a portfolio, rather than based on the single largest position and (4)(a) removing the description of the methodology in the Rules for calculating the gap risk haircut, (b) providing that, like the concentration threshold, gap risk haircuts would be calibrated from time to time based on backtesting and impact analysis and (c) changing the floor of the gap risk haircut from 10 percent to 5 percent for the largest position and adding a floor of the gap risk haircut of 2.5 percent for the second largest position subject to the Gap Risk Measure (''Gap Risk Measure Enhancements''). The volatility charge is one of the components of its Members' Required Fund Deposits—a key tool that NSCC uses to mitigate potential losses to NSCC associated with liquidating a Member's portfolio in the event of Member default. NSCC believes the proposed changes are consistent

[28] NSCC filed this advance notice as a proposed rule change (File No. SR–NSCC–2022–015) with the Commission pursuant to Section 19(b)(1) of the Act, 15 U.S.C. 78s(b)(1), and Rule 19b–4 thereunder, 17 CFR 240.19b–4. A copy of the proposed rule change is *available at https://www.dtcc.com/legal/sec-rule-filings.aspx.*

[29] *See* 12 U.S.C. 5461(b).

[30] 12 U.S.C. 5464(a)(2) and (b).

[31] 12 U.S.C. 5464(b).

with promoting robust risk management because they are designed to enable NSCC to better limit its exposure to Members in the event of a Member default.

The Gap Risk Measure Enhancements would enable NSCC to better address the potential idiosyncratic risks that it may face when liquidating a portfolio that contains a concentration of positions, such that, in the event of Member default, NSCC's operations would not be disrupted, and non-defaulting Members would not be exposed to losses they cannot anticipate or control. In particular, making the Gap Risk Measure additive would allow NSCC to collect the amount that results from a calculation of the Gap Risk Measure every time the concentration threshold is met which would improve NSCC's ability to mitigate idiosyncratic risks that it could face through the collection of the VaR Charge and better protect against more idiosyncratic risk scenarios than the current methodology. Modifying ETF positions that are subject to the Gap Risk Measure based on whether they are non-diversified rather than whether they are non-index would allow NSCC to more accurately determine which ETFs should be included and excluded from the Gap Risk Measure based on characteristics that indicate that such ETFs are more or less prone to the effects of gap risk events. Adjusting the Gap Risk Measure trigger and calculation to target the largest two non-diversified Net Unsettled Positions in a portfolio would cover concurrent gap moves involving more than one concentrated position providing more coverage of the Gap Risk Measure. Removing specific methodology metrics relating to the gap risk haircuts and adding that gap risk haircuts would be calibrated from time to time based on backtesting and impact analysis, lowering the floor for the gap risk haircut that applies to the largest of the two largest non-diversified Net Unsettled Positions and setting a floor of 2.5 percent for the second largest non-diversified Net Unsettled Positions would allow NSCC to calibrate and set appropriate gap risk haircuts based on the Gap Risk Measure being additive rather than a substitutive component to the VaR Charge.

Furthermore, NSCC believes that the changes proposed in this advance notice are consistent with promoting safety and soundness, which, in turn, is consistent with reducing systemic risks and supporting the stability of the broader financial system, consistent with Section 805(b) of the Clearing Supervision Act.[32] The proposed changes are designed to better limit NSCC's exposures to Members in the event of Member default. As discussed above, the proposed enhancements to Gap Risk Measure are designed to allow NSCC to improve its ability to collect sufficient financial resources to cover the exposure that it may face increased market impact costs in liquidating portfolios that are more susceptible to the effects of gap risk events. The proposed enhancements to the Gap Risk Measure would allow NSCC to collect margin at levels that better reflect the risk presented by these portfolios and would help NSCC limit its exposures to Members.

By better limiting NSCC's exposures to Members in the event of a Member default, the proposed changes are consistent with promoting safety and soundness, which, in turn, is consistent with reducing systemic risks and supporting the stability of the broader financial system.

As a result, NSCC believes the proposal would be consistent with the objectives and principles of Section 805(b) of the Clearing Supervision Act, which specify the promotion of robust risk management, promotion of safety and soundness, reduction of systemic risks and support of the stability of the broader financial system.[33]

(ii) Consistency With Section 805(a)(2) of the Clearing Supervision Act

Section 805(a)(2) of the Clearing Supervision Act authorizes the Commission to prescribe risk management standards for the payment, clearing and settlement activities of designated clearing entities, like NSCC, and financial institutions engaged in designated activities for which the Commission is the supervisory agency or the appropriate financial regulator.[34] The Commission has accordingly adopted risk management standards under Section 805(a)(2) of the Clearing Supervision Act and Section 17A of the Exchange Act (''Covered Clearing Agency Standards'').[35]

The Covered Clearing Agency Standards require registered clearing agencies to establish, implement, maintain, and enforce written policies and procedures that are reasonably designed to meet certain minimum requirements for their operations and risk management practices on an ongoing basis.[36] NSCC believes that the proposed changes are consistent with Rules 17Ad–22(e)(4)(i), (e)(6)(i) and (e)(23)(ii), each promulgated under the Act.[37]

Rule 17Ad–22(e)(4)(i) under the Act requires, in part, that NSCC establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence.[38]

As described above, NSCC believes that the proposed changes would enable it to better identify, measure, monitor, and, through the collection of Members' Required Fund Deposits, manage its credit exposures to Members by maintaining sufficient resources to cover those credit exposures fully with a high degree of confidence. Specifically, NSCC believes that the Gap Risk Measure Enhancements would provide improved backtesting performance, broader coverage for idiosyncratic risk scenarios and flexibility for model tuning to balance performance and cost considerations to Members, and would address the potential increased risks NSCC may face related to its ability to liquidate a portfolio that is susceptible to such risks in the event of a Member default. In particular, making the Gap Risk Measure additive would allow NSCC to collect the amount that results from a calculation of the Gap Risk Measure every time the concentration threshold is met which would improve NSCC's ability to mitigate idiosyncratic risks that it could face through the collection of the VaR Charge and better protect against more idiosyncratic risk scenarios than the current methodology. Modifying ETF positions that are subject to the Gap Risk Measure based on whether they are non-diversified rather than whether they are non-index would allow NSCC to more accurately determine which ETFs should be included and excluded from the Gap Risk Measure based on characteristics that indicate that such ETFs are more or less prone to the effects of gap risk events. Adjusting the Gap Risk Measure trigger and calculation to target the largest two non-diversified Net Unsettled Positions in a portfolio would cover concurrent gap moves involving more than one concentrated position

[32] 12 U.S.C. 5464(b).

[33] *Id.*

[34] 12 U.S.C. 5464(a)(2).

[35] 17 CFR 240.17Ad–22(e).

[36] *Id.*

[37] 17 CFR 240.17Ad–22(e)(4)(i), (e)(6)(i) and (e)(23)(ii).

[38] 17 CFR 240.17Ad–22(e)(4)(i).

providing more coverage of the Gap Risk Measure. Removing specific methodology metrics relating to the gap risk haircuts and adding that gap risk haircuts would be calibrated from time to time based on backtesting and impact analysis, lowering the floor for the gap risk haircut that applies to the largest of the two largest non-diversified Net Unsettled Positions and setting a floor of 2.5 percent for the second largest non-diversified Net Unsettled Positions would allow NSCC to calibrate and set appropriate gap risk haircuts based on the Gap Risk Measure being additive rather than a substitutive component to the VaR Charge. NSCC compared a number of different models for the Gap Risk Measure with different parameters and thresholds, including the Gap Risk Measure Enhancements and determined that the Gap Risk Measure Enhancements improved backtesting performance, provided broader coverage for idiosyncratic risk scenarios and flexibility for model tuning to balance performance and cost considerations to Members.

Therefore, NSCC believes that the proposal would enhance NSCC's ability to effectively identify, measure and monitor its credit exposures and would enhance its ability to maintain sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence. As such, NSCC believes the proposed changes are consistent with Rule 17Ad–22(e)(4)(i) under the Act.[39]

Rule 17Ad–22(e)(6)(i) under the Act requires, in part, that NSCC establish, implement, maintain and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market.[40]

The Required Fund Deposits are made up of risk-based components (as margin) that are calculated and assessed daily to limit NSCC's credit exposures to Members, including the VaR Charge. NSCC's proposed Gap Risk Measure Enhancements are designed to more effectively address the risks presented by a portfolio that meets the concentration threshold and, therefore, is more susceptible to the impacts of idiosyncratic risks. NSCC believes the enhanced VaR Charge, as a result of the Gap Risk Measure Enhancements would enable NSCC to assess a more appropriate level of margin that accounts for these risks. In particular, making the Gap Risk Measure additive would allow NSCC to collect the amount that results from a calculation of the Gap Risk Measure every time the concentration threshold is met which would improve NSCC's ability to mitigate idiosyncratic risks that it could face through the collection of the VaR Charge and better protect against more idiosyncratic risk scenarios than the current methodology. Rather than being applied only if the Gap Risk Measure calculation exceeds the Core Parametric Estimation and the Portfolio Margin Floor calculation, the Gap Risk Measure calculation would apply every time the top two positions exceed the concentration threshold. Based on impact studies, NSCC believes this broader application together with the other proposed changes outlined below would better protect against more idiosyncratic risk scenarios than the current methodology Modifying ETF positions that are subject to the Gap Risk Measure based on whether they are non-diversified rather than whether they are non-index would allow NSCC to more accurately determine which ETFs should be included and excluded from the Gap Risk Measure based on characteristics that indicate that such ETFs are more or less prone to the effects of gap risk events. Adjusting the Gap Risk Measure trigger and calculation to target the largest two non-diversified Net Unsettled Positions in a portfolio would cover concurrent gap moves involving more than one concentrated position providing more coverage of the Gap Risk Measure. Removing specific methodology metrics relating to the gap risk haircuts and adding that gap risk haircuts would be calibrated from time to time based on backtesting and impact analysis, lowering the floor for the gap risk haircut that applies to the largest of the two largest non-diversified Net Unsettled Positions and setting a floor of 2.5 percent for the second largest non-diversified Net Unsettled Positions would allow NSCC to calibrate and set appropriate gap risk haircuts based on the Gap Risk Measure being additive rather than a substitutive component to the VaR Charge. These proposed changes are designed to assist NSCC in maintaining a risk-based margin system that considers, and produces margin levels commensurate with, the risks and particular attributes of portfolios that meet the concentration threshold, as applied through the current methodology. Therefore, NSCC believes the proposed change is consistent with Rule 17Ad–22(e)(6)(i) under the Act.[41]

Rule 17Ad–22(e)(23)(ii) under the Act requires, in part, that NSCC establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in the covered clearing agency.[42] By making the proposed changes to provide transparency to the Rules by (a) removing the references to 30 percent as the concentration threshold to reflect that it is adjusted from time, (b) removing Footnote 1 relating to the application of Gap Risk Measure for SFT Positions from Rule 56, (c) changing the reference from ''positions'' to ''Net Unsettled Positions'' or ''Net Balance Order Unsettled Positions'', as applicable, (d) removing the unnecessary reference to ''the portfolio's'' in reference to backtesting results, (e) including a reference to ''impact analysis'' as a measure of what NSCC would review to determine and calibrate the concentration threshold and gap risk haircuts, (f) replacing ''would'' with ''shall'' in four places, (g) clarifying that the calculations would be referring to the gross market value of the positions and portfolios and (h) adding a sentence indicating that NSCC would announce updates of the concentration threshold and gap risk haircuts by Important Notice, the proposed changes would improve the transparency of the Rules. By providing Members with additional information that would enable them to evaluate the risks and material costs they incur by participating in NSCC, NSCC believes the proposed change is consistent with the requirements of Rule 17Ad–22(e)(23)(ii).[43]

III. Date of Effectiveness of the Advance Notice, and Timing for Commission Action

The proposed change may be implemented if the Commission does not object to the proposed change within 60 days of the later of (i) the date that the proposed change was filed with the Commission or (ii) the date that any additional information requested by the Commission is received. The clearing agency shall not implement the proposed change if the Commission has any objection to the proposed change.

The Commission may extend the period for review by an additional 60

[39] *Id.*

[40] 17 CFR 240.17Ad–22(e)(6)(i).

[41] *Id.*

[42] 17 CFR 240.17Ad–22(e)(23)(ii).

[43] *Id.*

days if the proposed change raises novel or complex issues, subject to the Commission providing the clearing agency with prompt written notice of the extension. A proposed change may be implemented in less than 60 days from the date the advance notice is filed, or the date further information requested by the Commission is received, if the Commission notifies the clearing agency in writing that it does not object to the proposed change and authorizes the clearing agency to implement the proposed change on an earlier date, subject to any conditions imposed by the Commission.

The clearing agency shall post notice on its website of proposed changes that are implemented.

The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the advance notice is consistent with the Clearing Supervision 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–NSCC–2022–802 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–NSCC–2022–802. 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 advance notice that are filed with the Commission, and all written communications relating to the advance notice 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 NSCC and on DTCC's website (*https://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–NSCC–2022–802 and should be submitted on or before January 11, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[44]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–27658 Filed 12–20–22; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice 11945]

Notice of Receipt of Request From the Government of the Republic of Uzbekistan Under Article 9 of the 1970 UNESCO Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property

SUMMARY: Notice of receipt of request from Uzbekistan for cultural property protection.

FOR FURTHER INFORMATION CONTACT: Anne Compton, Cultural Heritage Center, Bureau of Educational and Cultural Affairs: 202–632–6301; *culprop@state.gov;* include ''Uzbekistan'' in the subject line.

SUPPLEMENTARY INFORMATION: The Government of the Republic of Uzbekistan made a request to the Government of the United States on July 13, 2022, under Article 9 of the 1970 UNESCO *Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property.* Uzbekistan's request seeks U.S. import restrictions on archaeological and ethnological materials representing Uzbekistan's cultural patrimony. The Cultural Heritage Center website provides instructions for public comment and additional information on the request, including categories of material that may be included in import restrictions: *https://eca.state.gov/highlight/cultural-property-advisory-committee-meeting-January-30-February-02-2023.* This notice is published pursuant to authority vested in the Assistant Secretary of State for Educational and Cultural Affairs and pursuant to 19 U.S.C. 2602(f)(1).

Allison Davis,

Executive Director, Cultural Property Advisory Committee, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2022–27735 Filed 12–20–22; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 11947]

Notice of Receipt of Request From the Government of the Republic of North Macedonia Under Article 9 of the 1970 UNESCO Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property

SUMMARY: Notice of receipt of request from North Macedonia for cultural property protection.

FOR FURTHER INFORMATION CONTACT: Chelsea Freeland, Cultural Heritage Center, Bureau of Educational and Cultural Affairs: (202) 714–8403; *culprop@state.gov;* include ''North Macedonia'' in the subject line.

SUPPLEMENTARY INFORMATION: The Government of the Republic of North Macedonia made a request to the Government of the United States on July 29, 2022, under Article 9 of the 1970 UNESCO *Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property.* North Macedonia's request seeks U.S. import restrictions on archaeological and ethnological materials representing North Macedonia's cultural patrimony. The Cultural Heritage Center website provides instructions for public comment and additional information on the request, including categories of material that may be included in import restrictions: *https://eca.state.gov/highlight/cultural-property-advisory-committee-meeting-January-30-February-02-2023.* This notice is published pursuant to authority vested in the Assistant Secretary of State for

[44] 17 CFR 200.30–3(a)(91).

Educational and Cultural Affairs and pursuant to 19 U.S.C. 2602(f)(1).

Allison Davis,

Executive Director, Cultural Property Advisory Committee, Bureau of Educational and Cultural Affairs,Department of State.

[FR Doc. 2022–27737 Filed 12–20–22; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 11946]

Proposal To Extend and Amend Cultural Property Agreement Between the United States and Cambodia

SUMMARY: Proposal to extend and amend the *Memorandum of Understanding Between the Government of the United States of America and the Government of the Kingdom of Cambodia Concerning the Imposition of Import Restrictions on Categories of Archaeological Material of Cambodia.*

FOR FURTHER INFORMATION CONTACT: Anne Compton, Cultural Heritage Center, Bureau of Educational and Cultural Affairs: (202) 377–9783; *culprop@state.gov;* include ''Cambodia'' in the subject line.

SUPPLEMENTARY INFORMATION: Pursuant to the authority vested in the Assistant Secretary of State for Educational and Cultural Affairs, and pursuant to 19 U.S.C. 2602(f)(1), an extension and amendment of the *Memorandum of Understanding Between the Government of the United States of America and the Government of the Kingdom of Cambodia Concerning the Imposition of Import Restrictions on Categories of Archaeological Material of Cambodia* is hereby proposed.

The Government of the Kingdom of Cambodia has requested that the agreement be amended to include additional categories of archaeological and ethnological materials.

A copy of the *Memorandum of Understanding,* the Designated List of categories of material currently restricted from import into the United States, categories of material that may be included in amended import restrictions, and related information can be found at the Cultural Heritage Center website: *http://culturalheritage.state.gov.*

Allison Davis,

Executive Director, Cultural Property Advisory Committee, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2022–27738 Filed 12–20–22; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 11948]

Cultural Property Advisory Committee; Notice of Meeting

SUMMARY: The Department of State announces the location, dates, times, and agenda for the next meeting of the Cultural Property Advisory Committee (''the Committee'').

DATES: The Committee will meet January 30–February 2, from 9 a.m. to 5 p.m. (EST).

ADDRESSES: The Committee will meet at 2201 C Street NW, Washington, DC 20520. The public will participate via videoconference.

Participation: The public may participate in, or observe, the virtual open session on January 30, 2023, from 4 p.m. to 5 p.m. (EST). More information below.

FOR FURTHER INFORMATION CONTACT: Allison Davis, Bureau of Educational and Cultural Affairs—Cultural Heritage Center, (202–702–1166) (*culprop@state.gov*).

SUPPLEMENTARY INFORMATION: The Assistant Secretary of State for Educational and Cultural Affairs calls a hybrid meeting of the Cultural Property Advisory Committee (''the Committee'') in accordance with the Convention on Cultural Property Implementation Act (19 U.S.C. 2601–2613) (''the Act''). A portion of this meeting will be closed to the public pursuant to 5 U.S.C. 552b(c)(9)(B) and 19 U.S.C. 2605(h).

Meeting Agenda: The Committee will review the proposed extension and amendment of an agreement with the Government of the Kingdom of Cambodia, review a request from the Government of the Republic of North Macedonia seeking import restrictions on archaeological and ethnological materials, and review a request from the Government of Uzbekistan seeking import restrictions on archaeological and ethnological materials.

The Open Session: The general public can observe the virtual open session on January 30, 2023. Registered participants may provide oral comments for a maximum of five (5) minutes each. The Department provides specific instructions on how to observe or provide oral comments at the open session at *https://eca.state.gov/highlight/cultural-property-advisory-committee-meeting-January-30-February-02-2023.*

Oral Comments: Register to speak at the open session by sending an email with your name and organizational affiliation, as well as any requests for reasonable accommodation, to *culprop@state.gov* by January 23, 2023. Written comments are not required to make an oral comment during the open session.

Written Comments: The Committee will review written comments if received by 11:59 p.m. (EST) on January 23, 2023. Written comments may be submitted in two ways, depending on whether they contain confidential information:

- *General Comments:* For general comments, use *http://www.regulations.gov,* enter the docket [DOS–2022–0048], and follow the prompts.
- *Confidential Comments:* For comments that contain privileged or confidential information (within the meaning of 19 U.S.C. 2605(i)(1)), please email submissions to *culprop@state.gov.* Include ''Cambodia'', ''North Macedonia'', and/or ''Uzbekistan'' in the subject line.
- *Disclaimer:* The Cultural Heritage Center website contains additional information about each agenda item, including categories of archaeological and ethnological material that may be included in import restrictions: *https://eca.state.gov/highlight/cultural-property-advisory-committee-meeting-January-30-February-02-2023.* Comments should relate specifically to the determinations specified in the Act at 19 U.S.C. 2602(a)(1). Written comments submitted via regulations.gov are not private and are posted at *https://www.regulations.gov.* Because written comments cannot be edited to remove any personally identifying or contact information, we caution against including any such information in an electronic submission without appropriate permission to disclose that information (including trade secrets and commercial or financial information that are privileged or confidential within the meaning of 19 U.S.C. 2605(i)(1)). We request that any party soliciting or aggregating written comments from other persons inform those persons that the Department will not edit their comments to remove any identifying or contact information and that they therefore should not include any such information in their comments that they do not want publicly disclosed.

Allison Davis,

Executive Director, Cultural Property Advisory Committee, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2022–27736 Filed 12–20–22; 8:45 am]

BILLING CODE 4710–05–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Determination of Trade Surplus in Certain Sugar and Syrup Goods and Sugar-Containing Products of Chile, Morocco, Costa Rica, the Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, Peru, Colombia, and Panama

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: In accordance with the Harmonized Tariff Schedule of the United States (HTSUS), the Office of the United States Trade Representative (USTR) is providing notice of its determination of the trade surplus in certain sugar and syrup goods and sugar-containing products of Chile, Morocco, Costa Rica, the Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, Peru, Colombia, and Panama. The level of a country's trade surplus in these goods relates to the quantity of sugar and syrup goods and sugar-containing products for which the United States grants preferential tariff treatment under (i) the United States-Chile Free Trade Agreement (Chile FTA); (ii) the United States-Morocco Free Trade Agreement (Morocco FTA); (iii) the Dominican Republic-Central America-United States Free Trade Agreement (CAFTA–DR); (iv) the United States-Peru Trade Promotion Agreement (Peru TPA); (v) the United States-Colombia Trade Promotion Agreement (Colombia TPA); and (vi) the United States-Panama Trade Promotion Agreement (Panama TPA).

DATES: This notice is applicable on January 1, 2023.

FOR FURTHER INFORMATION CONTACT: Erin H. Nicholson, Office of Agricultural Affairs, (202) 395–9419 or *Erin.H.Nicholson@ustr.eop.gov.*

SUPPLEMENTARY INFORMATION:

I. Chile FTA

Pursuant to section 201 of the United States-Chile Free Trade Agreement Implementation Act (Pub. L. 108–77; 19 U.S.C. 3805 note), Presidential Proclamation No. 7746 of December 30, 2003 (68 FR 75789) implemented the Chile FTA on behalf of the United States and modified the HTSUS to reflect the tariff treatment provided for in the Chile FTA.

Note 3(a) to subchapter XXII of HTSUS chapter 98 requires USTR annually to publish a determination of the amount of Chile's trade surplus, by volume, with all sources for goods in Harmonized System (HS) subheadings 1701.12, 1701.13, 1701.14, 1701.91, 1701.99, 1702.20, 1702.30, 1702.40, 1702.60, 1702.90, 1806.10, 2101.12, 2101.20, and 2106.90, except that Chile's imports of goods classified under HS subheadings 1702.40 and 1702.60 that qualify for preferential tariff treatment under the Chile FTA are not included in the calculation of Chile's trade surplus.

Note 3(b) to subchapter XXII of HTSUS chapter 98 provides duty-free treatment for certain sugar and syrup goods and sugar-containing products of Chile entered under subheading 9822.02.01 in any calendar year (CY) (beginning in CY2016) in the quantity of goods equal to the amount of Chile's trade surplus in subdivision (a) of the note.

During CY2021, the most recent year for which data are available, Chile's imports of the sugar and syrup goods and sugar-containing products described above exceeded its exports of those goods by 685,827 metric tons according to data published by its customs authority, the *Servicio Nacional de Aduana.* Based on these data, USTR has determined that Chile's trade surplus is negative. Therefore, in accordance with U.S. Note 3(b) to subchapter XXII of HTSUS chapter 98, goods of Chile are not eligible to enter the United States duty-free under subheading 9822.02.01 in CY2023.

II. Morocco FTA

Pursuant to section 201 of the United States-Morocco Free Trade Agreement Implementation Act (Pub. L. 108–302; 19 U.S.C. 3805 note), Presidential Proclamation No. 7971 of December 22, 2005 (70 FR 76651) implemented the Morocco FTA on behalf of the United States and modified the HTSUS to reflect the tariff treatment provided for in the Morocco FTA.

Note 6(a) to subchapter XXII of HTSUS chapter 98 requires USTR annually to publish a determination of the amount of Morocco's trade surplus, by volume, with all sources for goods in HS subheadings 1701.12, 1701.13, 1701.14, 1701.91, 1701.99, 1702.40, and 1702.60, except that Morocco's imports of U.S. goods classified under HS subheadings 1702.40 and 1702.60 that qualify for preferential tariff treatment under the Morocco FTA are not included in the calculation of Morocco's trade surplus.

Note 6(b) to subchapter XXII of HTSUS chapter 98 provides duty-free treatment for certain sugar and syrup goods and sugar-containing products of Morocco entered under subheading 9822.03.01 in any CY in the quantity of goods equal to the amount of Morocco's trade surplus in subdivision (a) of the note.

During CY2021, the most recent year for which data are available, Morocco's imports of the sugar and syrup goods and sugar-containing products described above exceeded its exports of those goods by 881,526 metric tons according to data published by its customs authority, *the Office des Changes.* Based on these data, USTR has determined that Morocco's trade surplus is negative. Therefore, in accordance with U.S. Note 6(b) to subchapter XXII of HTSUS chapter 98, goods of Morocco are not eligible to enter the United States duty-free under subheading 9822.03.01 in CY2023.

III. CAFTA–DR

Pursuant to section 201 of the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act (Pub. L. 109–53; 19 U.S.C. 4031), Presidential Proclamation No. 7987 of February 28, 2006 (71 FR 10827), Presidential Proclamation No. 7991 of March 24, 2006 (71 FR 16009), Presidential Proclamation No. 7996 of March 31, 2006 (71 FR 16971), Presidential Proclamation No. 8034 of June 30, 2006 (71 FR 38509), Presidential Proclamation No. 8111 of February 28, 2007 (72 FR 10025), Presidential Proclamation No. 8331 of December 23, 2008 (73 FR 79585), and Presidential Proclamation No. 8536 of June 12, 2010 (75 FR 34311), implemented the CAFTA–DR on behalf of the United States and modified the HTSUS to reflect the tariff treatment provided for in the CAFTA–DR.

Note 25(b)(i) to subchapter XXII of HTSUS chapter 98 requires USTR annually to publish a determination of the amount of each CAFTA–DR country's trade surplus, by volume, with all sources for goods in HS subheadings 1701.12, 1701.13, 1701.14, 1701.91, 1701.99, 1702.40, and 1702.60, except that each CAFTA–DR country's exports to the United States of goods classified under HS subheadings 1701.12, 1701.13, 1701.14, 1701.91, and 1701.99 and its imports of goods classified under HS subheadings 1702.40 and 1702.60 that qualify for preferential tariff treatment under the CAFTA–DR are not included in the calculation of that country's trade surplus.

U.S. Note 25(b)(ii) to subchapter XXII of HTSUS chapter 98 provides duty-free treatment for certain sugar and syrup goods and sugar-containing products of each CAFTA–DR country entered under subheading 9822.05.20 in an amount equal to the lesser of that country's trade surplus or the specific quantity set out in that note for that country and that

CY. In each successive year after CY2021, the aggregate quantity for each country increases, from the aggregate quantity permitted in the prior CY, by the quantity set out in that note.

Costa Rica

During CY2021, the most recent year for which data are available, Costa Rica's exports of the sugar and syrup goods and sugar-containing products described above exceeded its imports of those goods by 136,992 metric tons according to data published by the *Costa Rican Customs Department, Ministry of Finance.* Based on these data, USTR has determined that Costa Rica's trade surplus is 136,992 metric tons. The specific quantity set out in U.S. Note 25(b)(ii) to subchapter XXII of HTSUS chapter 98 for Costa Rica for CY2023 is 14,740 metric tons. Therefore, in accordance with that note, the aggregate quantity of goods of Costa Rica that may be entered duty-free under subheading 9822.05.20 in CY2023 is 14,740 metric tons (*i.e.,* the amount that is the lesser of Costa Rica's trade surplus and the specific quantity set out in that note for Costa Rica for CY2023).

Dominican Republic

During CY2021, the most recent year for which data are available, the Dominican Republic's imports of the sugar and syrup goods and sugar-containing products described above exceeded its exports of those goods by 10,856 metric tons according to data published by the *General Directorate of Customs (DGA).* Based on these data, USTR has determined that the Dominican Republic's trade surplus is negative. Therefore, in accordance with U.S. Note 25(b)(ii) to subchapter XXII of HTSUS chapter 98, goods of the Dominican Republic are not eligible to enter the United States duty-free under subheading 9822.05.20 in CY2023.

El Salvador

During CY2021, the most recent year for which data are available, El Salvador's exports of the sugar and syrup goods and sugar-containing products described above exceeded its imports of those goods by 479,825 metric tons according to data published by the *Central Bank of El Salvador.* Based on these data, USTR has determined that El Salvador's trade surplus is 479,825 metric tons. The specific quantity set out in U.S. Note 25(b)(ii) to subchapter XXII of HTSUS chapter 98 for El Salvador for CY2023 is 38,080 metric tons. Therefore, in accordance with that note, the aggregate quantity of goods of El Salvador that may be entered duty-free under subheading 9822.05.20 in CY2023 is 38,080 metric tons (*i.e.,* the amount that is the lesser of El Salvador's trade surplus and the specific quantity set out in that note for El Salvador for CY2023).

Guatemala

During CY2021, the most recent year for which data are available, Guatemala's exports of the sugar and syrup goods and sugar-containing products described above exceeded its imports of those goods by 1,133,478 metric tons according to data published by the *Guatemalan Sugar Association (ASAZGUA) and Bank of Guatemala.* Based on these data, USTR has determined that Guatemala's trade surplus is 1,133,478 metric tons. The specific quantity set out in U.S. Note 25(b)(ii) to subchapter XXII of HTSUS chapter 98 for Guatemala for CY2023 is 52,640 metric tons. Therefore, in accordance with that note, the aggregate quantity of goods of Guatemala that may be entered duty-free under subheading 9822.05.20 in CY2023 is 52,640 metric tons (*i.e.,* the amount that is the lesser of Guatemala's trade surplus and the specific quantity set out in that note for Guatemala for CY2023).

Honduras

During CY2021, the most recent year for which data are available, Honduras' exports of the sugar and syrup goods and sugar-containing products described above exceeded its imports of those goods by 83,518 metric tons according to data published by the *Central Bank of Honduras.* Based on these data, USTR has determined that Honduras' trade surplus is 83,518 metric tons. The specific quantity set out in U.S. Note 25(b)(ii) to subchapter XXII of HTSUS chapter 98 for Honduras for CY2023 is 10,720 metric tons. Therefore, in accordance with that note, the aggregate quantity of goods of Honduras that may be entered duty-free under subheading 9822.05.20 in CY2023 is 10,720 metric tons (*i.e.,* the amount that is the lesser of Honduras' trade surplus and the specific quantity set out in that note for Honduras for CY2023).

Nicaragua

During CY2021, the most recent year for which data are available, Nicaragua's exports of the sugar and syrup goods and sugar-containing products described above exceeded its imports of those goods by 230,181 metric tons according to data published by the *National Committee of Sugar Producers (CNPA).* Based on these data, USTR has determined that Nicaragua's trade surplus is 230,181 metric tons. The specific quantity set out in U.S. Note 25(b)(ii) to subchapter XXII of HTSUS chapter 98 for Nicaragua for CY2023 is 29,480 metric tons. Therefore, in accordance with that note, the aggregate quantity of goods of Nicaragua that may be entered duty-free under subheading 9822.05.20 in CY2023 is 29,480 metric tons (*i.e.,* the amount that is the lesser of Nicaragua's trade surplus and the specific quantity set out in that note for Nicaragua for CY2023).

IV. Peru TPA

Pursuant to section 201 of the United States-Peru Trade Promotion Agreement Implementation Act (Pub. L. 110–138; 19 U.S.C. 3805 note), Presidential Proclamation No. 8341 of January 16, 2009 (74 FR 4105) implemented the Peru TPA on behalf of the United States and modified the HTSUS to reflect the tariff treatment provided for in the Peru TPA.

Note 28(c) to subchapter XXII of HTSUS chapter 98 requires USTR annually to publish a determination of the amount of Peru's trade surplus, by volume, with all sources for goods in HS subheadings 1701.12, 1701.13, 1701.14, 1701.91, 1701.99, 1702.40, and 1702.60, except that Peru's imports of U.S. goods classified under HS subheadings 1702.40 and 1702.60 that are originating goods under the Peru TPA and Peru's exports to the United States of goods classified under HS subheadings 1701.12, 1701.13, 1701.14, 1701.91, and 1701.99 are not included in the calculation of Peru's trade surplus.

Note 28(d) to subchapter XXII of HTSUS chapter 98 provides duty-free treatment for certain sugar goods of Peru entered under subheading 9822.06.10 in an amount equal to the lesser of Peru's trade surplus or the specific quantity set out in that note for that CY.

During CY2021, the most recent year for which data are available, Peru's imports of the sugar and syrup goods and sugar-containing products described above exceeded its exports of those goods by 193,803 metric tons according to data published by the *National Superintendence of Customs and Tax Administration (SUNAT).* Based on these data, USTR has determined that Peru's trade surplus is negative. Therefore, in accordance with U.S. Note 28(d) to subchapter XXII of HTSUS chapter 98, goods of Peru are not eligible to enter the United States duty-free under subheading 9822.06.10 in CY2023.

V. Colombia TPA

Pursuant to section 201 of the United States-Colombia Trade Promotion Agreement Implementation Act (Pub. L. 112–42; 19 U.S.C. 3805 note),

Presidential Proclamation No. 8818 of May 14, 2012 (77 FR 29519) implemented the Colombia TPA on behalf of the United States and modified the HTSUS to reflect the tariff treatment provided for in the Colombia TPA.

Note 32(b) to subchapter XXII of HTSUS chapter 98 requires USTR annually to publish a determination of the amount of Colombia's trade surplus, by volume, with all sources for goods in HS subheadings 1701.12, 1701.13, 1701.14, 1701.91, 1701.99, 1702.40 and 1702.60, except that Colombia's imports of U.S. goods classified under subheadings 1702.40 and 1702.60 that are originating goods under the Colombia TPA and Colombia's exports to the United States of goods classified under subheadings 1701.12, 1701.13, 1701.14, 1701.91 and 1701.99 are not included in the calculation of Colombia's trade surplus.

Note 32(c)(i) to subchapter XXII of HTSUS chapter 98 provides duty-free treatment for certain sugar goods of Colombia entered under subheading 9822.08.01 in an amount equal to the lesser of Colombia's trade surplus or the specific quantity set out in that note for that CY.

During CY2021, the most recent year for which data are available, Colombia's exports of the sugar and syrup goods and sugar-containing products described above exceeded its imports of those goods by 255,011 metric tons according to data published by the *Colombian National Tax and Customs Directorate (DIAN).* Based on these data, USTR has determined that Colombia's trade surplus is 255,011 metric tons. The specific quantity set out in U.S. Note 32(c)(i) to subchapter XXII of HTSUS chapter 98 for Colombia for CY2023 is 58,250 metric tons. Therefore, in accordance with that note, the aggregate quantity of goods of Colombia that may be entered duty-free under subheading 9822.08.01 in CY2023 is 58,250 metric tons (*i.e.,* the amount that is the lesser of Colombia's trade surplus and the specific quantity set out in that note for Colombia for CY2023).

VI. Panama TPA

Pursuant to section 201 of the United States-Panama Trade Promotion Agreement Implementation Act (Pub. L. 112–43; 19 U.S.C. 3805 note), Presidential Proclamation No. 8894 of October 29, 2012 (77 FR 66505) implemented the Panama TPA on behalf of the United States and modified the HTSUS to reflect the tariff treatment provided for in the Panama TPA.

Note 35(a) to subchapter XXII of HTSUS chapter 98 requires USTR annually to publish a determination of the amount of Panama's trade surplus, by volume, with all sources for goods in HS subheadings 1701.12, 1701.13, 1701.14, 1701.91, 1701.99, 1702.40 and 1702.60, except that Panama's imports of U.S. goods classified under subheadings 1702.40 and 1702.60 that are originating goods under the Panama TPA and Panama's exports to the United States of goods classified under subheadings 1701.12, 1701.13, 1701.14, 1701.91 and 1701.99 are not included in the calculation of Panama's trade surplus.

Note 35(c) to subchapter XXII of HTSUS chapter 98 provides duty-free treatment for certain sugar goods of Panama entered under subheading 9822.09.17 in an amount equal to the lesser of Panama's trade surplus or the specific quantity set out in that note for that CY.

During CY2021, the most recent year for which data are available, Panama's exports of the sugar and syrup goods and sugar-containing products described above exceeded its imports of those goods by 1,141 metric tons according to data published by the *National Institute of Statistics and Census, Office of the General Comptroller of Panama; and the Ministry of Commerce and Industry of Panama.* Based on these data, USTR has determined that Panama's trade surplus is 1,141 metric tons. The specific quantity set out in U.S. Note 35(c) to subchapter XXII of HTS chapter 98 for Panama for CY2023 is 560 metric tons. Therefore, in accordance with that Note, the aggregate quantity of goods of Panama that may be entered duty-free under subheading 9822.09.17 in CY2023 is 560 metric tons (*i.e.,* the amount that is the lesser of Panama's trade surplus and the specific quantity set out in that Note for Panama for CY2023).

Greta Peisch,

General Counsel, Office of the United States Trade Representative.

[FR Doc. 2022–27660 Filed 12–20–22; 8:45 am]

BILLING CODE 3390–F3–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Extensions for Reinstated Product Exclusions: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice.

SUMMARY: In prior **Federal Register** notices, the U.S. Trade Representative modified the actions being taken in the section 301 investigation of China's acts, policies, and practices related to technology transfer, intellectual property, and innovation by excluding certain products from additional duties. The U.S. Trade Representative subsequently extended 549 of these exclusions. In 2022, following public notice and comment, the U.S. Trade Representative determined to reinstate 352 of these exclusions. These reinstated exclusions are scheduled to expire on December 31, 2022. This notice announces the U.S. Trade Representative's determination to extend the reinstated exclusions for an additional nine months.

DATES: The extensions announced in this notice will apply as of January 1, 2023, and will extend through September 30, 2023.

FOR FURTHER INFORMATION CONTACT: For general questions about this notice, contact Associate General Counsel Philip Butler or Assistant General Counsel Edward Marcus at (202) 395–5725. For specific questions on customs classification or implementation of the product exclusions, contact *traderemedy@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

In the course of the investigation into China's acts, policies, and practices related to technology transfer, intellectual property, and innovation, the U.S. Trade Representative imposed additional duties on products of China in four tranches. *See* 83 FR 28710 (June 20, 2018) (the July 6, 2018 action); 83 FR 40823 (August 16, 2018) (the August 23, 2018 action); 83 FR 47974 (September 21, 2018), as modified by 83 FR 49153 (September 28, 2018); and 84 FR 43304 (August 20, 2019), as modified by 84 FR 69447 (December 18, 2019) and 85 FR 3741 (January 22, 2020). Each tranche is commonly known as a 'List', *e.g.,* List 1, List 2, etc. The fourth List was divided into two tranches, Lists 4A and 4B. No tariffs on List 4B are currently in effect.

For each List, the U.S. Trade Representative established a process by which U.S. stakeholders could request the exclusion of particular products subject to the action. The first tranche of exclusions expired in December 2019 and the final tranche of exclusions expired in October 2020. Starting in November 2019, the U.S. Trade Representative established processes for submitting public comments on whether to extend particular exclusions. *See, e.g.,* 85 FR 6687 (February 5, 2019) and 85 FR 38482 (June 26, 2020). Pursuant to these processes, the U.S. Trade

Representative determined to extend 137 exclusions covered under List 1, 59 exclusions covered under List 2, 266 exclusions covered under List 3, and 87 exclusions covered under List 4. With the exception of certain exclusions related to the COVID–19 pandemic, all of these 549 exclusions expired. In particular, the exclusions for most of these products expired by December 31, 2020, and the remaining exclusions expired in 2021. *See* 85 FR 15849 (March 19, 2020) and 85 FR 20332 (April 10, 2020).

On October 8, 2021, the U.S. Trade Representative invited the public to submit comments on whether to reinstate certain exclusions previously granted and extended. 86 FR 56345 (October 8, 2021) (the October 8 notice). The October 8 notice set out factors to be considered in decisions on possible reinstatement, and invited public comment. Those factors included whether, despite the imposition of additional duties beginning in September 2018, the excluded products remain available only from China and whether or not reinstating the exclusions would impact or result in severe economic harm to the commenter or other U.S. interests.

Pursuant to Sections 301(b), 301(c), and 307(a) of the Trade Act of 1974, as amended, on March 28, 2022, the U.S. Trade Representative determined to further modify the action by reinstating 352 of the 549 expired exclusions. The reinstated exclusions applied as of October 12, 2021, and extend through December 31, 2022. *See* 87 FR 17380 (March 28, 2022).

In accordance with Section 307(c)(3) of the Trade Act of 1974, on September 8, 2022, the USTR announced that it would be conducting a review of the July 6, 2018 and August 23, 2018 actions, as modified. *See* 87 FR 26797 (May 5, 2022); 87 FR 55073 (September 8, 2022). Section 307(c) of the Trade Act of 1974 requires the U.S. Trade Representative to conduct a review of: (A) the effectiveness in achieving the objectives of Section 301 of (i) such action, and (ii) other actions that could be taken (including actions against other products or services), and (B) the effects of such actions on the United States economy, including consumers. *See* 19 U.S.C. 2417(c)(3)(A) and (B). In a notice published on October 17, 2022 (87 FR 62914), USTR announced that it was opening a docket on November 15, 2022 (USTR–2022–0014) for interested persons to submit comments with respect to any aspect of Section 307(c) considerations, including whether certain tariff headings should remain covered by the actions.

B. Determination To Extend Exclusions

Based on a continued consideration of the factors and criteria set forth in the October 8 notice, and in light of the ongoing statutory four-year review of the July 6, 2018 and August 23, 2018 actions, the U.S. Trade Representative has determined to extend the 352 reinstated exclusions, as set out in the Annex to this notice. The U.S. Trade Representative's determination to extend the reinstated exclusions takes into account public comments previously submitted in response to the October 8 notice, which indicated that reinstatement of the previously extended exclusions was appropriate based on the unavailability of particular products outside of China, or possible severe economic harm. The determination also takes into account the advice of advisory committees and the advice of the interagency Section 301 Committee.

Extending the reinstated exclusions will allow the U.S. Trade Representative to consider and align, as appropriate, the reinstated exclusions with the results of the statutory four-year review of the July 6, 2018 and August 23, 2018 actions, as modified. *See* 87 FR 62914 (October 17, 2022); 87 FR 55073 (September 8, 2022). Interested persons wishing to submit comments on whether certain tariff headings with a reinstated product exclusion should remain covered by the actions or removed, may submit comments on docket number USTR–2022–0014. Comments must be submitted through the online portal (*https://comments.USTR.gov*) by January 17, 2023 at 11:59 p.m. EST.

The reinstated exclusions are available for any product that meets the description in the product exclusion. In particular, the scope of each exclusion is governed by the scope of the ten-digit Harmonized Tariff Schedule of the United States (HTSUS) statistical reporting numbers and product descriptions in note 20(ttt) to subchapter III of chapter 99 of the HTSUS. The U.S. Trade Representative has determined to extend the reinstated exclusions through September 30, 2023, and may consider further extensions and/or additional modifications as appropriate.

U.S. Customs and Border Protection will issue instructions on entry guidance and implementation.

Annex

The U.S. Trade Representative has determined to extend all exclusions previously reinstated under heading 9903.88.67 and U.S. notes 20(ttt)(i), 20(ttt)(ii), 20(ttt)(iii), and 20(ttt)(iv) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS). *See* 87 FR 17380 (March 28, 2022). The extension is effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern standard time on January 1, 2023, and before 11:59 p.m. eastern daylight time on September 30, 2023. Effective on January 1, 2023, the article description of heading 9903.88.67 of the HTSUS is modified by deleting ''December 31, 2022,'' and by inserting ''September 30, 2023,'' in lieu thereof.

Greta Peisch,

General Counsel, Office of the United States Trade Representative.

[FR Doc. 2022–27637 Filed 12–20–22; 8:45 am]

BILLING CODE 3390–F3–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Approval of LaGuardia Airport (LGA) Noise Compatibility Program

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of approval of the LaGuardia Airport (LGA) noise compatibility program.

SUMMARY: The Federal Aviation Administration (FAA) announces its findings for the noise compatibility program submitted by LGA, see supplementary information for details. On July 6, 2022 the FAA determined that the revised noise exposure maps submitted by LGA were in compliance with applicable requirements and that the noise compatibility program would be initiating final review for approval or disapproval. On December 15, 2022, the FAA approved the LGA noise compatibility program. The noise compatibility program contained 23 recommended measures, including eight noise abatement measures, three land use measures, and 12 program management measures. Of the measures proposed, 14 were approved, five were approved as voluntary, three were disapproved, and one was determined to have no FAA action. Five of the eight noise abatement procedures proposed at LGA are related to new or revised flight procedures.

DATES: The effective date of the FAA's approval of the LGA noise compatibility program is December 15, 2022.

FOR FURTHER INFORMATION CONTACT: Andrew Brooks, Regional

Environmental Program Manager, Airports Division, Federal Aviation Administration, 1 Aviation Plaza, Room 516, Jamaica, NY 11434. Phone Number: 718–553–2511.

SUPPLEMENTARY INFORMATION: This notice announces FAA's approval of the noise compatibility program (NCP) for LGA, effective on December 15, 2022. Per United States Code section 47504 (49 U.S.C. 47504) and Title 14, Code of Federal Regulations (CFR) part 150, an airport sponsor who previously submitted a noise exposure map (NEM) may submit to the FAA a noise compatibility program which sets forth the measures taken or proposed by the airport sponsor for the reduction of existing non-compatible land uses and prevention of additional non-compatible land uses within the area covered by the NEMs. As required by 49 U.S.C. 47504, such programs must be developed in consultation with interested and affected parties including local communities, government agencies, airport users, and the FAA. The FAA does not substitute its judgment for that of the airport sponsor with respect to which measures should be recommended for action. The FAA approval or disapproval of an airports recommendations in their noise compatibility program are made in accordance with the requirements and standards pursuant to 49 U.S.C. 47504 and 14 CFR part 150, which is limited to the following determinations:

a. The noise compatibility program was developed in accordance with the provisions and procedures of 14 CFR 150.23;

b. Program measures are reasonably consistent with achieving the goals of reducing existing non-compatible land uses around the airport and preventing the introduction of additional non-compatible land uses;

c. Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical uses, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal Government; and

d. Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of the navigable airspace and air traffic control systems, or adversely affecting other powers and responsibilities of the Administrator prescribed by law.

Specific limitations of FAA's approval of NCPs are delineated in 14 CFR 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, state, or local law. Approval does not by itself constitute an FAA implementing action. A request for Federal action or approval to implement specific noise compatibility measures may be required, and an FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the noise compatibility program nor a determination that all measures covered by the NCP are eligible for grant-in-aid funding from the FAA. Where federal funding is sought, requests must be submitted to the FAA New York Airports District Office at 1 Aviation Plaza, Room 111, Jamaica, New York 11434.

On June 15, 2022, the Port Authority of New York and New Jersey submitted to the FAA a revised ''With Program'' 2021 NEM, descriptions, and other documentation that were produced during the development of the ''LaGuardia Airport Title 14 Code of Federal Regulations (CFR) Part 150 Noise Compatibility Program,'' dated June 2022. The revised ''With Program'' 2021 NEM was submitted to show changes made to the LaGuardia Airport 2021 NEM previously accepted by the FAA on May 15, 2017 (Noise Exposure Map Notice for LaGuardia Airport, New York City, New York, volume 82, **Federal Register**, pages 22714–5, May 15, 2017). The revisions to the previously approved 2021 NEM depict changes to noise contours from implementation of noise abatement measures contained within the concurrent NCP submittal. It was requested that the FAA review this material as the NEM, as described in 49 U.S.C. 47503 of the Act, and that the noise mitigation measures, to be implemented jointly by the airport and surrounding communities, be approved as a NCP under 49 U.S.C. 47504. Notice of this NEM determination and intent to review the NCP was published in the **Federal Register** on July 11, 2022 (Notice of Acceptance of a Noise Exposure Map and Review of a Noise Compatibility Program, volume 87, **Federal Register**, pages 41160–2, July 11, 2022). That **Federal Register** Notice also announced the start of a 60-day period of public review for the NCP documentation. The FAA received no comments from interested parties during the public review period.

The LGA proposed NCP is comprised of actions designed for phased implementation by airport management and adjacent jurisdictions within the next one to five years. It was requested that the FAA evaluate and approve this material as a noise compatibility program as described in 49 U.S.C. 47504. The FAA began its review of the program on July 6, 2022 and was required by a provision of 49 U.S.C. 47504 to approve or disapprove the program within 180 days, other than the use of new or modified flight procedures for noise control. Failure to approve or disapprove such program within the 180-day period shall be deemed an approval of such program.

The submitted program contained 23 proposed measures to minimize impacts of aviation noise on and off the airport. The FAA completed its review and determined that the procedural and substantive requirements of the 49 U.S.C. 47504 and 14 CFR part 150 were satisfied. A Record of Approval for the overall program was issued by the FAA effective December 15, 2022.

The specific program elements and their individual determinations are as follows:

Noise Abatement (NA) Measure 1: Modify NTHNS and GLDMN Runway 13 RNAV SIDs to Direct Aircraft Away from Flushing, New York—Approved as Voluntary.

NA Measure 2: Create New Runway 13 Departure Procedure with an Immediate Left Turn over Compatible Land Uses—Disapproved.

NA Measure 3: Implement Offset Approach to Runway 22 to Reduce Noise Exposure Over Clason Point—Approved as Voluntary.

NA Measure 4: Reduce Runway 4 Departure Noise Over Clason Point—Approved as Voluntary.

NA Measure 5: Reduce Runway 13 Departures at Night—Approved as Voluntary

NA Measure 6: Implement Noise Abatement Departure Profiles on a Voluntary Basis for Runways 4 and 13—Disapproved for Purposes of Part 150.

NA Measure 7: Implement Nighttime Optimized Profile Descent Procedures—Disapproved for Purposes of Part 150.

NA Measure 8: Continue Existing Mandatory Departure Noise Limit—No Action.

Land Use (LU) Measure 1: Sound-Insulate Eligible Dwelling Units—Approved.

LU Measure 2: Sound-Insulate Eligible Non-Residential Noise—Sensitive Structures- Approved.

LU Measure 3: Include Aircraft Noise in Real Estate Disclosures—Approved.

Program Management (PM) Measure 1: Maintain Noise Office—Approved.

PM Measure 2: Maintain Noise and Operations Management System—Approved.

PM Measure 3: Maintain Public Flight Tracking Portal—Approved.

PM Measure 4: Maintain Noise Complaint Management System—Approved.

PM Measure 5: Maintain Noise Office website—Approved.

PM Measure 6: Continue Community Outreach Activities—Approved.

PM Measure 7: Establish and Manage a Fly Quiet Program—Approved as Voluntary.

PM Measure 8: Make Aircraft Noise Contours Available in a Geographic Information System (GIS)—Approved.

PM Measure 9: Update the Noise Exposure Map—Approved.

PM Measure 10: Update the Noise Compatibility Program—Approved.

PM Measure 11: Post Monthly Color-Coded DNL Values on Port Authority website—Approved.

PM Measure 12: The Port Authority to Coordinate with the FAA on Development and Implementation of NextGen Procedures—Approved.

These determinations are set forth in detail in the Record of Approval signed by the FAA Airports Eastern Division Director on December 15, 2022. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal, are available for review at the FAA office listed above. The Record of Approval also will be available on the internet on the FAA's website at *http://www.faa.gov/airports/environmental/airport_noise/part_150/states/* and the Port Authority of New York and New Jersey's website at *http://panynjpart150.com/LGA_documents.asp.*

Issued in Jamaica, NY, on December 16, 2022.

David A. Fish,

Director, Airports Division, Eastern Region.

[FR Doc. 2022–27702 Filed 12–20–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Summit County, Utah

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (USDOT), Utah Department of Transportation (UDOT).

ACTION: Notice of intent to prepare an Environmental Impact Statement (EIS).

SUMMARY: The FHWA, on behalf of the Utah Department of Transportation (UDOT), is issuing this Notice of Intent (NOI) to solicit comment and advise the public, agencies, and stakeholders that an EIS will be prepared for transportation improvements in the Kimball Junction area which includes the I–80 and SR–224 interchange and SR–224 through the two at-grade intersections to the south of I–80 (Ute Boulevard and Olympic Parkway) in Summit County, Utah. Persons and agencies who may be interested in or affected by the proposed project are encouraged to comment on the information in this NOI and the NOI Supplemental Information document. All comments received in response to this NOI will be considered, and any information presented herein, including the draft purpose and need, preliminary alternatives, and identified impacts, may be revised in consideration of the comments.

DATES: Comments on the NOI must be received on or before January 27, 2023.

ADDRESSES: This NOI is available in the docket referenced above at *www.regulations.gov* and on the project website (*kimballjunctioneis.udot.utah.gov*). Interested parties are invited to submit comments by any of the following methods:

Website: For access to the documents, go to the Federal eRulemaking Portal located at *www.regulations.gov* or the project website (*kimballjunctioneis.udot.utah.gov*). Follow the online instructions for submitting comments.

Mailing address or for hand delivery or courier: UDOT Environmental Services Division, 4501 South 2700 West, P.O. Box 148450, Salt Lake City, Utah 84114–8450.

Email address: kimballjunctioneis@utah.gov.

All submissions should include the agency name and the docket number that appears in the heading of this Notice. All comments received will be posted without change to *www.regulations.gov* or *kimballjunctioneis.udot.utah.gov.*

The Draft EIS will include a summary of the comments received.

FOR FURTHER INFORMATION CONTACT: Carissa Watanabe, Environmental Program Manager, UDOT Environmental Services Division, 4501 South 2700 West, P.O. Box 148450, Salt Lake City, Utah 84114–8450; telephone: (503) 939–3798; email: *cwatanabe@utah.gov.* Grant Farnsworth, PE, Kimball Junction EIS Project Manager, UDOT Region Two, 2010 South 2760 West, Salt Lake City, UT 84104; telephone: (801) 663–9985 email: *gfarnsworth@utah.gov.*

Persons interested in receiving the project information can also use the project email address referenced above to be added to the project mailing list.

SUPPLEMENTARY INFORMATION: The environmental review, consultation, and other actions required by applicable federal environmental laws for this project are being or have been carried out by UDOT pursuant to 23 U.S.C. 327 and a Memorandum of Understanding dated May 26, 2022 and executed by FHWA and UDOT. UDOT, as the assigned National Environmental Policy Act (NEPA) agency, will prepare an EIS to evaluate transportation solutions in the Kimball Junction area which includes the Interstate 80 (I–80) and State Route (SR) 224 interchange and SR–224 through the two at-grade intersections to the south (Ute Boulevard and Olympic Parkway). The proposed project study area extends on I–80 from the Jeremy Ranch interchange (I–80 milepost 142) to the US–40 interchange (I–80 milepost 147). The EIS will be conducted in accordance with the requirements of NEPA, as amended (42 United States Code [U.S.C.] Section 4321, *et seq.*), 23 U.S.C. 139, Council on Environmental Quality (CEQ) regulations implementing NEPA (40 CFR parts 1500–1508), FHWA regulations implementing NEPA (23 CFR 771.101– 771.139), and all applicable federal, state, and local governmental laws and regulations.

In 2021, UDOT, in partnership with Summit County, published the Kimball Junction and SR–224 Area Plan (Area Plan) that was prepared to identify and evaluate future transportation improvements at the interchange of I–80 and SR–224 and through the two at-grade intersections on SR–224 (Ute Boulevard and Olympic Parkway) in Summit County, Utah. The Area Plan was conducted using UDOT's Solutions Development process which is a local planning process that seeks to capture the unique context of an area or corridor and develop a set of solutions to meet its transportation needs. The Area Plan evaluated multimodal improvements to address congestion, mobility, safety, access, and travel time reliability at the Kimball Junction interchange and on SR–224 in the Kimball Junction area.

Transportation problems as well as opportunities to solve the problems were established in the study area via input from study partners and the public. Other criteria were developed to balance transportation and environmental goals and objectives. Further input from the study partners and the public was incorporated to develop the goals. The problems and opportunities developed during the Area Plan process informed the draft

purpose and need of this EIS. The Area Plan process analyzed several solutions (30) and narrowed the options down to three alternatives, including intersection and pedestrian improvements and larger, more complex transportation solutions that will be evaluated in the EIS. The alternatives evaluation process included developing screening criteria based on addressing the problems and opportunities and study goals, developing a full range of alternatives, and documenting the elimination of alternatives. The 2021 Area Plan may be viewed at the project website (*kimballjunctioneis.udot.utah.gov*).

Purpose and Need for the Proposed Action

The purpose of this project as identified by UDOT is to improve operations and travel time on SR–224 from the I–80 interchange through Olympic Parkway; improve safety by reducing queues on I–80 off-ramps; improve pedestrian and bicyclist mobility and accessibility throughout the study area; and maintain or improve transit travel times. The need for the project is based on future (2050) failing conditions at the SR–224 and the I–80, Ute Boulevard, and Olympic Parkway intersections create delay and unreliable travel times; off-ramp queues extending onto mainline I–80 resulting in unsafe travel conditions; and growing east-west active transportation demand across SR–224. Agencies and the public are invited to comment on the draft purpose and need statement and technical memorandum available on the project website (*kimballjunctioneis.udot.utah.gov*). The purpose and need statement and supporting documentation, including data and public input summary, will be available in the Draft EIS. The purpose and need statement might be revised based on comments received during the comment period on this NOI.

Preliminary Description of the Proposed Action and Alternatives the EIS Will Consider

The currently contemplated range of alternatives proposed to be considered in the EIS consists of the following: (1) taking no action; (2) capacity improvements to I–80 and SR–224 such as adding general-purpose or auxiliary lanes and interchange improvements; (3) modified accesses to and from I–80 and SR–224; (4) additional or modified road, bicycle and pedestrian crossings on I–80 and SR–224; (5) combinations of any of the above, and (6) other reasonable alternatives identified during the EIS process. Three alternatives identified in the Area Plan meet the range of alternatives listed above and include Alternative A: a split-diamond interchange with intersection improvements; Alternative B: an alternative that has grade-separated intersections with one-way frontage roads to the I–80 interchange; and Alternative C: an alternative that combines HOV-focused improvements. Additional information on the alternatives, as well as maps and figures illustrating the project location, are available for review on the project website noted in the **ADDRESSES** section. Alternatives that do not meet the project's purpose and need or that are otherwise not reasonable will not be carried forward for detailed consideration in the EIS. The alternatives to be retained will be finalized after UDOT considers the comments received during the comment period on this NOI. The alternatives might be revised based on UDOT's consideration of public comments. The concepts not retained will also be documented in the Draft EIS. Alternatives carried forward in the EIS process will be evaluated along with the No Action alternative. The No Action alternative assumes all transportation improvements identified in the current long-range transportation plan would be built except the interchange improvements proposed in this study.

Summary of Expected Impacts

The EIS will evaluate the expected social, economic, and environmental effects resulting from the implementing the action alternatives and the no action alternative. The following resources are the most sensitive resources in the project area as identified in the Area Plan and will be evaluated by UDOT in the EIS:

Water Quality and Water Resources including Wetlands and other Waters of the United States: Project alternatives could require placing fill in waters of the United States and impacts to wetlands considered to be jurisdictional. These impacts would require a permit from the U.S. Army Corps of Engineers (USACE) for the discharge of dredged or fill material into waters of the United States, including wetlands.

Section 4(f) Resources: Project alternatives might use section 4(f) recreation resources and eligible historic properties. Section 4(f) is in reference to the U.S. Department of Transportation Act of 1966.

Environmental Justice Communities: Project alternatives might impact communities eligible for consideration as environmental justice communities that are low-income and minority due to right-of-way requirements, increases in noise, or other environmental factors. Additional analysis and public involvement will be conducted during the NEPA process to assess if the potential action alternatives would result in any disproportionately high and adverse impacts on the low-income and minority communities.

Property Acquisitions: Project alternatives could require acquiring private properties and relocating the tenants or owners of the properties. UDOT will work closely with the impacted stakeholders and designers to reduce the number of acquisitions and relocations.

The EIS will evaluate the expected impacts of and benefits to the known resources listed above as well as the following resources: land use, social and community resources, traffic, economics, pedestrian and bicyclist considerations, air quality, noise, wildlife resources, floodplains, cultural resources, hazardous material sites, and visual resources. The level of review of the identified resources for the EIS will be commensurate with the anticipated effects on each resource from the proposed project and will be governed by the statutory or regulatory requirements protecting those resources.

The analyses and evaluations conducted for the EIS will identify the potential for effects; avoidance measures; whether the anticipated effects would be adverse; and mitigation measures for adverse effects. UDOT welcomes comments on the expected impacts to be analyzed in the Draft EIS during the NOI comment period.

Agencies, stakeholders, and the public are invited to comment on the expected resources and anticipated impacts. The environmental impact analysis will not begin until the purpose and need, range of alternatives, and impact categories are finalized based on the public comments on this NOI. UDOT might revise the identification of impacts as a result of considering public comments. The studies to identify the impacts, as well as the analyses of impacts from the retained alternatives, will be presented in the Draft EIS.

Anticipated Permits and Other Authorizations

The project might require a permit from the U.S. Army Corps of Engineers (USACE) under Section 404 of the Clean Water Act. Additional state or local permits that may be required include stream alteration permits (PGP–10) from the Utah Division of Water Rights, Clean Water Act section 401 Certification from the Utah Division of Water Quality, Clean Water Act Section 402 Utah

Pollution Discharge Elimination System General Permit for Construction Activities from the Utah Division of Water Quality, floodplain development permits from local jurisdictions (cities or counties), and other construction related permits (such as Air Quality Approval Orders and Fugitive Dust Emission Control Plan from the Utah Division of Air Quality). A section 4(f) de minimis impact and/or section 106 affected properties would require concurrence from the official with jurisdiction.

Scoping and Public Review

Agency Coordination

A coordination plan is being prepared to define the agency and public participation procedures for the environmental review process. The plan will establish cooperating and participating agency roles and a review schedule and will be posted on the project website (*kimballjunctioneis.udot.utah.gov*). Cooperating agencies that have been preliminarily identified include the USACE and the U.S. Environmental Protection Agency.

Agency and Public Review

UDOT will initiate a scoping process in December 2022 to gather information and solicit input after this NOI is issued. To ensure that a full range of issues are addressed in the EIS and potential issues are identified, comments and suggestions are invited from all interested parties. During Scoping, UDOT requests comments and suggestions on the draft purpose and need, potential project alternatives and impacts, the draft alternatives screening methodology, and the identification of any relevant information, studies, or analyses of any kind concerning impacts to the quality of the human and natural environment. The purpose of this request is to bring relevant comments, information, and analyses to the attention of UDOT, as early in the process as possible, to enable the agency to make maximum use of this information in decision making.

A public scoping period will be held between December 27, 2022 and January 27, 2023. As part of the scoping process, UDOT will provide an opportunity for public and agency comments on the draft purpose and need statement and technical memorandum, and preliminary alternatives screening methodology. These documents will be available on the project website (*kimballjunctioneis.udot.utah.gov*) on December 27, 2022. Final versions of these documents, along with a scoping summary report, will be available on the project website when they are completed.

Public scoping meetings will be held in-person and virtually. An in-person public scoping meeting will be held on January 10, 2023 from 5:30 p.m. to 8:00 p.m. at Ecker Hill Middle School, 2465 Kilby Road, Park City, Utah. A virtual public scoping meeting will be held on January 11, 2023 from 6:00 p.m. to 7:30 p.m. via Zoom. To register for the virtual public meeting or to obtain information regarding the scoping meetings, please visit the project website.

Public involvement is a critical component of the project development process and will continue throughout the development of the EIS. All individuals and organizations expressing interest in the project will be able to participate in the process through various public outreach opportunities, and they can sign up to receive email announcements and notifications on the project website (*kimballjunctioneis.udot.utah.gov*). These opportunities include, but are not limited to, public meetings and hearing(s), the project website, and press releases. Public notice will be given regarding the time and place of all public meetings and hearing(s). A public scoping period and 30-day public comment period is planned between December 27, 2022 and January 27, 2023. Pursuant to 40 CFR 1501.9(d), during the scoping period, all interested parties are requested to provide comments on the draft purpose and need statement, the range of potential alternatives for the project, the preliminary alternatives screening methodology, and resources to be considered in the EIS, and to identify any relevant information, studies, or analyses relevant to the project. Written comments or questions should be directed to UDOT representatives at the mail or email addresses provided above.

Public hearings will be held during the course of the EIS, as described below. Generally, the locations, dates, and times for each public hearing will be publicized on the project website (*kimballjunctioneis.udot.utah.gov*) and in newspapers with local and regional circulation, including The Salt Lake Tribune, the Deseret News, the Park Record, and Townlift. Materials will be available at the meetings in English and Spanish, and oral and written comments will be solicited.

Public Hearing on the Draft EIS

Notice of availability of the Draft EIS for public and agency review will be published in the **Federal Register** and through other methods which will identify where interested parties can review a copy of the Draft EIS. A public hearing will be conducted by UDOT and announced a minimum of 15 days in advance of the scheduled hearing date. UDOT will provide information for the public hearing, including the location, date, and time for the meeting, through a variety of means including the project website (*kimballjunctioneis.udot.utah.gov*) and by newspaper advertisement.

Schedule for the Decision-Making Process

After this NOI is issued, UDOT will coordinate with the participating and cooperating agencies to develop study documentation and the Draft EIS.

The Draft EIS is anticipated to be issued in Winter 2023.

The combined Final EIS and Record of Decision is anticipated to be issued in the Fall of 2024, within 24 months of the publication of this NOI.

Any other federal permits, if necessary, will be obtained within 90 days after the Record of Decision is issued.

Request for Identification of Potential Alternatives, Information, and Analyses Relevant to the Proposed Action

To ensure that a full range of issues related to the project are addressed and all potential issues are identified, UDOT invites comments and suggestions from all interested parties. The project team requests comments and suggestions regarding potential alternatives and impacts and the identification of any relevant information, studies, or analyses of any kind concerning impacts affecting the quality of the human environment. Any information presented in this NOI, including the draft purpose and need statement, preliminary range of alternatives, and identification of impacts, might be revised after UDOT considers the comments. The purpose of this request is to bring relevant comments, information, and analyses to UDOT's attention, as early in the process as possible, to enable UDOT to make maximum use of this information in decision making. Comments may be submitted according to the instructions in the **ADDRESSES** section of this NOI.

(h) Contact Information

For more information, please visit the project website at *kimballjunctioneis.udot.utah.gov.* Information requests or comments can also be emailed to *kimballjunctioneis@utah.gov.*

UDOT: Carissa Watanabe, Environmental Program Manager, UDOT Environmental Services Division, 4501 South 2700 West, P.O. Box 148450, Salt Lake City, Utah 84114–8450; telephone: (503) 939–3798; email: *cwatanabe@utah.gov.*

(Catalog of Federal and Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on federal programs and activities apply to this program.)

Dated: December 14, 2022.

Ivan Marrero,

Division Administrator, Federal Highway Administration, Salt Lake City, Utah.

[FR Doc. 2022–27728 Filed 12–20–22; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[FHWA Docket No. FHWA–2022–0013]

Revision of Stewardship and Oversight Agreement Template

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of revised Stewardship and Oversight Agreement template, request for comments.

SUMMARY: The FHWA has completed a revision to the Federal-State Stewardship and Oversight (S&O) Agreement template. The revised S&O Agreement template that is the subject of this notice is an updated version of a template issued by FHWA in 2015. The revisions address such issues as changes in applicable laws and the evolution of FHWA's risk-based stewardship and oversight program. The FHWA is requesting comments on the revised S&O Agreement template. The FHWA will publish a **Federal Register** notice announcing the final S&O Agreement template, including any changes FHWA makes in response to public comments.

DATES: The public comment period closes on February 21, 2023.

ADDRESSES: All comments should include the docket number that appears in the heading of this document and may be submitted in any of the following ways:

- *Electronically through the Federal eRulemaking Portal: www.regulations.gov.* This website allows the public to enter comments on any **Federal Register** notice issued by any agency. Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590 between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

Instructions: You should identify the docket number at the beginning of your comments. If you submit your comments by mail, submit two copies. To receive confirmation that DOT received your comments, include a self-addressed stamped postcard. Late comments will be considered to the extent practicable. Note that all comments received will be posted without change to *www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Lloyd Rue, Office of Infrastructure, (202) 366–6125, office hours are from 8 a.m. to 4:30 p.m., MT, Monday through Friday, except Federal holidays, or Ms. Alla Shaw, Office of the Chief Counsel, (202) 366–1042, office hours are from 8 a.m. to 4:30 p.m., ET, Federal Highway Administration, 1200 New Jersey Avenue SE, Washington, DC 20590. Offices are open Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

This document and the revised S&O Agreement template may be viewed online under the docket number noted above through the Federal eRulemaking portal at: *www.regulations.gov.* Electronic submission and retrieval help and guidelines are available on the website. Please follow the online instructions.

In addition to being available in the electronic docket, the revised S&O Agreement template may also be viewed online at: *https://www.fhwa.dot.gov/federalaid/stewardship/Draft_stewardship_and_oversight_template.docx.*

An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at: *http://www.archives.gov/federal-register* and the U.S. Government Publishing Office's website at: *http://www.govinfo.gov/.*

Physical access to the docket is available at the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20950, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination in the docket at the above address. Comments received after the comment closing date will be filed in the docket and will be considered to the extent practicable. In addition to late comments, FHWA will also continue to file relevant information in the docket as it becomes available after the comment period closing date and interested persons should continue to examine the docket for new material.

Background

In enacting 23 United States Code (U.S.C.) 106(c), as amended, Congress established authority for States to enter into agreements with FHWA under which the States carry out certain project responsibilities traditionally handled by FHWA. Congress also recognized the importance of a risk-based approach to FHWA oversight of the Federal-aid highway program (FAHP), establishing requirements in 23 U.S.C. 106(g). The S&O Agreement is a key element of FHWA's risk-based S&O approach. The S&O Agreements are formal instruments executed between each FHWA Division Office and its corresponding State department of transportation (State DOT). The S&O Agreement defines the roles and responsibilities of FHWA and the State DOT with respect to Title 23, U.S.C. project approvals and related responsibilities, and documents methods that will be used for FAHP oversight activities.

In response to Office of Inspector General recommendations,[1] FHWA revised its national S&O procedures to require use of a uniform template for developing an S&O Agreement and instituted a legal review of each S&O Agreement. In 2015, FHWA issued the template currently in use. Each of the 52 FHWA Division Offices and their respective State DOTs executed a new S&O Agreement based on the 2015 S&O Agreement template.

Since the issuance of the 2015 S&O Agreement template and implementation of the new S&O Agreements, statutes and regulations applicable to the FAHP have changed.

[1] ''Improvements to Stewardship and Oversight Agreements Are Needed to Enhance Federal-aid Highway Program Management,'' OIG, DOT, Report Number MH–2013–001 (October 1, 2012), available online at *https://www.oig.dot.gov/library-item/28742.*

In addition, FHWA identified improvements for the 2015 template. For these reasons, FHWA initiated updates to the 2015 S&O Agreement template.

Finally, section 11307 of the Bipartisan Infrastructure Law (Pub. L. 117–58) directed the Secretary of Transportation to publish a template created by the Secretary for Federal-State S&O agreements in the **Federal Register** along with a notice requesting public comment on ways to improve the template. Accordingly, FHWA is making available the revised template and the 2015 template in the docket established for this notice. The 2015 template is included for reference, and it may also be viewed at *https://go.usa.gov/xtQcM.* The FHWA is requesting comments on the revised template, which FHWA believes addresses many concerns expressed by stakeholders since 2015.

Discussion of Changes

Revisions to the 2015 S&O Agreement template include the removal of redundant language and outdated text; revisions to the project-level approval actions, listed in attachment A to the template, including revisions based on changes in Federal law that have occurred since March 2015; and reorganization of the template.

The revised S&O Agreement template is more concise. The text of the 2015 S&O Agreement template is 12 pages, excluding signature pages and the attachments. The text of the revised S&O Agreement template is 7 pages, excluding signature pages and the attachments.

The 2015 S&O Agreement template has 12 sections. The revised S&O Agreement template is now nine sections. The revised section headings are:

Section I. Background and Introduction
Section II. Intent and Purpose of Agreement
Section III. Permissible Areas of Assumption Under 23 U.S.C. 106(c)
Section IV. Assumption of Responsibilities for Federal-Aid Projects on the NHS
Section V. Assumption of Responsibilities for Federal-Aid Projects off the NHS
Section VI. FHWA Oversight Program Under 23 U.S.C. 106(g)
Section VII. State DOT Oversight Responsibilities
Section VIII. Agreement Execution and Modifications
Section IX. Agreement Term and Termination

The title of the agreement is unchanged.

The 2015 S&O Agreement template included three attachments: (1) attachment A—Project Action Responsibility Matrix; (2) attachment B—Program Responsibility Matrix; and (3) attachment C—Manuals, Agreements, Control, Monitoring, And Reporting Documents. The revised S&O Agreement template eliminates attachment B—Program Responsibility Matrix of the 2015 agreement template. The purpose of attachment B in the 2015 template was to identify FHWA and State DOT offices involved in carrying out various program-level actions under the FAHP. That detailed level of information is not necessary in this more focused and concise version of the S&O Agreement template.

The revised S&O Agreement template includes three attachments: (1) attachment A—Project Action Responsibility Matrix; (2) attachment B—Manuals, Agreements, Control, Monitoring, And Reporting Documents; and (3) attachment C—Stewardship and Oversight Indicators.

Request for Comments

Although comments may address any part or provision of the template, FHWA is specifically requesting comments on the following:

- Whether revisions are needed to the template to delete standard terms requiring approval by the Secretary of the policies, procedures, processes, or manuals of the States, or other State actions, if Federal law (including regulations) does not specifically require an approval. The FHWA encourages commenters to specify each provision that should be revised.
- Opportunities to modify the template to allow adjustments to the review schedules for State practices or actions, including through risk-based approaches, program reviews, process reviews, or other means.
- Provisions of the template that describe how FHWA will perform oversight under 23 U.S.C. 106(g), such as reviewing State DOT practices or actions through risk-based approaches, program reviews, process reviews, or other means. The FHWA is interested in how commenters believe FHWA could improve these provisions in the template.
- Whether FHWA should allow the template to be modified by individual division offices and State DOTs to include State-specific provisions that do not otherwise conflict with the template and, if so, examples of what might be included in those provisions. The FHWA is particularly interested in whether commenters believe FHWA should allow the addition of such State-specific provisions under Section VI. FHWA Oversight Program Under 23 U.S.C. 106(g) and Section VII. State DOT Oversight Responsibilities and, if so, examples of additional provisions commenters believe might be covered in these sections.
- Provisions of the template that describe project approval actions that are assumable by State DOTs. In particular, FHWA is seeking comments on whether those actions are adequately described or addressed, and whether there are additional project-level approval actions that commenters believe arise out of Title 23, U.S.C. or title 23, Code of Federal Regulations and that may be assumed by State DOTs under 23 U.S.C. 106(c).
- Provisions of the template that describes State responsibilities for oversight of subrecipients. A State DOT is responsible for project oversight (23 U.S.C. 106(g)(4)) for federally assisted projects using apportioned Federal-aid highway funds. The FHWA is interested in whether the provisions in section VII of the template in conjunction with other existing FHWA policies, regulations, guidance, and technical assistance are sufficient for State DOTs to adequately provide subrecipient oversight and how commenters believe FHWA could improve the provisions in the template.
- Procedures for future updates to the S&O Agreement template. Comments are sought on how frequently the S&O Agreement template should be updated and on how future revisions to the S&O Agreement template should be managed to ensure the S&O Agreement template remains reasonably up to date without creating an overly burdensome process.
- Procedures for processing updates to FHWA-State DOT S&O Agreements. Comments are sought on how FHWA should process and execute revisions to existing FHWA-State DOT S&O Agreements, amendments to existing FHWA-State DOT S&O Agreements and new FHWA-State DOT S&O Agreements.

Further Proceedings

The FHWA is providing a 60-day comment period. After considering public comments in response to this notice, FHWA will publish a notice in the **Federal Register** that includes:

- The final S&O Agreement template, including any changes FHWA makes in response to public comments and any alternatives to those changes.
- A summary response to public comments, including the basis for FHWA's decision whether to revise the template in response to comments. This will include an explanation of the basis for retaining any requirement for FHWA approval of State policies, procedures, processes, or manuals, or other State actions if Federal law (including

regulations) does not specifically require the approval.

- An implementation plan and schedule for use of the new template.

Stephanie Pollack,

Deputy Administrator, Federal Highway Administration.

Stewardship and Oversight Agreement on Project Assumption and Program Oversight By and Between the Federal Highway Administration, [State Name] Division Office, and the [State Name DOT/STA Organization]

Section I. Background and Introduction

The Federal-aid Highway Program (FAHP) provides for a Federally-assisted State program. In enacting section 106(c) of title 23, United States Code (U.S.C.), as amended, Congress established authority for a State Department of Transportation (State DOT) to carry out certain project responsibilities traditionally handled by the Federal Highway Administration (FHWA) through a delegation from the Secretary of the U.S. Department of Transportation (''Secretary''). The authority in 23 U.S.C. 106(c) applies to projects that are subject to the requirements of title 23, U.S.C. (''title 23'') because the State DOT receives Federal funding or because the State DOT needs an FHWA action for the project even though the project may not use Federal funds. Congress also recognized the importance of a risk-based approach to FHWA oversight of the FAHP, establishing requirements in 23 U.S.C. 106(g). In addition to assumptions of responsibility, FHWA-State DOT Stewardship and Oversight Agreements cover certain oversight activities relating to the oversight requirements of 23 U.S.C. 106(g).

The FHWA may not assign its decisionmaking authority to a State DOT unless authorized by law. The authorities FHWA assigns to a State DOT under 23 U.S.C. 106(c)(1) and (2) are listed in Attachment A of the applicable FHWA-State DOT Stewardship and Oversight Agreement. A decision, determination, or action carried-out by a State DOT under the authority of a Stewardship and Oversight Agreement (''Agreement'') does not constitute an eligibility, participation, obligation, reimbursement, authorization, or compliance decision by or for FHWA.

For clarity, Attachment A also lists certain other actions FHWA may have allowed a State DOT to undertake based on delegation or assumption provisions in other Federal laws. As noted in those Attachment A listings, a State DOT exercise of those authorities is governed by separate agreements between FHWA and that State DOT.

For project responsibilities that are not assumed by a State DOT under 23 U.S.C. 106(c), and are not otherwise delegated or assigned in accordance with another Federal law, FHWA may authorize a State DOT to perform work needed to reach the FHWA decision point, or to implement FHWA's decision. However, such decisions themselves are reserved to FHWA.

Section II. Intent and Purpose of Agreement

This Stewardship and Oversight Agreement (''Agreement'') establishes the roles and responsibilities of the FHWA [State name] Division Office and the [State name DOT/STA organization (abbreviation)] with respect to certain title 23 project approvals and related responsibilities, and FAHP oversight activities. Nothing in this Agreement affects the Secretary's authority, or authority delegated to FHWA, to oversee compliance with Federal requirements. These authorities include but are not limited to 23 U.S.C. 114, under which the Secretary has the right to conduct such inspections and take such corrective action as the Secretary determines to be appropriate.

This Agreement carries out 23 U.S.C. 106(c)(3), which requires FHWA and the State DOT enter into an agreement relating to the extent to which the State DOT assumes project responsibilities pursuant to section 106(c). This Agreement also documents certain oversight activities that FHWA and the [State name DOT/STA abbreviation] will use to efficiently and effectively deliver the FAHP.

Section IV of this Agreement covers assumption of project approvals on the National Highway System (NHS). Section V covers assumption of project approvals off the NHS.

The Project Action Responsibility Matrix, Attachment A to this Agreement, describes responsibilities that the [State name DOT/STA abbreviation] assumes from FHWA pursuant to 23 U.S.C. 106(c) and other legal authorities.

Upon execution of this Agreement, Attachment A controls and, except as specifically noted in Attachment A (including any amendment thereto done in accordance with section VIII) and sections IV and V of this Agreement, no other agreements, attachments, or other documents shall have the effect of delegating or assigning FHWA approvals to the [State name DOT/STA abbreviation] under 23 U.S.C 106(c), or have the effect of altering Attachment A.

Section III. Permissible Areas of Assumption Under 23 U.S.C. 106(c)

FHWA has determined the activities and actions that are assumable under 23 U.S.C. 106(c). Those activities and actions are listed in a template issued by FHWA to create this Agreement and cover only activities or actions in the following areas:

A. Design, which includes preliminary engineering, engineering, and design-related services directly relating to the construction of a FAHP-funded project, including engineering, design, project development and management, construction project management and inspection, surveying, mapping (including the establishment of temporary and permanent geodetic control in accordance with specifications of the National Oceanic and Atmospheric Administration), and architectural-related services.

B. Plans, specifications and estimates (PS&E), which represents an array of actions and approvals required before authorization of construction and carried out during construction. The PS&E package includes standards, drawings, specifications, project estimates, certifications relating to completion of right-of-way acquisition and relocation, utility work, and railroad work.

C. Contract awards, which include procurement of professional and other consultant services and construction-related services to include advertising, evaluating, and awarding contracts.

D. Inspections, which include general contract administration, material testing and quality assurance, review, and inspections of Federal-aid contracts as well as final inspection/acceptance.

E. Approvals and related responsibilities affecting real property as provided in 23 CFR 710.201(h) and any successor regulation.

The [State name DOT/STA abbreviation] is to exercise any and all assumptions of the FHWA's responsibilities in accordance with the Federal laws, regulations, policies, Executive Orders, and procedures that would apply if the responsibilities were carried out by FHWA. For all projects and programs carried out under title 23, the [State name DOT/STA abbreviation] will comply with title 23 and all applicable non-title 23 Federal-aid program requirements.

Section IV. Assumption of Responsibilities for FederaL-Aid Projects on the NHS

For projects under title 23 that are on the NHS, including projects on the Interstate System, the [State name DOT/

STA abbreviation] may assume FHWA's title 23 responsibilities for activities or actions assumable under 23 U.S.C. 106(c) if the FHWA [State name] Division Office determines that assumption of responsibilities is appropriate and the [State name DOT/STA abbreviation] agrees.

A. The activities or actions on the NHS assumed by the [State name DOT/STA abbreviation] under this Agreement are listed in Attachment A.

B. Activities or actions for which the [State name DOT/STA abbreviation] has assumed the FHWA's responsibilities apply program-wide except when superseded by provisions in a stewardship and oversight plan adopted by the FHWA [State name] Division Office for a specific project. Additional discussion on FHWA project involvement is included in section VI.D of this Agreement.

C. In accordance with 23 U.S.C. 106(c)(4), the DOT Secretary may define high-risk categories for Interstate projects on a national basis, a State-by-State basis, or a national and State-by-State basis. A State DOT may not assume responsibilities for Interstate projects in a designated category. Currently, FHWA has not designated any high-risk categories applicable to [State name] in accordance with 23 U.S.C. 106(c)(4). If the FHWA makes a future designation that applies to [State name], then that designation will immediately supersede the assumptions of responsibilities elsewhere in this Agreement.

Section V. Assumption of Responsibilities for Federal-Aid Projects Off the NHS

For projects under title 23 that are not on the NHS, the [State name DOT/STA abbreviation] must assume FHWA's title 23 responsibilities for activities or actions assumable under 23 U.S.C. 106(c) unless the [State name DOT/STA abbreviation] determines that assumption of responsibilities is not appropriate (23 U.S.C. 106(c)(2)).

A. The activities or actions off the NHS assumed by the [State name DOT/STA abbreviation] under this Agreement are listed in Attachment A.

B. Activities or actions for which the [State name DOT/STA abbreviation] has assumed the FHWA's responsibilities apply programwide except when superseded by provisions in a stewardship and oversight plan for a specific project adopted by the FHWA [State name] Division Office. For non-NHS projects, the [State name DOT/STA abbreviation] must determine that superseding an assumption listed in Attachment A for a specific project is appropriate. Additional discussion on FHWA project involvement is included in section VI.D of this Agreement.

C. Except as provided in 23 U.S.C.109(o), the [State name DOT/STA abbreviation] is to exercise FHWA's approvals and related responsibilities on these projects in accordance with Federal laws, regulations, policies, Executive Orders, and procedures that would apply if the responsibilities were carried out by FHWA.

D. In accordance with 23 U.S.C. 109(o), non-NHS projects shall be designed and constructed in accordance with State laws, regulations, directives, safety standards, design standards, and construction standards, except that a local jurisdiction may use a roadway design guide recognized by FHWA and adopted by the local jurisdiction that is different from the roadway design guide used by the State in which the local jurisdiction is located for the design of projects on all roadways under the ownership of the local jurisdiction for which the local jurisdiction is the project sponsor, provided that the design complies with all other applicable Federal laws.

Section VI. FHWA Oversight Program Under 23 U.S.C. 106(g)

The Secretary must establish an oversight program to monitor the effective and efficient use of funds authorized to carry out the FAHP (23 U.S.C. 106(g)). This includes FHWA oversight of the [State name DOT/STA abbreviation] processes and management practices, including those involved in carrying out the approvals and related responsibilities assumed by the [State name DOT/STA abbreviation] under 23 U.S.C. 106(c).

Section 106(g) requires, at a minimum, FHWA's oversight program be responsive to all areas relating to financial integrity and project delivery. To carry out the requirements of 23 U.S.C. 106(g), FHWA uses a risk management framework to evaluate financial integrity, project delivery, and other aspects of the FAHP. The objective is to balance risk while considering staffing, budget resources, and the State's transportation needs.

The FHWA [State name] Division Office and the [State name DOT/STA abbreviation] may use a variety of methods to identify, analyze, and manage risks and develop response strategies, such as oversight techniques, manuals and operating agreements, stewardship and oversight indicators, and FHWA project involvement.

Oversight Techniques

Techniques the FHWA [State name] Division Office and the [State name DOT/STA abbreviation] may use to identify and analyze risks and develop response strategies include, but are not limited to, the following:

- program assessments;
- FHWA Financial Integrity Review and Evaluations reviews;
- program reviews;
- certification reviews;
- recurring or periodic reviews such as the FHWA Compliance Assessment Program;
- inspections of project elements or phases.

Manuals and Operating Agreements

The [State name DOT/STA abbreviation] manuals, agreements and other control, monitoring, and reporting documents that are used on Federal-aid projects are listed in Attachment B to this Agreement.

Stewardship and Oversight Indicators

[*Drafting note: Select the paragraph that applies.*]

Option 1

The FHWA [State name] Division Office and the [State name DOT/STA abbreviation] have established stewardship and oversight indicators (indicators) to help monitor performance of responsibilities assumed under this Agreement. Indicators are those intended to provide evidence of how well a State DOT assumption of responsibilities is functioning. Indicators set targets, track trends, and may help determine when countermeasures and actions are implemented or adjusted. The indicators are agreed to as provided in Attachment C.

Option 2

The FHWA [State name] Division Office and the [State name DOT/STA abbreviation] have not established indicators as part of this Agreement.

FHWA Project Involvement

The FHWA [State name] Division Office may select projects (individually or by type) for risk-based FHWA project involvement and stewardship and oversight activities. In some instances, the programwide assumption by the [State name DOT/STA abbreviation] of FHWA's responsibilities under Attachment A to this Agreement may be superseded by provisions in a stewardship and oversight plan for a specific project, per sections IV and V of this Agreement. The FHWA [State name] Division Office will document

the additional activities in a stewardship and oversight plan for the affected project(s).

Section VII. State DOT Oversight Responsibilities

• Oversight of State DOT Performance of Assumed Responsibilities.This section addresses how 23 U.S.C. 106(c) assumed authorities are carried out by the [State name DOT/STA abbreviation]. The actions include monitoring to assure that the [State name DOT/STA abbreviation] is properly carrying out its responsibilities in accordance with this Agreement. The [State name DOT/STA abbreviation] is responsible for demonstrating to FHWA how it is carrying out its responsibilities in accordance with this Agreement. The [State name DOT/STA abbreviation] will provide information to the FHWA [State name] Division Office upon request.

The [State name DOT/STA abbreviation] represents that processes, procedures, and practices from manuals, agreements, and other documents listed in Attachment B to this Agreement comply with applicable Federal requirements.

Subrecipient Oversight

The [State name DOT/STA abbreviation] is responsible for ensuring that its subrecipients meet applicable Federal requirements (2 CFR 200.332). This includes but is not limited to providing adequate oversight of sub-recipients with respect to both the subaward and any 23 U.S.C. 106(c) assumed responsibilities the [State name DOT/STA abbreviation] delegates to a subrecipient. The [State name DOT/STA abbreviation] is responsible for determining that subrecipients of Federal funds are suitably staffed and equipped and have adequate project delivery systems and sufficient accounting controls to properly manage these funds (23 U.S.C. 106(g)).

Section VIII. Agreement Execution and Modifications

A. Agreement Execution

This Agreement is effective when fully executed by the FHWA [State name] Division Administrator and authorized representative of the [State name DOT/STA abbreviation]. The [State name DOT/STA abbreviation] duly-authorized official shall execute this Agreement and then submit it to the FHWA [State name] Division Administrator, who shall sign this Agreement last.

B. Agreement Modifications

The FHWA [State name] Division Office and the [State name DOT/STA abbreviation] acknowledge that Agreement modifications (minor revisions or amendments) are needed periodically. Either party may initiate a request to modify this Agreement.

1. Minor Revisions

The FHWA [State name] Division Office and the [State name DOT/STA abbreviation] may make minor revisions to this Agreement without an amendment. For purposes of this Agreement, a minor revision makes a technical correction, addresses non-substantive changes such as a change in points-of-contact or document names, or revises aspects of procedures that do not materially change the terms of this Agreement. Changes to Attachments B or C are considered minor revisions. Minor revisions are recorded in a change log by the FHWA [State name] Division Office. Minor revisions may be executed without FHWA legal sufficiency review or coordination with FHWA's Office of Infrastructure.

2. Amendments

Modifications to this Agreement that exceed the definition of a minor revision in paragraph B.1. of this section shall require execution of an amendment to this Agreement. Amendments include any change to Attachment A. The amendment shall follow the execution procedure set forth in paragraph A of this section. Amendments require FHWA legal sufficiency review and coordination with FHWA's Office of Infrastructure.

New Agreement

This Agreement will be replaced in its entirety and a new Agreement executed between the FHWA [State name] Division Office and the [State name DOT/STA abbreviation] when mutually agreed upon by the parties, or as requested by the FHWA Office of Infrastructure. New Agreements require FHWA legal sufficiency review and coordination with FHWA's Office of Infrastructure prior to execution.

The electronic Agreement file shall contain the executed Agreement, any change logs, and amendments.

IX. Agreement Term and Termination

A. This Agreement shall have a term of [insert term of no greater than six (6) years] years, effective on the date of the signature of the FHWA [State name] Division Administrator in accordance with section VIII(A) of this Agreement.

B. Before the expiration of the term of this Agreement, a new agreement must be executed by both parties or the Agreement will expire (refer to section VIII.C. and IX.D.).

C. The FHWA [State name] Division Office may terminate this Agreement at any time if the FHWA [State name] Division Office determines that this Agreement is no longer in the public interest. Except in an extraordinary circumstance where immediate action is needed, prior to termination, the FHWA [State name] Division Office will issue a written notice to the [State name DOT/STA abbreviation] describing the FHWA's [State name] Division Office concerns and give the [State name DOT/STA abbreviation] a reasonable period of time to submit a written response addressing the FHWA [State name] Division Office concerns. The FHWA [State name] Division Office shall review the [State name DOT/STA abbreviation] response and make a final determination within 30 business days of receipt of the [State name DOT/STA abbreviation] response. The FHWA [State name] Division Office will notify the [State name DOT/STA abbreviation] in writing of the final determination and the effective date of any termination.

D. Expiration or termination of this Agreement shall mean that the assumption of project approvals by the [State name DOT/STA abbreviation] as set forth in this Agreement and Attachment A hereto is automatically revoked upon the date of expiration or termination and the [State name DOT/STA abbreviation] must immediately cease exercising any decision, determination, or action under the authority of this Agreement, including any amendments.

Attachment A: Project Action Responsibility Matrix

This matrix identifies the Federal-aid highway program (FAHP) project approvals and related responsibilities. The matrix specifies which actions are assumed by the [State name DOT/STA abbreviation] pursuant to this Stewardship and Oversight Agreement (''Agreement'') and certain other applicable authorities as specified in the tables in this Attachment A.

The [State name DOT/STA abbreviation] is responsible for ensuring all individual elements of the project are eligible for FAHP funding. Where the [State name DOT/STA abbreviation] assumes authority to make a decision, approval, determination or action, the [State name DOT/STA abbreviation] decision does not constitute an eligibility, obligation, reimbursement, authorization, or compliance decision by or for the Federal Highway Administration (FHWA). Final

decisions on those matters must be made by FHWA.

TABLE 1—FINANCIAL MANAGEMENT

#	Action	Agency responsible NHS	Agency responsible non-NHS
1	Review and accept financial plan and annual updates for Federal major projects [23 U.S.C. 106(h)].	FHWA	FHWA.
2	Review cost estimates for Federal major projects [23 U.S.C. 106(h)]	FHWA	FHWA.
3	Obligate funds/authorize Federal-aid project agreement (including advance construction authorization and conversion), modifications, and project closures (project authorizations) [23 U.S.C. 106(a)(2), 23 CFR 630.106, 630.703, 630.709].	FHWA	FHWA.
4	Authorize to advertise for bids when all preconditions are met [23 CFR 635.112(a), 635.309].	FHWA or STATE	STATE.
5	Approve reimbursements including authorizing current bill (23 U.S.C. 121)	FHWA	FHWA.
6	Approval of reimbursement for bond-issue projects [23 U.S.C. 122, 23 CFR part 140, Subpart F].	FHWA	FHWA.

TABLE 2—ENVIRONMENT

#	Action	Agency responsible NHS	Agency responsible non-NHS
7	EA/FONSI, EIS/ROD, 4(f), 106, 6(f) and other approval actions required by Federal environmental laws and regulations (Note: The FHWA may assign these NEPA actions and other environmental responsibilities to a State DOT as provided by 23 U.S.C. 327).	FHWA or Administered in accordance with 23 U.S.C. 327 MOU.	FHWA or Administered in accordance with 23 U.S.C. 327 MOU.
8	Categorical exclusion approval actions [Note: The FHWA may assign this action and other FHWA environmental responsibilities to a State DOT as provided by 23 U.S.C. 326 and 327. The FHWA also may administratively delegate responsibility for categorical exclusion determinations to a State DOT through a programmatic agreement pursuant to Section 1318(d) of MAP–21 and implementing regulations in 23 CFR 771.117(g)].	FHWA or Administered in accordance with applicable 23 U.S.C. 326 or 327 MOUs, or Programmatic Categorical Exclusion Agreement.	FHWA or Administered in accordance with applicable 23 U.S.C. 326 or 327 MOUs, or Programmatic Categorical Exclusion Agreement.

TABLE 3—PRELIMINARY DESIGN

#	Action	Agency responsible NHS	Agency responsible non-NHS
9	Approval before utilizing a consultant to act in a management support role for the contracting agency [23 CFR 172.7(b)(5)(i)].	FHWA or Administered in accordance with procedures approved per 23 CFR 172.5(c).	FHWA or Administered in accordance with procedures approved per 23 CFR 172.5(c).
10	Approval of noncompetitive procurement method for engineering and design-related services [23 CFR 172.7(a)(3)].	FHWA or STATE	STATE.
11	Approve exceptions to design standards [23 CFR 625.3(f)]	FHWA or STATE	Not subject to 23 CFR 625.3(f).
12	Airport highway clearance coordination and respective public interest finding (if required). [23 CFR 620.104]	FHWA or STATE	STATE.
13	Approve project management plan for Federal major projects [23 U.S.C. 106(h)]	FHWA	FHWA.
14	Approval of Interstate System access change [23 U.S.C. 111]	FHWA	Not subject to 23 U.S.C. 111.
15	Determine the engineering and operational acceptability of points of ingress or egress with the Interstate System (justification reports) for new freeway-freeway interchanges (system), modification of freeway-freeway interchanges, and new partial interchanges or new ramps to/from continuous frontage roads that create a partial interchange [23 U.S.C. 111(e)].	FHWA	Not subject to 23 U.S.C. 111(e).
16	Determine the engineering and operational acceptability of points of ingress or egress with the Interstate System (justification reports) for new and modified freeway-to-crossroad (service) interchanges, and completion of basic movements at existing partial interchanges. [23 U.S.C. 111(e)].	FHWA or Administered in Accordance with Programmatic Agreement.	Not subject to 23 U.S.C. 111(e).
17	Approve innovative and public-private partnership projects in accordance with TE–045, SEP–14, SEP–15, or SEP–16. [23 U.S.C. 502(b)].	FHWA	FHWA.
18	Approve any betterment to be incorporated into the project and for which emergency relief funding is requested (23 U.S.C. 125, 23 CFR 668.109).	FHWA	FHWA.

TABLE 3—PRELIMINARY DESIGN—Continued

#	Action	Agency responsible NHS	Agency responsible non-NHS
19	Prior written approval of the Federal awarding agency for the direct charge of up-front acquisition cost of equipment (2 CFR 200.439).	FHWA	FHWA.

TABLE 4—FINAL DESIGN

#	Action	Agency responsible NHS	Agency responsible non-NHS
20	Approve retaining right-of-way encroachments [23 CFR 1.23(b), 1.23(c)]	FHWA or STATE	STATE.
21	Approve use of publicly owned equipment [23 CFR 635.106]	FHWA or STATE	STATE.
22	Concur in use of publicly furnished materials [23 CFR 635.407(a)]	FHWA or STATE	STATE.
23	Determine use of more costly signing, pavement marking and signal materials (or equipment) is in the public interest [23 CFR 655.606].	FHWA or STATE	STATE.
24	Exception to designation of Interstate project as significant for work zones [23 CFR 630.1010(d)].	FHWA or STATE	Not subject to23 CFR 630.1010(d).
25	Determination that a United States Coast Guard Permit is not required for bridge construction [23 CFR 650.805, 650.807, 23 U.S.C. 144(c)].	FHWA	FHWA.

TABLE 5—REALTY

#	Action	Agency responsible NHS	Agency responsible non-NHS
26	Completion of ROW clearance, utility, and railroad work concurrently with construction: Make feasibility/practicability determination for allowing authorization to advertise for bids or to proceed with force account construction prior to completion of ROW clearance, utility and railroad work [23 CFR 635.309(b)].	FHWA or STATE	STATE.
27	Approve non-highway use and occupancy of real property interests [23 CFR 1.23(c), 710.405].	FHWA for Interstate FHWA or STATE for Non-Interstate	STATE.
28	Approve disposal at fair market value of real property acquired with Federal-aid assistance, including disposals of access control [23 CFR 710.403(e), 710.409].	FHWA for Interstate FHWA or STATE for Non-Interstate.	STATE.
29	Approve disposal at less than fair market value of federally funded right-of-way, including disposals of access control [23 U.S.C. 156, 23 CFR 710.403(e)].	FHWA	FHWA.
30	Conditional ROW certification, bid advertisement: Make public interest finding on whether State may proceed with bid advertisement even though ROW acquisition/relocation activities are not complete for some parcels [23 CFR 635.309(c)(3)(i)].	FHWA or STATE	STATE.
31	Conditional ROW certification, construction—Make finding of exceptional circumstances that make it in the public interest to allow State to proceed with construction even though ROW acquisition/relocation activities are not complete for some parcels [23 CFR 635.309(c)(3)(ii)].	FHWA	FHWA.
32	Approve hardship and protective buying [23 CFR 710.503]	FHWA	FHWA.
33	Requests for credits toward the non-Federal share of construction costs for early acquisitions, donations or other contributions applied to a project [23 U.S.C. 323, 23 CFR 710.507].	FHWA	FHWA.
34	Federal land transfers [23 CFR part 710, subpart F]	FHWA	FHWA.
35	Functional replacement of property [23 CFR 710.509]	FHWA	FHWA.
36	Waiver of the policy of the availability of comparable replacement dwelling before displacement under specified circumstances [49 CFR 24.204(b)].	FHWA	FHWA.

TABLE 6—PS&E AND ADVERTISING

#	Action	Agency responsible NHS	Agency responsible non-NHS
37	Approve PS&E [23 CFR 635.309(a)]	FHWA or STATE	STATE.
38	Approve utility or railroad force account work (23 CFR 140.916, 645.113, 646.216)	FHWA or STATE	STATE.
39	Approve utility and railroad agreements (23 CFR 140.916, 645.113, 646.216)	FHWA or STATE	STATE.
40	Approve use of consultants by utility and railroad companies [23 CFR 645.109(b), 646.216(b)].	FHWA or STATE	STATE.
41	Approve exceptions to maximum railroad protective insurance limits (23 CFR 140.916, 646.111).	FHWA or STATE	STATE.
42	Approve use of guaranty and warranty clauses for projects other than design-build projects [23 CFR 635.413(b)].	FHWA or STATE	STATE.
43	Recovery of railroad material—Approval of additional measures for restoration of areas affected by the removal of salvaged material for Railroad work (23 CFR 140.908).	FHWA or STATE	STATE.

TABLE 6—PS&E AND ADVERTISING—Continued

#	Action	Agency responsible NHS	Agency responsible non-NHS
44	Approve use of lump sum payments to reimburse railroad for work by its forces [23 CFR 646.216(d)(3)].	FHWA or STATE	STATE.
45	Waive Buy America provisions (23 CFR 635.410)	FHWA	FHWA.
46	Training special provision—Approval of new project training programs [23 CFR 230.111(d), 230.111(e)].	FHWA	FHWA.

TABLE 7—CONTRACT ADVERTISEMENT AND AWARD

#	Action	Agency responsible NHS	Agency responsible non-NHS
47	Approve cost-effectiveness determinations for construction work performed by contract awarded by other than competitive bidding or by force account (23 CFR 635.104, 635.204).	FHWA or STATE	STATE.
48	Approve emergency determinations for construction work performed by contract awarded by other than competitive bidding or by force account (23 CFR 635.104, 635.204).	FHWA or STATE	STATE.
49	Subrecipient project administration—Approve arrangements for local agency to serve as the supervising agency for the project (23 CFR 635.105).	FHWA or STATE	STATE.
50	Approve advertising period less than 3 weeks [23 CFR 635.112(b)]	FHWA or STATE	STATE.
51	Approve addenda during advertising period [23 CFR 635.112(c)]	FHWA or STATE	STATE.
52	Concur in award of contract or rejection of all bids (23 CFR 635.114)	FHWA or STATE	STATE.
53	Approval of design-build requests-for-proposals (RFP) and addenda for major changes to the RFP during solicitation period [23 CFR 635.112(i)(4)].	FHWA or STATE	STATE.
54	Approve award to the next low bidder [23 CFR 635.114(f)]	FHWA or STATE	STATE.

TABLE 8—CONSTRUCTION

#	Action	Agency responsible NHS	Agency responsible non-NHS
55	Approve contract changes and extra work (23 CFR 635.120)	FHWA or STATE	STATE.
56	Approve contract time extensions [23 CFR 635.120, 635.121(b)]	FHWA or STATE	STATE.
57	Concur in use of mandatory borrow/disposal sites (23 CFR 635.407)	FHWA or STATE	STATE.
58	Approval of administrative settlements and contract claim awards and settlements (23 CFR 140.505, 635.124).	FHWA or STATE	STATE.
59	Concur in termination of construction contracts [23 CFR 635.125(b)]	FHWA or STATE	STATE.

TABLE 9—CONSTRUCTION MANAGER/GENERAL CONTRACTOR (CM/GC) AND INDEFINITE DELIVERY/INDEFINITE QUANTITY (ID/IQ) CONTRACTING

#	Action	Agency responsible NHS	Agency responsible non-NHS
60	Approval of advertising for bids or proposals for a CM/GC construction services phase contract [23 CFR 635.504(b)(6)].	FHWA or STATE	STATE.
61	Determination of indirect cost rate for preconstruction services for a CM/GC project in accordance with [23 CFR 635.504(e)(2)].	FHWA or STATE	STATE.
62	Approval of preconstruction price and cost/price analysis for preconstruction services for a CM/GC project [23 CFR 635.506(b)(2)].	FHWA or STATE	STATE.
63	Approval of price estimate for construction costs for the entire project for CM/GC project [23 CFR 635.506(d)(2)].	FHWA or STATE	STATE.
64	Approval of construction price analysis and agreed price for construction services of a CM/GC project or portion of the project [23 CFR 635.506(d)(4)].	FHWA or STATE	STATE.
65	Approval of CM/GC project preconstruction services contract award [23 CFR 635.506(e)].	FHWA or STATE	STATE.
66	Concur in advertising an ID/IQ solicitation prior to completion of NEPA [23 CFR 635.605(a)(2)].	FHWA or STATE	STATE.
67	Concur in awarding an ID/IQ contract prior to completion of NEPA [23 CFR 635.605(a)(3)].	FHWA or STATE	STATE.
68	Approve a time extension of an ID/IQ contract [23 CFR 635.604(a)(6)(i)]	FHWA or STATE	STATE.

Attachment B (Drafting Example): Manuals, Agreements, Control, Monitoring, And Reporting Documents

State department of transportation (State DOT) manuals, agreements and other control, monitoring, and reporting documents that are used on Federal-aid projects. (The following provides examples of the types of manuals, guidelines and procedures that will be listed in Attachment B and the type of information needed for each document. The format is optional and the items listed are not all inclusive or applicable to all States.)

Example for Construction Specifications

- Standard Specifications
  - Elements that require the Federal Highway Administration (FHWA) approval:
    - Specifications that will be used on the National Highway System (NHS). (23 CFR 625.3)

Example State DOT Manuals That Will Be Used on Federal-Aid Projects

- Highway Design Manual—information and guidance to design road projects.
  - Elements that require FHWA approval:
    - Roadway design standards for 3R and preventative maintenance projects on the NHS. [23 CFR 625.3, 625.4(a)(3)]
  - Elements required by Federal law or regulation included in this manual that do not require FHWA approval:
    - Erosion and Sediment Control Guidelines (23 CFR 650.211)
- Right of Way Manual—right-of-way organization, policies, and procedures. Describes functions and procedures for all phases of the real estate program, including appraisal and appraisal review, negotiation and eminent domain, property management, and relocation assistance.
  - Elements that require FHWA approval:
    - All elements. Right-of-way organization, policies, and procedures (23 CFR 710.201)

Additional Manuals, Agreements, Control, Monitoring, and Reporting Documents

- Noise Analysis and Abatement Policy (23 CFR part 772)
- Programmatic Agreement for Processing Interstate Access Requests (MAP–21, Section 1505)
- Asset Management Plan [23 U.S.C 119(e)(5)]
- Value Engineering Policy and Procedures [23 CFR 627.1]
- Quality Assurance Program [23 CFR 637.205]
- Construction Manager/General Contractor (CM/GC) procurement procedures [23 CFR 635.504(c)]
- Pavement Design Policy [23 CFR part 626]

Attachment C *(Drafting Example):* **Stewardship and Oversight Indicators**

Indicators used to monitor assumptions of responsibility per section VI. C. of this Agreement. (This list is provided as an example. The format is optional and the items listed are not all inclusive or applicable to all states).

Example Stewardship a6nd Oversight Indicator

- Fiscal year Disadvantaged Business Enterprise (DBE) overall participation rate.
- Percent of DBE goal achieved.
- Average number of bidders per project per type of work per year.
- Percent of projects with low bid within +/− 10 percent of Engineer's Estimate.
- Percentage of projects that are awarded within 120 days of authorization.
- Number of National Bridge Inspection Standards metrics that are fully compliant.
- Percent of environmental mitigation commitments completed.
- Average number of days between the date of project final acceptance by State department of transportation and project close out date in the Financial Management Information System (FMIS).
- Percent of projects closed out with final costs within 110 percent of award amount.
- Percent of projects closed out with final time expended within 135 percent of original contract time.
- Percent of current year projects in the State Transportation Improvement Program advanced as scheduled.
- Percent of projects with right-of-way (ROW) acquired by acquisition due date.
- Number of projects with conditional ROW certifications.
- Number of disposals of excess ROW below fair market value.
- Number of non-Interstate access breaks and/or encroachments approved.
- Number of modifications to project end dates in FMIS.
- Expenditures determined to be ineligible for Federal participation.

[FR Doc. 2022–27705 Filed 12–20–22; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2010–0061]

Union Pacific Railroad's Request To Amend Its Positive Train Control Safety Plan and Positive Train Control System

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of availability and request for comments.

SUMMARY: This document provides the public with notice that, on December 12, 2022, Union Pacific Railroad (UP) submitted a request for amendment (RFA) to its FRA-approved Positive Train Control Safety Plan (PTCSP). As this RFA may involve a request for FRA's approval of proposed material modifications to an FRA-certified positive train control (PTC) system, FRA is publishing this notice and inviting public comment on the railroad's RFA to its PTCSP.

DATES: FRA will consider comments received by January 10, 2023. FRA may consider comments received after that date to the extent practicable and without delaying implementation of valuable or necessary modifications to a PTC system.

ADDRESSES:

Comments: Comments may be submitted by going to *https://www.regulations.gov* and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and the applicable docket number. The relevant PTC docket number for this host railroad is Docket No. FRA–2010–0061. For convenience, all active PTC dockets are hyperlinked on FRA's website at *https://railroads.dot.gov/train-control/ptc/ptc-annual-and-quarterly-reports.* All comments received will be posted without change to *https://www.regulations.gov;* this includes any personal information.

FOR FURTHER INFORMATION CONTACT: Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816–516–7168, email: *Gabe.Neal@dot.gov.*

SUPPLEMENTARY INFORMATION: In general, title 49 United States Code (U.S.C.) section 20157(h) requires FRA to certify that a host railroad's PTC system complies with title 49 Code of Federal Regulations (CFR) part 236, subpart I, before the technology may be operated in revenue service. Before making

certain changes to an FRA-certified PTC system or the associated FRA-approved PTCSP, a host railroad must submit, and obtain FRA's approval of, an RFA to its PTCSP under 49 CFR 236.1021.

Under 49 CFR 236.1021(e), FRA's regulations provide that FRA will publish a notice in the **Federal Register** and invite public comment in accordance with 49 CFR part 211, if an RFA includes a request for approval of a material modification of a signal and train control system. Accordingly, this notice informs the public that, on December 12, 2022, UP submitted an RFA to its PTCSP for its Interoperable Electronic Train Management System (I–ETMS), and that RFA is available in Docket No. FRA–2010–0061.

Interested parties are invited to comment on UP's RFA to its PTCSP by submitting written comments or data. During FRA's review of this railroad's RFA, FRA will consider any comments or data submitted within the timeline specified in this notice and to the extent practicable, without delaying implementation of valuable or necessary modifications to a PTC system. *See* 49 CFR 236.1021; *see also* 49 CFR 236.1011(e). Under 49 CFR 236.1021, FRA maintains the authority to approve, approve with conditions, or deny a railroad's RFA to its PTCSP at FRA's sole discretion.

Privacy Act Notice

In accordance with 49 CFR 211.3, FRA solicits comments from the public to better inform its decisions. DOT posts these comments, without edit, including any personal information the commenter provides, to *https://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See *https://www.regulations.gov/privacy-notice* for the privacy notice of regulations.gov. To facilitate comment tracking, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. If you wish to provide comments containing proprietary or confidential information, please contact FRA for alternate submission instructions.

Issued in Washington, DC.

Carolyn R. Hayward-Williams,

Director, Office of Railroad Systems and Technology.

[FR Doc. 2022–27667 Filed 12–20–22; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2022–0098]

Brightline Trains Florida's Request for Approval To Field Test Positive Train Control

AGENCY: Federal Railroad Administration (FRA), U.S. Department of Transportation (DOT).

ACTION: Notice of availability and request for comments.

SUMMARY: This document provides the public with notice that on December 9, 2022, Brightline Trains Florida (BTF) submitted a document entitled, ''Brightline OX Line Segment Test Request 120922,'' dated December 9, 2022, to FRA. BTF asks FRA to approve its request so that BTF may field test its trains that have been equipped with positive train control (PTC) technology.

DATES: FRA will consider comments received by February 21, 2023. FRA may consider comments received after that date to the extent practicable and without delaying implementation of valuable or necessary modifications to a PTC system.

ADDRESSES: All comments should identify the agency name and Docket Number FRA–2022–0098 and may be submitted on *https://www.regulations.gov.* Follow the online instructions for submitting comments. All comments received will be posted without change to *https://www.regulations.gov;* this includes any personal information.

FOR FURTHER INFORMATION CONTACT: Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816–516–7168, email: *Gabe.Neal@dot.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 49 CFR 236.1035, a railroad must obtain FRA's approval before field testing an uncertified PTC system, or a product of an uncertified PTC system, or any regression testing of a certified PTC system on the general rail system. *See* 49 CFR 236.1035(a). BTF is requesting FRA's approval to field test the Interoperable Electronic Train Management System on territory BTF owns between Cocoa Junction and the Orlando International Airport, which BTF's test request refers to as the Orlando Extension (OX) Line Segment. As discussed below, please see BTF's test request for the required information, including a complete description of BTF's Concept of Operations and its specific test procedures, including the measures that will be taken to ensure safety during testing.

BTF's test request is available for review online at *https://www.regulations.gov* (Docket No. FRA–2022–0098). Interested parties are invited to comment on the test request by submitting written comments or data. During its review of the test request, FRA will consider any comments or data submitted. However, FRA may elect not to respond to any particular comment, and under 49 CFR 236.1035, FRA maintains the authority to approve, approve with conditions, or deny the test request at its sole discretion.

Privacy Act Notice

In accordance with 49 CFR 211.3, FRA solicits comments from the public to better inform its decisions. DOT posts these comments, without edit, including any personal information the commenter provides, to *https://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See *https://www.regulations.gov/privacy-notice* for the privacy notice of regulations.gov. To facilitate comment tracking, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. If you wish to provide comments containing proprietary or confidential information, please contact FRA for alternate submission instructions.

Issued in Washington, DC.

Carolyn R. Hayward-Williams,

Director, Office of Railroad Systems and Technology.

[FR Doc. 2022–27668 Filed 12–20–22; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

RIN 1505–AC62

IMARA Calculation for Calendar Year 2023 Under the Terrorism Risk Insurance Program

AGENCY: Departmental Offices, Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury (Treasury) is providing notice to the public of the insurance marketplace aggregate retention amount (IMARA) for calendar year 2023 for purposes of the Terrorism Risk Insurance Program (TRIP or the Program) under the Terrorism Risk Insurance Act, as amended (TRIA or the Act). As explained below, Treasury has

determined that the IMARA for calendar year 2023 is $44,979,144,932.

DATES: The IMARA for calendar year 2023 is applicable January 1, 2023 through December 31, 2023.

FOR FURTHER INFORMATION CONTACT: Richard Ifft, Senior Insurance Regulatory Policy Analyst, Federal Insurance Office, 202–622–2922 or Jeremiah Pam, Senior Insurance Regulatory Policy Analyst, Federal Insurance Office, 202–622–7009.

SUPPLEMENTARY INFORMATION:

I. Background

TRIA—which established TRIP—was signed into law on November 26, 2002, following the attacks of September 11, 2001, to address disruptions in the market for terrorism risk insurance, to help ensure the continued availability and affordability of commercial property and casualty insurance for terrorism risk, and to allow for the private markets to stabilize and build insurance capacity to absorb any future losses for terrorism events.[1] TRIA requires insurers to ''make available'' terrorism risk insurance for commercial property and casualty losses resulting from certified acts of terrorism, and provides for shared public and private compensation for such insured losses. The Program has been reauthorized four times, most recently by the Terrorism Risk Insurance Program Reauthorization Act of 2019.[2] The Secretary of the Treasury (Secretary) administers the Program, with assistance from the Federal Insurance Office (FIO).[3]

TRIA provides for an ''industry marketplace aggregate retention amount'' or ''IMARA'' to be used for determining whether Treasury must recoup any payments it makes under the Program. Under the Act, if total annual payments by all participating insurers are below the IMARA, then Treasury must recoup all amounts expended by it up to the IMARA threshold. If total annual payments by all participating insurers are above the IMARA, then Treasury has the discretionary authority (but not the obligation) to recoup all of the expended amounts that are above the IMARA threshold.[4]

TRIA provides for a schedule of defined IMARA values from calendar year 2015 through calendar year 2019.[5] For calendar year 2020 and beyond, TRIA states that the IMARA ''shall be revised to be the amount equal to the annual average of the sum of insurer deductibles for all insurers participating in the Program for the prior 3 calendar years,'' as such sum is determined pursuant to final rules issued by the Secretary.[6]

On November 15, 2019, Treasury issued a final rule for calculation of the IMARA.[7] This rule, which is codified at 31 CFR 50.4(m)(2), provides that the IMARA will be calculated by averaging the annual industry aggregate deductibles over the prior three calendar years, based upon the direct earned premiums (DEP) reported to Treasury by insurers in Treasury's annual data calls. Insurer deductibles under the Program are based upon the DEP of individual insurers reported to Treasury in the prior year (*e.g.,* 2021 DEP for 2022 calendar year program deductibles).

Accordingly, for purposes of determining the IMARA for calendar 2023, Treasury has averaged the aggregate insurer deductibles for calendar years 2022, 2021, and 2020 (as reported to Treasury in each of these years), which are based on the reported DEP for calendar years 2021, 2020, and 2019, respectively.

For purposes of the 2023 IMARA calculation, those figures are as follows:

TRIP-ELIGIBLE DEP BY INSURER CATEGORY[8]

	2020 TRIP data call		2021 TRIP data call		2022 TRIP data call	
	2019 DEP in TRIP-eligible lines	% of total	2020 DEP in TRIP-eligible lines	% of total	2021 DEP in TRIP-eligible lines	% of total
Alien Surplus Lines Ins.	$11,149,972,542	5	$11,043,111,847	5	$ 12,107,214,064	5
Captive Insurers	9,083,384,310	4	10,534,614,720	5	14,359,289,661	6
Non-Small Insurers	172,970,757,331	80	175,272,463,804	80	186,901,545,992	78
Small Insurers	22,882,139,290	11	22,156,599,520	10	26,226,080,899	11
Total	216,086,253,473	100	219,006,789,891	100	239,594,130,617	100

Treasury has used these reported premiums to calculate the IMARA for calendar year 2023. The average annual DEP figure for the combined period of 2019, 2020, and 2021 is $224,895,724,660 [($216,086,253,473 + $219,006,789,891 + $239,594,130,617)/3 = $224,895,724,660]. The average aggregate deductible for the prior three years is 20 percent of $224,895,724,660, which equals $44,979,144,932.[9] Accordingly, the IMARA for purposes of calendar year 2023 is $44,979,144,932.

Dated: December 15, 2022.

Steven E. Seitz,

Director, Federal Insurance Office.

[FR Doc. 2022–27669 Filed 12–20–22; 8:45 am]

BILLING CODE 4810–25–P

[1] Public Law 107–297, sec. 101(b), 116 Stat. 2322, codified at 15 U.S.C. 6701 note. Because the provisions of TRIA (as amended) appear in a note instead of particular sections of the U.S. Code, the provisions of TRIA are identified by the sections of the law.

[2] See Terrorism Risk Insurance Extension Act of 2005, Public Law 109–144, 119 Stat. 2660; Terrorism Risk Insurance Program Reauthorization Act of 2007, Public Law 110–160, 121 Stat. 1839; Terrorism Risk Insurance Program Reauthorization Act of 2015, Public Law 114–1, 129 Stat. 3 (2015 Reauthorization Act); Terrorism Risk Insurance Program Reauthorization Act of 2019, Public Law 116–94, 133 Stat. 2534.

[3] 31 U.S.C. 313(c)(1)(D).

[4] *See* TRIA, sec. 103(e)(7); see also 31 CFR part 50 subpart J (Recoupment and Surcharge Procedures).

[5] In 2015, the IMARA was $29.5 billion; it increased to $31.5 billion in 2016, $33.5 billion in 2017, $35.5 billion in 2018, and $37.5 billion in 2019. *See* TRIA, sec. 103(e)(6)(B).

[6] TRIA, sec. 103(e)(6)(B)(ii) and (e)(6)(C). An insurer's deductible under the Program for any particular year is 20 percent of its direct earned premium subject to the Program during the preceding year. TRIA, sec. 102(7). For example, an insurer's calendar year 2022 Program deductible is 20 percent of its calendar year 2021 direct earned premium.

[7] *See* 84 FR 62450 (November 15, 2019) (Final Rule).

[8] The figures from the 2021 and 2020 TRIP data calls were previously reported in the IMARA calculation for calendar year 2022. *See* 86 FR 73100 (December 23, 2021). The figures from the 2022 TRIP data call were previously reported in FIO's June 2022 Report on the Effectiveness of the Terrorism Risk Insurance Program (June 2022), 11 (Figure 1), *https://home.treasury.gov/system/files/311/2022%20Program%20Effectiveness%20Report%20%28FINAL%29.pdf* and have been updated to include data received by FIO after the reporting deadline. Some figures may not add up on account of rounding.

[9] *See* note 7.

FEDERAL REGISTER

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Part II

Department of Health and Human Services

45 CFR Parts 153, 155, and 156
Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2024; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 153, 155, and 156

[CMS–9899–P]

RIN 0938–AU97

Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2024

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule includes proposed payment parameters and provisions related to the HHS-operated risk adjustment and risk adjustment data validation programs, as well as proposed 2024 user fee rates for issuers offering qualified health plans (QHPs) through Federally-facilitated Exchanges (FFEs) and State-based Exchanges on the Federal platform (SBE–FPs). This proposed rule also proposes requirements related to updating standardized plan options and reducing plan choice overload; re-enrollment hierarchy; plan and plan variation marketing name requirements for QHPs; essential community providers (ECPs) and network adequacy; failure to file and reconcile; special enrollment periods (SEPs); the annual household income verification; the deadline for QHP issuers to report enrollment and payment inaccuracies; requirements related to the State Exchange improper payment measurement program; and requirements for agents, brokers, and web-brokers assisting FFE and SBE–FP consumers.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by no later than 5 p.m. on January 30, 2023.

ADDRESSES: In commenting, please refer to file code CMS–9899–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9899–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9899–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

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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 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.

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I. Executive Summary

We are proposing changes to the provisions and parameters implemented through prior rulemaking to implement the Patient Protection and Affordable Care Act (ACA).[1] These proposals are published under the authority granted to the Secretary by the ACA and the Public Health Service (PHS) Act.[2] In this proposed rule, we propose changes related to some of these ACA provisions and parameters we previously implemented and propose to implement new provisions. Our goal with the proposals is providing quality, affordable coverage to consumers while minimizing administrative burden and ensuring program integrity. The changes proposed in this rule are also intended to help advance health equity and mitigate health disparities.

[1] The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Healthcare and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this rulemaking, the two statutes are referred to collectively as the ''Patient Protection and Affordable Care Act,'' ''Affordable Care Act,'' or ''ACA.''

[2] See sections 1311, 1312, 1313, 1321, and 1343 of the ACA and section 2792 of the PHS Act.

II. Background

A. Legislative and Regulatory Overview

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new title XXVII to the PHS Act to establish various reforms to the group and individual health insurance markets.

These provisions of the PHS Act were later augmented by other laws, including the ACA. Subtitles A and C of title I of the ACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. The term ''group health plan'' includes both insured and self-insured group health plans.

Section 2702 of the PHS Act, as added by the ACA, establishes requirements for guaranteed availability of coverage in the group and individual markets.

Section 1301(a)(1)(B) of the ACA directs all issuers of QHPs to cover the essential health benefit (EHB) package described in section 1302(a) of the ACA, including coverage of the services described in section 1302(b) of the ACA, adherence to the cost-sharing limits described in section 1302(c) of the ACA, and meeting the AV levels established in section 1302(d) of the ACA. Section 2707(a) of the PHS Act, which is effective for plan or policy years beginning on or after January 1, 2014, extends the requirement to cover the EHB package to non-grandfathered individual and small group health insurance coverage, irrespective of whether such coverage is offered through an Exchange. In addition, section 2707(b) of the PHS Act directs non-grandfathered group health plans to ensure that cost-sharing under the plan does not exceed the limitations described in section 1302(c)(1) of the ACA.

Section 1302 of the ACA provides for the establishment of an EHB package that includes coverage of EHBs (as defined by the Secretary of HHS), cost-sharing limits, and AV requirements. The law directs that EHBs be equal in scope to the benefits provided under a typical employer plan, and that they cover at least the following 10 general categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. Section 1302(d) of the ACA describes the various levels of coverage based on their AV. Consistent with section 1302(d)(2)(A) of the ACA, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the ACA directs the Secretary of HHS to develop guidelines that allow for de minimis variation in AV calculations. Sections 1302(b)(4)(A) through (D) of the ACA establish that the Secretary must define EHB in a manner that: (1) Reflects appropriate balance among the 10 categories; (2) is not designed in such a way as to discriminate based on age, disability, or expected length of life; (3) takes into account the health care needs of diverse segments of the population; and (4) does not allow denials of EHBs based on age, life expectancy, disability, degree of medical dependency, or quality of life.

Section 1311(c) of the ACA provides the Secretary the authority to issue regulations to establish criteria for the certification of QHPs. Section 1311(c)(1)(B) of the ACA requires, among the criteria for certification that the Secretary must establish by regulation that QHPs ensure a sufficient choice of providers. Section 1311(e)(1) of the ACA grants the Exchange the authority to certify a health plan as a QHP if the health plan meets the Secretary's requirements for certification issued under section 1311(c) of the ACA, and the Exchange determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the State. Section 1311(c)(6)(C) of the ACA directs the Secretary of HHS to require an Exchange to provide for special enrollment periods and section 1311(c)(6)(D) of the ACA directs the Secretary of HHS to require an Exchange to provide for a monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act.

Section 1311(d)(3)(B) of the ACA permits a State, at its option, to require QHPs to cover benefits in addition to EHB. This section also requires a State to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional State-required benefits.

Section 1312(c) of the ACA generally requires a health insurance issuer to consider all enrollees in all health plans (except grandfathered health plans) offered by such issuer to be members of a single risk pool for each of its individual and small group markets. States have the option to merge the individual and small group market risk

pools under section 1312(c)(3) of the ACA.

Section 1312(e) of the ACA provides the Secretary with the authority to establish procedures under which a State may allow agents or brokers to (1) enroll qualified individuals and qualified employers in QHPs offered through Exchanges and (2) assist individuals in applying for premium tax credits (PTC) and cost-sharing reductions (CSRs) for QHPs sold through an Exchange.

Sections 1313 and 1321 of the ACA provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State Exchange activities. Section 1313(a)(5)(A) of the ACA provides the Secretary with the authority to implement any measure or procedure that the Secretary determines is appropriate to reduce fraud and abuse in the administration of the Exchanges. Section 1321 of the ACA provides for State flexibility in the operation and enforcement of Exchanges and related requirements.

Section 1321(a) of the ACA provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of the ACA, including such other requirements as the Secretary determines appropriate. When operating an FFE under section 1321(c)(1) of the ACA, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the ACA to collect and spend user fees. Office of Management and Budget (OMB) Circular A–25 Revised establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.

Section 1321(d) of the ACA provides that nothing in title I of the ACA must be construed to preempt any State law that does not prevent the application of title I of the ACA. Section 1311(k) of the ACA specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 1343 of the ACA establishes a permanent risk adjustment program to provide payments to health insurance issuers that attract higher-than-average risk populations, such as those with chronic conditions, funded by payments from those that attract lower-than-average risk populations, thereby reducing incentives for issuers to avoid higher-risk enrollees. Section 1343(b) of the ACA provides that the Secretary, in consultation with States, shall establish criteria and methods to be used in carrying out the risk adjustment activities under this section. Consistent with section 1321(c) of the ACA, the Secretary is responsible for operating the risk adjustment program in any State the fails to do so.[3]

Section 1401(a) of the ACA added section 36B to the Internal Revenue Code (the Code), which, among other things, requires that a taxpayer reconcile APTC for a year of coverage with the amount of the PTC the taxpayer is allowed for the year.

Section 1402 of the ACA provides for, among other things, reductions in cost-sharing for EHB for qualified low- and moderate-income enrollees in silver level QHPs offered through the individual market Exchanges. This section also provides for reductions in cost-sharing for Indians enrolled in QHPs at any metal level.

Section 1411(c) of the ACA requires the Secretary to submit certain information provided by applicants under section 1411(b) of the ACA to other Federal officials for verification, including income and family size information to the Secretary of the Treasury. Section 1411(d) of the ACA provides that the Secretary must verify the accuracy of information provided by applicants under section 1411(b) of the ACA, for which section 1411(c) of the ACA does not prescribe a specific verification procedure, in such manner as the Secretary determines appropriate.

Section 1411(f) of the ACA requires the Secretary, in consultation with the Treasury and Homeland Security Department Secretaries and the Commissioner of Social Security, to establish procedures for hearing and making decisions governing appeals of Exchange eligibility determinations. Section 1411(f)(1)(B) of the ACA requires the Secretary to establish procedures to redetermine eligibility on a periodic basis, in appropriate circumstances, including eligibility to purchase a QHP through the Exchange and for advance payments of the premium tax credit (APTC) and CSRs.

Section 1411(g) of the ACA allows the use of applicant information only for the limited purposes of, and to the extent necessary to, ensure the efficient operation of the Exchange, including by verifying eligibility to enroll through the Exchange and for APTC and CSRs, and limits the disclosure of such information.

Section 5000A of the Code, as added by section 1501(b) of the ACA, requires individuals to have minimum essential coverage (MEC) for each month, qualify for an exemption, or make an individual shared responsibility payment. Under the Tax Cuts and Jobs Act, which was enacted on December 22, 2017, the individual shared responsibility payment is reduced to $0, effective for months beginning after December 31, 2018. Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals age 30 and above qualify to enroll in catastrophic coverage under §§ 155.305(h) and 156.155(a)(5).

1. Premium Stabilization Programs

The premium stabilization programs refer to the risk adjustment, risk corridors, and reinsurance programs established by the ACA.[4] For past rulemaking, we refer readers to the following rules:

- In the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule), we implemented the premium stabilization programs.
- In the March 11, 2013 **Federal Register** (78 FR 15409) (2014 Payment Notice), we finalized the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs.
- In the October 30, 2013 **Federal Register** (78 FR 65046), we finalized the modification to the HHS-operated methodology related to community rating States.
- In the November 6, 2013 **Federal Register** (78 FR 66653), we published a correcting amendment to the 2014 Payment Notice final rule to address how an enrollee's age for the risk score calculation would be determined under the HHS-operated risk adjustment methodology.
- In the March 11, 2014 **Federal Register** (79 FR 13743) (2015 Payment Notice), we finalized the benefit and payment parameters for the 2015 benefit year to expand the provisions related to the premium stabilization programs, set forth certain oversight provisions, and established payment parameters in those programs.
- In the May 27, 2014 **Federal Register** (79 FR 30240), we announced

[3] In the 2014 through 2016 benefit years, HHS operated the risk adjustment program in every State and the District of Columbia, except Massachusetts. Beginning with the 2017 benefit year, HHS has operated the risk adjustment program in all 50 States and the District of Columbia.

[4] See ACA section 1341 (transitional reinsurance program), ACA section 1342 (risk corridors program), and ACA section 1343 (risk adjustment program).

the 2015 fiscal year sequestration rate for the risk adjustment program.

• In the February 27, 2015 **Federal Register** (80 FR 10749) (2016 Payment Notice), we finalized the benefit and payment parameters for the 2016 benefit year to expand the provisions related to the premium stabilization programs, set forth certain oversight provisions, and established the payment parameters in those programs.

• In the March 8, 2016 **Federal Register** (81 FR 12203) (2017 Payment Notice), we finalized the benefit and payment parameters for the 2017 benefit year to expand the provisions related to the premium stabilization programs, set forth certain oversight provisions, and established the payment parameters in those programs.

• In the December 22, 2016 **Federal Register** (81 FR 94058) (2018 Payment Notice), we finalized the benefit and payment parameters for the 2018 benefit year, added the high-cost risk pool parameters to the HHS risk adjustment methodology, incorporated prescription drug factors in the adult models, established enrollment duration factors for the adult models, and finalized policies related to the collection and use of enrollee-level External Data Gathering Environment (EDGE) data.

• In the April 17, 2018 **Federal Register** (83 FR 16930) (2019 Payment Notice), we finalized the benefit and payment parameters for 2019 benefit year, created the State flexibility framework permitting States to request a reduction in risk adjustment State transfers calculated by HHS, and adopted a new methodology for HHS–RADV adjustments to transfers.

• In the May 11, 2018 **Federal Register** (83 FR 21925), we published a correction to the 2019 risk adjustment coefficients in the 2019 Payment Notice final rule.

• On July 27, 2018, consistent with 45 CFR 153.320(b)(1)(i), we updated the 2019 benefit year final risk adjustment model coefficients to reflect an additional recalibration related to an update to the 2016 enrollee-level EDGE dataset.[5]

• In the July 30, 2018 **Federal Register** (83 FR 36456), we adopted the 2017 benefit year risk adjustment methodology as established in the final rules published in the March 23, 2012 (77 FR 17220 through 17252) and March 8, 2016 editions of the **Federal Register** (81 FR 12204 through 12352). The final rule set forth an additional explanation of the rationale supporting the use of Statewide average premium in the HHS-operated risk adjustment State payment transfer formula for the 2017 benefit year, including the reasons why the program is operated in a budget-neutral manner. The final rule also permitted HHS to resume 2017 benefit year risk adjustment payments and charges. HHS also provided guidance as to the operation of the HHS-operated risk adjustment program for the 2017 benefit year in light of the publication of the final rule.

• In the December 10, 2018 **Federal Register** (83 FR 63419), we adopted the 2018 benefit year HHS-operated risk adjustment methodology as established in the final rules published in the March 23, 2012 (77 FR 17219) and the December 22, 2016 (81 FR 94058) editions of the **Federal Register**. In the rule, we set forth an additional explanation of the rationale supporting the use of Statewide average premium in the HHS-operated risk adjustment State payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner.

• In the April 25, 2019 **Federal Register** (84 FR 17454) (2020 Payment Notice), we finalized the benefit and payment parameters for 2020 benefit year, as well as the policies related to making the enrollee-level EDGE data available as a limited data set for research purposes and expanding the HHS uses of the enrollee-level EDGE data, approval of the request from Alabama to reduce risk adjustment transfers by 50 percent in the small group market for the 2020 benefit year, and updates to HHS–RADV program requirements.

• On May 12, 2020, consistent with 153.320(b)(1)(i), we published the 2021 Benefit Year Final HHS Risk Adjustment Model Coefficients on the CCIIO website.[6]

• In the May 14, 2020 **Federal Register** (85 FR 29164) (2021 Payment Notice), we finalized the benefit and payment parameters for 2021 benefit year, as well as adopted updates to the risk adjustment models' hierarchical condition categories (HCCs) to transition to ICD–10 codes, approved the request from Alabama to reduce risk adjustment transfers by 50 percent in small group market for the 2021 benefit year, and modified the outlier identification process under the HHS–RADV program.

• In the December 1, 2020 **Federal Register** (85 FR 76979) (Amendments to the HHS-Operated Risk Adjustment Data Validation Under the Patient Protection and Affordable Care Act's HHS-Operated Risk Adjustment Program (2020 HHS–RADV Amendments Rule)), we adopted the creation and application of Super HCCs in the sorting step that assigns HCCs to failure rate groups, finalized a sliding scale adjustment in HHS–RADV error rate calculation, and added a constraint for negative error rate outliers with a negative error rate. We also established a transition from the prospective application of HHS–RADV adjustments to apply HHS–RADV results to risk scores from the same benefit year as that being audited.

• In the September 2, 2020 **Federal Register** (85 FR 54820), we issued an interim final rule containing certain policy and regulatory revisions in response to the COVID–19 public health emergency (PHE), wherein we set forth risk adjustment reporting requirements for issuers offering temporary premium credits in the 2020 benefit year.

• In the May 5, 2021 **Federal Register** (86 FR 24140), we issued part 2 of the 2022 Payment Notice final rule (2022 Payment Notice) finalizing a subset of proposals from the 2022 Payment Notice proposed rule, including policy and regulatory revisions related to the risk adjustment program, finalization of the benefit and payment parameters for the 2022 benefit year, and approval of the request from Alabama to reduce risk adjustment transfers by 50 percent in the individual and small group markets for the 2022 benefit year. In addition, this final rule established a revised schedule of collections for HHS–RADV and updated the provisions regulating second validation audit (SVA) and initial validation audit (IVA) entities.

• On July 19, 2021, consistent with § 153.320(b)(1)(i), we released Updated 2022 Benefit Year Final HHS Risk Adjustment Model Coefficients on the CCIIO website, announcing some minor revisions to the 2022 benefit year final risk adjustment adult model coefficients.[7]

• In the May 6, 2022 **Federal Register** (87 FR 27208) (2023 Payment Notice), we finalized revisions related to the risk adjustment program, including the benefit and payment parameters for the 2023 benefit year, risk adjustment model recalibration, and collection and extraction of enrollee-level EDGE data.

[5] CMS. (2018, July 27). *Updated 2019 Benefit Year Final HHS Risk Adjustment Model Coefficients. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Updtd-Final-HHS-RA-Model-Coefficients.pdf.*

[6] CMS. (2020, May 12). *Final 2021 Benefit Year Final HHS Risk Adjustment Model Coefficients. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf.*

[7] *See* CMS. (2021, July 19). *2022 Benefit Year Final HHS Risk Adjustment Model Coefficients. https://www.cms.gov/files/document/updated-2022-benefit-year-final-hhs-risk-adjustment-model-coefficients-clean-version-508.pdf.*

We also finalized the adoption of the interacted HCC count specification for the adult and child models, along with modified enrollment duration factors for the adult model models, beginning with the 2023 benefit year.[8] We also repealed the ability for States, other than prior participants, to request a reduction in risk adjustment State transfers starting with the 2024 benefit year. In addition, we approved a 25 percent reduction to 2023 benefit year transfers in Alabama's individual market and a 10 percent reduction to 2023 benefit year transfers in Alabama's small group market. We also finalized further refinements to the HHS–RADV error rate calculation methodology beginning with the 2021 benefit year and beyond.

2. Program Integrity

We have finalized program integrity standards related to the Exchanges and premium stabilization programs in two rules: the ''first Program Integrity Rule'' published in the August 30, 2013 **Federal Register** (78 FR 54069), and the ''second Program Integrity Rule'' published in the October 30, 2013 **Federal Register** (78 FR 65045). We also refer readers to the 2019 Patient Protection and Affordable Care Act; Exchange Program Integrity rule published in the December 27, 2019 **Federal Register** (84 FR 71674).

3. Market Rules

For past rulemaking related to the market rules, we refer readers to the following rules:

- In the April 8, 1997 **Federal Register** (62 FR 16894), HHS, with the Department of Labor and Department of the Treasury, published an interim final rule relating to the HIPAA health insurance reforms. In the February 27, 2013 **Federal Register** (78 FR 13406) (2014 Market Rules), we published the health insurance market rules.
- In the May 27, 2014 **Federal Register** (79 FR 30240) (2015 Market Standards Rule), we published the Exchange and Insurance Market Standards for 2015 and Beyond.
- In the December 22, 2016 **Federal Register** (81 FR 94058), we provided additional guidance on guaranteed availability and guaranteed renewability.
- In the April 18, 2017 **Federal Register** (82 FR 18346) (Market Stabilization final rule), we further interpreted the guaranteed availability provision.
- In the April 17, 2018 **Federal Register** (83 FR 17058) (2019 Payment Notice final rule), we clarified that certain exceptions to the special enrollment periods only apply to coverage offered outside of the Exchange in the individual market.
- In the June 19, 2020 **Federal Register** (85 FR 37160) (2020 section 1557 final rule), in which HHS discussed section 1557 of the ACA, HHS removed nondiscrimination protections based on gender identity and sexual orientation from the guaranteed availability regulation.
- In part 2 of the 2022 Payment Notice final rule in the May 5, 2021 **Federal Register** (86 FR 24140), we made additional amendments to the guaranteed availability regulation regarding special enrollment periods and finalized new special enrollment periods related to untimely notice of triggering events, cessation of employer contributions or government subsidies to COBRA continuation coverage, and loss of APTC eligibility.
- In the September 27, 2021 **Federal Register** (86 FR 53412) (part 3 of the 2022 Payment Notice final rule), which was published by HHS and the Department of the Treasury, we finalized additional amendments to the guaranteed availability regulations regarding special enrollment periods.
- In the May 6, 2022 **Federal Register** (87 FR 27208), we finalized a revision to our interpretation of the guaranteed availability requirement to prohibit issuers from applying a premium payment to an individual's or employer's past debt owed for coverage and refusing to effectuate enrollment in new coverage.

4. Exchanges

We published a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to States on Exchanges on November 18, 2010. In the March 27, 2012 **Federal Register** (77 FR 18309) (Exchange Establishment Rule), we implemented the Affordable Insurance Exchanges (''Exchanges''), consistent with title I of the ACA, to provide competitive marketplaces for individuals and small employers to directly compare available private health insurance options on the basis of price, quality, and other factors. This included implementation of components of the Exchanges and standards for eligibility for Exchanges, as well as network adequacy and ECP certification standards.

In the 2014 Payment Notice and the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541), we set forth standards related to Exchange user fees. We established an adjustment to the FFE user fee in the Coverage of Certain Preventive Services under the Affordable Care Act final rule, published in the July 2, 2013 **Federal Register** (78 FR 39869) (Preventive Services Rule).

In the 2016 Payment Notice, we also set forth the ECP certification standard at § 156.235, with revisions in the 2017 Payment Notice in the March 8, 2016 **Federal Register** (81 FR 12203) and the 2018 Payment Notice in the December 22, 2016 **Federal Register** (81 FR 94058).

In an interim final rule, published in the May 11, 2016 **Federal Register** (81 FR 29146), we made amendments to the parameters of certain special enrollment periods (2016 Interim Final Rule). We finalized these in the 2018 Payment Notice final rule, published in the December 22, 2016 **Federal Register** (81 FR 94058).

In the April 18, 2017 Market Stabilization final rule **Federal Register** (82 FR 18346), we amended standards relating to special enrollment periods and QHP certification. In the 2019 Payment Notice final rule, published in the April 17, 2018 **Federal Register** (83 FR 16930), we modified parameters around certain special enrollment periods. In the April 25, 2019 **Federal Register** (84 FR 17454), the final 2020 Payment Notice established a new special enrollment period.

We published the final rule in the May 14, 2020 **Federal Register** (85 FR 29164) (2021 Payment Notice).

In the January 19, 2021 **Federal Register** (86 FR 6138), we finalized part 1 of the 2022 Payment Notice final rule that finalized only a subset of the proposals in the 2022 Payment Notice proposed rule. In the May 5, 2021 **Federal Register** (86 FR 24140), we published part 2 of the 2022 Payment Notice final rule. In the September 27, 2021 **Federal Register** (86 FR 53412) part 3 of the 2022 Payment Notice final rule, in conjunction with the Department of the Treasury, we finalized amendments to certain policies in part 1 of the 2022 Payment Notice final rule.

In the May 6, 2022 **Federal Register** (87 FR 27208), we finalized changes to maintain the user fee rate for issuers offering plans through the FFEs and maintain the user fee rate for issuers offering plans through the SBE–FPs. We also finalized various policies to address certain agent, broker, and web-broker practices and conduct. We also finalized updates to the requirement that all

[8] On May 6, 2022, we also published the *2023 Benefit Year Final HHS Risk Adjustment Model Coefficients* at *https://www.cms.gov/files/document/2023-benefit-year-final-hhs-risk-adjustment-model-coefficients.pdf*.

Exchanges conduct special enrollment period verifications.

5. Essential Health Benefits

On December 16, 2011, HHS released a bulletin that outlined an intended regulatory approach for defining EHB, including a benchmark-based framework. We established requirements relating to EHBs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was published in the February 25, 2013 **Federal Register** (78 FR 12833) (EHB Rule). In the 2019 Payment Notice, published in the April 17, 2018 **Federal Register** (83 FR 16930), we added § 156.111 to provide States with additional options from which to select an EHB-benchmark plan for plan years (PYs) 2020 and beyond.

B. Summary of Major Provisions

The regulations outlined in this proposed rule would be codified in 45 CFR parts 153, 155, and 156.

1. 45 CFR Part 153

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2023, the permanent risk adjustment program is subject to the fiscal year 2023 sequestration.[9] Therefore, the risk adjustment program will be sequestered at a rate of 5.7 percent for payments made from fiscal year 2023 resources (that is, funds collected during the 2023 fiscal year). The funds that are sequestered in fiscal year 2023 from the risk adjustment program will become available for payment to issuers in fiscal year 2024 without further Congressional action. HHS did not receive any requests from States to operate risk adjustment for the 2024 benefit year; therefore, HHS will operate risk adjustment in every State and the District of Columbia for the 2024 benefit year.

We propose to recalibrate the 2024 benefit year risk adjustment models using the 2018, 2019, and 2020 benefit year enrollee-level EDGE data, with an exception for the use of the 2020 benefit year to recalibrate the adult model age-sex coefficients. We propose to use only 2018 and 2019 benefit year enrollee-level EDGE data in the recalibration of the adult age-sex coefficients to account for the observed anomalies in the 2020 benefit year enrollee-level EDGE data for older adult enrollees, especially older adult female enrollees.

For the 2024 benefit year, we propose to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the risk adjustment models (see, for example, 84 FR 17463 through 17466). In addition, we are soliciting comment on whether to consider adding a new payment HCC for gender dysphoria to the risk adjustment models for future years.

We propose under § 153.320(d) to repeal the flexibility for States to request reductions of risk adjustment State transfers calculated by HHS under the State payment transfer formula in all State market risk pools, including prior participant States that previously requested a reduction, for the 2025 benefit year and beyond. We also seek comment on the requests from Alabama to reduce risk adjustment State transfers in its individual and small group markets by 50 percent for the 2024 benefit year.

Additionally, we propose, beginning with the 2023 benefit year, to collect and extract from issuers' EDGE servers through issuers' EDGE Server Enrollment Submission (ESES) files and risk adjustment recalibration enrollment files a new data element, a Qualified Small Employer Health Reimbursement Arrangement (QSEHRA) indicator. In addition, we propose to extract the plan identifier and rating area data elements from issuers' EDGE servers for benefit years prior to the 2021 benefit year. We also propose a risk adjustment user fee for the 2024 benefit year of $0.21 per member per month (PMPM).

Beginning with the 2022 benefit year HHS–RADV, we propose to change the materiality threshold established under § 153.630(g)(2) for random and targeted sampling from $15 million in total annual premiums Statewide to 30,000 total billable member months (BMM) Statewide, calculated by combining an issuer's enrollment in a State's individual non-catastrophic, catastrophic, small group, and merged markets, as applicable, in the benefit year being audited.

Beginning with the 2021 benefit year HHS–RADV, we propose to no longer exempt exiting issuers from adjustments to risk scores and risk adjustment transfers when they are negative error rate outliers in the applicable benefit year's HHS–RADV. Thus, HHS would apply HHS–RADV results to adjust the plan liability risk scores and State transfers of all issuers. We also solicit comments on discontinuing the use of the lifelong permanent condition list and the use of Non-EDGE Claims in HHS–RADV.

We propose to shorten the window to confirm the findings of the second validation audit (SVA) (if applicable),[10] or file a discrepancy report to dispute the SVA findings, to within 15 calendar days of the notification by HHS, beginning with the 2022 benefit year HHS–RADV.

We propose to amend the EDGE discrepancy materiality threshold set forth at § 153.710(e) to align with and mirror the policy finalized in preamble in part 2 of the 2022 Payment Notice (86 FR 24194 through 24195). That is, the materiality threshold at § 153.710(e) would be revised to provide that the amount in dispute must equal or exceed $100,000 or one percent of the total estimated transfer amount in the applicable State market risk pool, whichever is less.

2. 45 CFR Part 155

In part 155, we propose to revise the Exchange Blueprint approval timelines for States transitioning from either a FFE to a SBE–FP or to a State-based Exchange (SBE), or from a SBE–FP to a SBE. We propose to remove the deadlines for when HHS provides approval, or conditional approval, on an Exchange Blueprint, and instead propose to require that such approval is provided at some point prior to the date on which the Exchange proposes to begin open enrollment either as an SBE or SBE–FP.

We propose a change to address the standards applicable to Navigators and other assisters and their consumer service functions. At § 155.210(d)(8), we propose to remove the prohibition on Navigators from going door-to-door or using other unsolicited means of direct contact to help provide consumers with enrollment assistance. The proposal would also apply to non-Navigator assistance personnel in FFEs and in State Exchanges if funded with section 1311(a) Exchange Establishment grants, through the reference to § 155.210(d) in § 155.215(a)(2)(i). In § 155.225(g)(5), we propose to remove the prohibition on certified application counselors from going door-to-door or using unsolicited means of direct contact to help consumers fill out applications or enroll in health coverage. We believe that these proposals would allow Navigators and other assisters in the FFEs to help more consumers.

In part 155, we propose changes to address certain agent, broker, and web-

[9] OMB. (2022, March 28). OMB Report to the Congress on the BBEDCA 251A Sequestration for Fiscal Year 2023. *https://www.whitehouse.gov/wpcontent/uploads/2022/03/BBEDCA_251A_Sequestration_Report_FY2023.pdf.*

[10] Only those issuers who have insufficient pairwise agreement between the Initial Validation Audit (IVA) and SVA receive SVA findings. See 84 FR 17495; 86 FR 24201.

broker practices. We propose to allow HHS up to an additional 15 calendar days to review evidence submitted by agents, brokers, or web-brokers to rebut allegations that led to suspension of their Exchange agreement(s). We also propose to allow HHS up to an additional 30 calendar days to review evidence submitted by agents, brokers, or web-brokers that led to termination of their Exchange agreement(s). The proposal would provide HHS with up to 45 or 60 calendar days to review and respond to such evidence or requests for reconsideration submitted by agents, brokers, or web-brokers stemming from the suspension or termination of their Exchange agreement(s), respectively.

Further, we propose to require agents, brokers, or web-brokers assisting consumers with completing eligibility applications through the FFEs and SBE–FPs or assisting an individual with applying for APTC and CSRs for QHPs to document that eligibility application information has been reviewed by and confirmed to be accurate by the consumer or their authorized representative prior to application submission. We propose that the documentation would be required to include: the date the information was reviewed; the name of the consumer or their authorized representative; an explanation of the attestations at the end of the eligibility application; and the name of the assisting agent, broker, or web-broker. Furthermore, the documentation would be required to be maintained by the agent, broker, or web-broker for a minimum of 10 years and produced upon request in response to monitoring, audit, and enforcement activities.

We also propose to require agents, brokers, or web-brokers assisting consumers with applying and enrolling through FFEs and SBE–FPs, making updates to an existing application, or assisting an individual with applying for APTC and CSRs for QHPs to document the receipt of consent from the consumer or their authorized representative seeking assistance prior to providing assistance, which would include the consumer taking an action that produces a record of consent and the maintenance of that record by the agent, broker, or web-broker. We also propose standards for the content of the documentation of consent, including that it would be required to include a description of the scope, purpose, and duration of the consent provided by the consumer or their authorized representative, the date consent was given, name of the consumer or their authorized representative, and the name of the agent, broker, web-broker, or agency being granted consent, as well as the process by which the consumer or their authorized representative may rescind consent. Further, we propose that agents, brokers, or web-brokers would be required to maintain the consent documentation for a minimum of 10 years and produced upon request in response to monitoring, audit, and enforcement activities.

We propose to revise the failure to file and reconcile (FTR) process at § 155.305(f)(4). First, we are proposing codify CMS's guidance that, for plan year 2023 coverage, the Exchanges on the Federal platform would not act on data from the IRS for consumers who have failed to file tax returns and reconcile a previous year's APTC with the PTC allowed for the year. Second, we propose to provide that, beginning on January 1, 2024, Exchanges must once again determine enrollees ineligible for APTC when HHS notifies the Exchange that a taxpayer (or a taxpayer's spouse, if married) has failed to file a Federal income tax return and reconcile their past APTC. However, we propose that an Exchange may only determine enrollees ineligible for APTC after a taxpayer (or a taxpayer's spouse, if married) has failed to file a Federal income tax return and reconcile their past APTC for two consecutive years. We also propose a technical correction to § 155.305(f)(4) to clarify that HHS receives data from the IRS for consumers who have failed to file tax returns and reconcile a previous year's APTC.

We propose to amend § 155.320 to require Exchanges to accept an applicant's attestation of projected annual household income when the Exchange requests tax return data from the IRS to verify attested projected annual household income, but the IRS confirms there is no such tax return data available. Further, we propose to revise § 155.315 to add that an enrollee with income inconsistencies must receive a 60-day extension in addition to the 90 days currently provided in § 155.315(f)(2)(ii). These changes would ensure consumers are treated equitably, ensure continuous coverage, and strengthen the risk pool.

In the 2023 Payment Notice proposed rule (87 FR 584, 652), we solicited comments on revising the re-enrollment hierarchy at § 155.335(j) at a later date, and, after considering comments, we now propose amending and adding several provisions to this regulation to provide Exchanges (including Exchanges on the Federal platform and SBEs) with the option to make certain changes to the re-enrollment hierarchy beginning for PY 2024. Specifically, we propose to allow Exchanges to direct re-enrollment for CSR-eligible enrollees from a bronze QHP to a silver QHP with a lower or equivalent net premium under the same product and QHP issuer, regardless of whether the enrollee's current plan is available. We believe directing re-enrollment into lower or same cost, high generosity plans would place enrollees in more affordable plans with lower out-of-pocket costs, which would lower health insurance costs for those lower-income (CSR-eligible) individuals. We also propose to allow the Exchange to incorporate provider network considerations into the Exchange re-enrollment hierarchy.

We are proposing changes related to SEPs at § 155.420. First, we propose two technical corrections to § 155.420(a)(4)(ii)(A) and (B) to align the text with § 155.420(a)(d)(6)(i) and (ii). The proposed revisions would clarify that only one person in a tax household applying for coverage or financial assistance through the Exchange must qualify for an SEP in order for the entire tax household to qualify for the SEP. Second, we propose to change the current coverage effective date requirements at § 155.420(b)(2)(iv) to permit Exchanges to offer earlier coverage effective start dates for consumers attesting to a future loss of MEC. These changes would ensure qualifying individuals are able to seamlessly transition from other forms of coverage to Exchange coverage as quickly as possible with minimal coverage gaps.

Third, to mitigate coverage gaps, we are proposing to add § 155.420(c)(6) in which Exchanges would have the option to implement a new special rule for consumers eligible for a SEP under § 155.420(d)(1) due to loss of Medicaid or CHIP coverage which would give consumers up to 90 days after their loss of Medicaid or CHIP coverage to select a plan for Exchange coverage. Fourth, we are proposing to revise § 155.420(d)(12) to align the policy of the Exchanges on the Federal platform for granting SEPs to persons who are adversely affected by a plan display error with current plan display error SEP operations. The proposal would remove the burden from the consumer to solely demonstrate to the Exchange that a material plan display error has influenced the consumer's decision to purchase a QHP through the Exchange.

We propose to add § 155.430(b)(3) to explicitly prohibit issuers participating in Exchanges on the Federal platform from terminating coverage for a dependent child prior to the end of the plan year because the dependent child has reached the applicable maximum

age. This change would provide clarity to issuers participating in Exchanges on the Federal platform regarding their obligation to maintain coverage for dependent children, as well as to enrollees regarding their ability to maintain coverage for dependent children. This proposal would be optional for State Exchanges.

We propose to revise § 155.505(g) to acknowledge the ability of the CMS Administrator to review Exchange eligibility appeals decisions prior to judicial review. This change would provide appellants and other parties with accurate information about the availability of administrative review by the CMS Administrator if they are dissatisfied with their eligibility appeal decision.

HHS proposes to implement a new Improper Payment Pre-Testing and Assessment (IPPTA) program under which State Exchanges will be required to participate in pre-audit activities that will prepare State Exchanges for complying with audits required under the Payment Integrity Information Act of 2019 (PIIA). Activities under the proposed IPPTA program would provide State Exchanges experience helpful to preparing for future PIIA audits and will help HHS design and refine appropriate requirements for future PIIA audits of State Exchanges.

3. 45 CFR Part 156

In part 156, we propose user fee rates for the 2024 benefit year for all issuers participating on the Exchanges using the Federal platform. For the 2024 benefit year, we propose an FFE user fee rate of 2.5 percent of total monthly premiums and an SBE–FP user fee rate of 2.0 percent of total monthly premiums. HHS will issue the 2024 benefit year premium adjustment percentage index and related payment parameters in guidance, consistent with the policy finalized in part 2 of the 2022 Payment Notice.

For PY 2024 and subsequent PYs, HHS would maintain a large degree of continuity with the approach to standardized plan options finalized in the 2023 Payment Notice and proposes only minor updates in this proposed rule. In particular, in contrast to the policy finalized in the 2023 Payment Notice, we are proposing to no longer include a standardized plan option for the non-expanded bronze metal level, mainly due to AV constraints. Thus, for PY 2024 and subsequent PYs, we propose standardized plan options for the following metal levels: one bronze plan that meets the requirement to have an AV up to five percentage points above the 60 percent standard, as specified in § 156.140(c) (known as an expanded bronze plan); one standard silver plan; one version of each of the three income-based silver CSR plan variations; one gold plan; and one platinum plan. We would continue to differentially display standardized plan options, including those standardized plan options required under State action that took place on or before January 1, 2020, on *HealthCare.gov,* and would continue enforcement of the standardized plan options display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic Direct Enrollment (DE) and Enhanced Direct Enrollment (EDE) Pathways.

To mitigate the risk of choice overload, HHS proposes to limit the number of non-standardized plan options that QHP issuers may offer through the Exchanges using the Federal platform to two non-standardized plan options per product network type and metal level (excluding catastrophic plans), in any service area for PY 2024 and beyond. In addition, HHS proposes, as an alternative to the proposal to limit the number of non-standardized plan options that an FFE or SBE–FP issuer may offer on the Exchange, to apply a meaningful difference standard which would be more stringent than the previous standard. HHS proposes to strengthen the standard by modifying the criteria and difference thresholds used to determine whether plans are ''meaningfully different'' from one another.

We propose to require stand-alone dental plan (SADP) issuers to use age on effective date as the sole method to calculate an enrollee's age for rating and eligibility purposes beginning with Exchange certification for PY 2024. Requiring SADPs to use the age on effective date methodology to calculate an enrollee's age as a condition of QHP certification, and consequently removing the less commonly used and more complex age calculation methods, would reduce consumer confusion and promote operational efficiency. We propose that this policy would apply to Exchange-certified SADPs as a requirement of certification, whether they are sold on- or off-Exchange.

In addition, we propose to require Exchange-certified SADP issuers to submit guaranteed rates as a condition of QHP certification beginning with Exchange certification for PY 2024. This change would help reduce the risk of incorrect APTC calculation for the pediatric dental EHB portion of premiums, thereby reducing the risk of consumer harm. We propose that this policy would apply to Exchange-certified SADPs as a requirement of certification, whether they are sold on- or off-Exchange.

We propose at § 156.225 to require that plan and plan variation marketing names for QHPs offered through Exchanges on the Federal platform include correct information, without omission of material fact, and not include content that is misleading. If finalized as proposed, CMS would review plan and plan variation marketing names during the annual QHP certification process in close collaboration with State regulators.

We propose to revise the network adequacy and ECP standards at §§ 156.230 and 156.235 to provide that all individual market QHPs and SADPs and all Small Business Health Options Program (SHOP) QHPs across all Exchanges must use a network of providers that complies with the network adequacy and ECP standards in those sections, and to remove the exception that these sections do not apply to plans that do not use a provider network.

To expand access to care for low-income and medically underserved consumers, we propose to establish two additional stand-alone ECP categories at § 156.235(a)(2)(ii)(B) for PY 2024 and subsequent PYs, Mental Health Facilities and Substance Use Disorder Treatment Centers. HHS also proposes to require QHP issuers to contract with at least 35 percent of available FQHCs and at least 35 percent of available Family Planning Providers that qualify as an ECP in the plan's service area, in addition to meeting the current overall 35 percent ECP threshold requirement in the plan's service area.

We propose to add a timeliness standard to the requirement at § 156.270(f) for QHP issuers to send enrollees a notice of payment delinquency. Specifically, we propose to require issuers to send notices of payment delinquency promptly and without undue delay. This proposed revision will help ensure that enrollees are aware they are at risk of losing coverage and can avoid losing coverage by paying any outstanding premium amounts promptly.

We propose to revise the final deadline in § 156.1210(c) for issuers to report data inaccuracies identified in payment and collections reports for discovered underpayments of APTC to the issuer and user fee overpayments to HHS. Specifically, we propose to remove the deadline set forth at § 156.1210(c)(2). Under this proposal, we would retain only the deadline at

§ 156.1210(c)(1), which requires that issuers describe all inaccuracies identified in a payment and collections report within three years of the end of the applicable plan year to which the inaccuracy relates to be eligible to receive an adjustment to correct an underpayment of APTC to the issuer and user fee overpayments to HHS. Under this proposal, beginning with the 2020 plan year coverage, HHS would not pay additional APTC payments or reimburse user fee payments for FFE, SBE–FP, and SBE issuers for data inaccuracies reported after the 3-year deadline. Further, we propose that HHS would not accept or take action that results in an outgoing payment on data inaccuracies or payment errors (except those identifying an overpayment by HHS) for the 2015 through 2019 plan year coverage that are reported after December 31, 2023. This proposal would better align with the existing IRS limitation on filing corrected Federal tax returns and reduce administrative and operational burden on issuers, State Exchanges, and HHS when handling payment and enrollment dispute.

III. Provisions of the Proposed Regulations

A. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment

In subparts A, D, G, and H of part 153, we established standards for the administration of the risk adjustment program. The risk adjustment program is a permanent program created by section 1343 of the ACA that transfers funds from lower-than-average risk, risk adjustment covered plans to higher-than-average risk, risk adjustment covered plans in the individual, small group markets, or merged markets, inside and outside the Exchanges. In accordance with § 153.310(a), a State that is approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf.[11] HHS did not receive any requests from States to operate risk adjustment for the 2024 benefit year. Therefore, HHS will operate risk adjustment in every State and the District of Columbia for the 2024 benefit year.

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2023, the permanent risk adjustment program is subject to the fiscal year 2023 sequestration.[12] The Federal Government's 2023 fiscal year began on October 1, 2022. Therefore, the risk adjustment program will be sequestered at a rate of 5.7 percent for payments made from fiscal year 2023 resources (that is, funds collected during the 2023 fiscal year).

HHS, in coordination with OMB, has determined that, under section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985,[13] as amended, and the underlying authority for the risk adjustment program, the funds that are sequestered in fiscal year 2023 from the risk adjustment program will become available for payment to issuers in fiscal year 2024 without further Congressional action. If Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, the program would be sequestered in future fiscal years, and any sequestered funding would become available in the fiscal year following that in which it was sequestered.

Additionally, we note that the Infrastructure Investment and Jobs Act[14] amended section 251A(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 and extended sequestration for the risk adjustment program through fiscal year 2031 at a rate of 5.7 percent per fiscal year.[15] [16]

2. HHS Risk Adjustment (§ 153.320)

The HHS risk adjustment models predict plan liability for an average enrollee based on that person's age, sex, and diagnoses (also referred to as hierarchical condition categories (HCCs)), producing a risk score. The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for clinical and cost differences in each age group. In the adult and child models, the relative risk assigned to an individual's age, sex, and diagnoses are added together to produce an individual risk score. Additionally, to calculate enrollee risk scores in the adult models, we added enrollment duration factors beginning with the 2017 benefit year,[17] and prescription drug categories (RXCs) beginning with the 2018 benefit year.[18] Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of diagnoses. If applicable, the risk score for adults, children, or infants is multiplied by a cost-sharing reduction (CSR) factor. The enrollment-weighted average risk score of all enrollees in a particular risk adjustment covered plan (also referred to as the plan liability risk score (PLRS)) within a geographic rating area is one of the inputs into the risk adjustment State payment transfer formula,[19] which determines the State transfer payment or charge that an issuer will receive or be required to pay for that plan for the applicable State market risk pool. Thus, the HHS risk adjustment models predict average group costs to account for risk across plans, in keeping with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

a. Data for Risk Adjustment Model Recalibration for 2024 Benefit Year

We propose to use 2018, 2019 and 2020 benefit year enrollee-level EDGE data to recalibrate the 2024 benefit year risk adjustment models with an exception to exclude the 2020 benefit year data from the blending of the age-sex coefficients for the adult models.

In accordance with § 153.320, HHS develops and publishes the risk adjustment methodology applicable in States where HHS operates the program, including the draft factors to be employed in the models for the benefit year. This includes information related to the annual recalibration of the risk adjustment models using data from the most recent available prior benefit years trended forwarded to reflect the

[11] See also 42 U.S.C. 18041(c)(1).

[12] OMB. (2022, March 28). OMB Report to the Congress on the BBEDCA 251A Sequestration for Fiscal Year 2023. *https://www.whitehouse.gov/wp-content/uploads/2022/03/BBEDCA_251A_Sequestration_Report_FY2023.pdf.*

[13] Public Law 99–177 (1985).

[14] Public Law 117–58, 135 Stat. 429 (2021).

[15] 2 U.S.C. 901a.

[16] The Coronavirus Aid, Relief, and Economic Security (CARES) Act previously amended section 251A(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 and extended sequestration for the risk adjustment program through fiscal year 2023 at a rate of 5.7 percent per fiscal year. Section 4408 of the CARES Act, Public Law 116–136, 134 Stat. 281 (2020).

[17] For the 2017 through 2022 benefit years, there is a set of 11 binary enrollment duration factors in the adult models that decrease monotonically from one to 11 months, reflecting the increased annualized costs associated with fewer months of enrollments. See, for example, 81 FR 94071 through 94074. These enrollment duration factors were replaced beginning with the 2023 benefit year with HCC-contingent enrollment duration factors for up to 6 months in the adult models. See, for example, 87 FR 27228 through 27230.

[18] For the 2018 benefit year, there were 12 RXCs, but starting with the 2019 benefit year, the two severity-only RXCs were removed from the adult risk adjustment models. See, for example, 83 FR 16941.

[19] The State payment transfer formula refers to the part of the HHS risk adjustment methodology that calculates payments and charges at the State market risk pool level prior to the calculation of the high-cost risk pool payment and charge terms that apply beginning with the 2018 BY. See, for example, 81 FR 94080.

applicable benefit year of risk adjustment.

Our proposed approach for 2024 recalibration aligns with the approach finalized in the 2022 Payment Notice (86 FR 24151 through 24155) and reiterated in the 2023 Payment Notice (87 FR 27220 through 27221), that involves use of the 3 most recent consecutive years of enrollee-level EDGE data that are available at the time we incorporate the data in the draft recalibrated coefficients published in the proposed rule for the applicable benefit year, and not updating the coefficients between the proposed and final rules if an additional year of enrollee-level EDGE data becomes available for incorporation. We continue to believe this approach promotes stability, better meets the goal of the risk adjustment program, and allows issuers more time to incorporate this information when pricing their plans for the upcoming benefit year than the previous approach which allowed for updates to the data used for recalibration if more data became available between the proposed and final rules.

As such, we propose to determine coefficients for the 2024 benefit year based on a blend of separately solved coefficients from the 2018, 2019, and 2020 benefit years of enrollee-level EDGE data, with an exception to exclude the 2020 benefit year data from the blending of the age-sex coefficients for the adult models. For all adult model age-sex coefficients, we propose to use only 2018 and 2019 benefit year enrollee-level EDGE data in recalibration to account for the observed anomalous decreases in the unconstrained coefficients [20] for the 2020 benefit year enrollee-level EDGE data for older adult enrollees, especially older adult female enrollees.

To further explain, due to the potential impact of the COVID–19 PHE on costs and utilization of services in 2020, HHS considered whether the 2020 enrollee-level EDGE data was appropriate for use in the annual model recalibration for the HHS-operated risk adjustment program applicable to the individual and small group (including merged) markets. As part of this analysis, we considered comments received in response to the 2023 Payment Notice proposed rule (87 FR 598), wherein we sought comments on the future use of the 2020 enrollee-level EDGE data due to the potential impact of the COVID–19 PHE. The current policy that involves using the 3 most recent years of EDGE data available as of the proposed rule for the annual risk adjustment model recalibration promotes stability and ensures the models reflect the year-over-year changes to the markets' patterns of utilization and spending without over-relying on any factors unique to one particular year. This approach was put in place based on feedback from issuers and other interested parties and our experience operating the program since the 2014 benefit year. Furthermore, we know from our experience that every year of data can be unique and therefore some level of deviation from year to year is expected.[21] These general considerations all weigh in favor of including the 2020 benefit year data in the recalibration of the risk adjustment models.

However, we recognize that if a benefit year has significant changes that differentially impact certain conditions or populations relative to others, or is sufficiently anomalous relative to expected future patterns of care, we should carefully consider what impact that benefit year of data could have if it is used in the annual model recalibration for the HHS-operated risk adjustment program. This includes consideration of whether to exclude or adjust that benefit year of data to increase the models' predictive validity or otherwise limit the impact of anomalous trends. The situation presented by the COVID–19 PHE and its potential impact on utilization and costs in the 2020 benefit year is an example [22] of a situation that requires this additional consideration. Thus, to help further inform HHS' decision on whether it is appropriate to use 2020 enrollee-level EDGE data to calibrate the risk adjustment coefficients, HHS analyzed the 2020 benefit year enrollee-level EDGE recalibration data to assess how it compares to 2019 benefit year enrollee-level EDGE recalibration data. Our results found:

- The total sample size in the recalibration data set was similar between the 2019 and 2020 benefit years, with the individual market at the national level seeing an increase in enrollment in the 2020 benefit year and the small group market at the national level seeing a slight decrease in enrollment in the 2020 benefit year.
- In the 2020 EDGE enrollee-level recalibration data set, even though PMPM spending dropped substantially between March and April 2020, the total PMPM spending in the 2020 benefit year was similar to the 2019 benefit year, with the institutional and professional services PMPM slightly decreasing, preventive services PMPM notably decreasing, and the drug PMPM increasing. This represents a departure from historical medical costs trends, which have generally seen increases year-over-year in all cost categories.
- Across all data submitted through issuer's EDGE servers for the 2020 benefit year, we observed a large increase in telehealth paid claims amounts when compared to all data submitted through issuer's EDGE servers for the 2019 benefit year.
- The number of enrollees with one or more HCC was relatively stable between the 2019 and 2020 benefit year enrollee-level EDGE recalibration data sets in both the recalibration and full data sets.[23]
- Individual HCC frequencies and costs generally remained constant between the 2019 and 2020 benefit year enrollee-level EDGE recalibration data sets, even for the HCCs related to the severe manifestations of COVID–19. An exception was a notable increase in frequency for HCC 127 *Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes,* which was likely coded for cases in which acute respiratory distress syndrome (ARDS) was a manifestation of COVID–19, but relative allowed charges, and therefore, risk adjustment model coefficients, for HCC 127 remained similar in 2020 compared to 2019.

[20] HHS constrains the risk adjustment models in multiple distinct ways during model recalibration. These include (1) coefficient estimation groups, also referred to as G-Groups in the Risk Adjustment Do It Yourself (DIY) Software, (2) a priori stability constraints, and (3) hierarchy violation constraints. Of these, coefficient estimation groups and a priori stability constraints are applied prior to model fitting. The hierarchy violation constraints are applied after the initial estimates of coefficients are produced. We refer to the models and coefficients prior to the application of hierarchy violation constraints as the ''unconstrained models'' and ''unconstrained coefficients,'' respectively. For a description of the various constraints we apply to the risk adjustment models, see, CMS' ''Potential Updates to HHS–HCCs for the HHS-operated Risk Adjustment Program'' (the ''2019 White Paper'') (June 17, 2019). *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Potential-Updates-to-HHS-HCCs-HHS-operated-Risk-Adjustment-Program.pdf.*

[21] Every year we expect some shifting in treatment and cost patterns, for example as new drugs come to market. Our goal in using multiple years of data for model calibration is to capture some degree of year-to-year cost shifting without over-relying on any factors unique to one particular year.

[22] In the 10 years since the start of HHS model calibration for benefit year 2014, the COVID–19 PHE has been the only such situation to date. Other events and policy changes have not risen to the same level of uniqueness or impact.

[23] CMS. (2021, June 30). Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year. *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf.*

• RXC frequencies and costs were generally stable between the 2019 and 2020 benefit year enrollee-level EDGE recalibration data sets, with the exception of RXC 10 *Cystic Fibrosis Agents,* for which a new drug was introduced that increased costs in the 2020 data compared to the 2019 data.

• The unconstrained coefficients for the 2020 benefit year enrollee-level EDGE recalibration data are similar to the 2019 benefit year's unconstrainted coefficients with one exception. The exception exists within the age-sex coefficients in the adult models where we found decreases among coefficients for older enrollees, especially female enrollees, which are likely due to decreases in discretionary spending among this age group in the 2020 benefit year.

In short, on many key dimensions, HHS found that the 2019 benefit year and 2020 benefit year enrollee-level EDGE data recalibration were largely comparable.

With this analysis in mind, and based on the comments received in response to the 2023 Payment Notice proposed rule,[24] HHS considered six different options for handling the 2020 benefit year enrollee-level EDGE recalibration data for purposes of the annual recalibration of the HHS risk adjustment models for the 2024 benefit year.[25] Four options involve the use of 2020 benefit year enrollee-level EDGE recalibration data in the risk adjustment model recalibration, and two involve the exclusion of the 2020 benefit year data. These six options are as follows:

• *Option 1:* Maintain the current policy, recalibrating the 2024 benefit year risk adjustment models using 2018, 2019, and 2020 enrollee-level EDGE data with no exceptions or modifications.

• *Option 2:* Maintain the current policy, recalibrating the 2024 benefit year risk adjustment models using 2018, 2019, and 2020 benefit year enrollee-level EDGE recalibration data, but assign a lower weight to 2020 data. Assigning a lower weight to the 2020 data would dampen its impact on the models while continuing to capture in part the utilization and spending patterns underlying the data.

• *Option 3:* Utilize 4 years of enrollee-level EDGE data, instead of three, to recalibrate the 2024 benefit year risk adjustment models using 2017, 2018, 2019, and 2020 benefit year data. This would serve the purpose of dampening the effect of the 2020 data on the models by incorporating an extra year of data from a prior benefit year that was not impacted by the COVID–19 PHE.

• *Option 4:* Maintain the current policy, recalibrating the 2024 benefit year risk adjustment models using 2018, 2019, and 2020 enrollee-level EDGE recalibration data with an exception to exclude the 2020 benefit year data from the blending of the age-sex coefficients for the adult models. Under this option, we would determine coefficients for the 2024 benefit year based on a blend of separately solved coefficients from the 2018, 2019, and 2020 benefit years of enrollee-level EDGE recalibration data and would exclude the 2020 benefit year from the recalibration of the adult models' age-sex coefficients. Instead, only 2018 and 2019 benefit year enrollee-level EDGE recalibration data would be used to recalibrate the adult risk adjustment models age-sex coefficients.[26]

• *Option 5:* Exclude the 2020 benefit year enrollee-level EDGE recalibration data and instead use the 2017, 2018, and 2019 benefit year enrollee-level EDGE recalibration data, trended forward to the 2024 benefit year, in recalibration of the risk adjustment models for the 2024 benefit year, or use the final 2023 risk adjustment model coefficients for the 2024 benefit year without trending the data to account for inflation and changes in costs and utilization between the 2023 and 2024 benefit years.

• *Option 6:* Exclude the 2020 benefit year enrollee-level EDGE recalibration data and instead use only 2 years of enrollee-level EDGE data for recalibration—that is, use only 2018 and 2019 benefit year data to recalibrate the 2024 risk adjustment models.

Although it is true our analyses found that the 2019 and 2020 benefit year enrollee-level EDGE recalibration data were largely comparable, there were observed anomalous decreases in the unconstrained age-sex coefficients for the 2020 benefit year enrollee-level EDGE recalibration data for older adult enrollees, especially older female enrollees. We are therefore concerned that not making any adjustments with respect to the use of 2020 enrollee-level EDGE recalibration data could have an undue impact on the risk captured by the age-sex factors in the adult models such that these factors would less accurately reflect the expected spending patterns for the 2024 benefit year. Option 1 would not address the identified anomalous trend that is not expected to continue in future benefit years. Option 2 represents a middle ground between those commenters who expressed support for including 2020 benefit year data in model recalibration and those who expressed support for excluding the data, by capturing the utilization and spending patterns underlying the 2020 data while dampening its effects in the models. However, we are concerned this approach would require identifying an appropriate weighting methodology other than the equal weighting that we generally use to blend the factors from the 3 data years, and we do not believe there is a self-evident method of weighting 2020 data differently for this purpose. Furthermore, we are concerned that dampening the effect of the 2020 benefit year data in all of the models for all factors (as opposed to just the age-sex factors in the adult models) defeats the purpose of using the next available benefit year of data to recalibrate the models, because doing so would prevent the models from reflecting changes in utilization and cost of care that are unrelated to the impact of the COVID–19 PHE. There are similar concerns with option 3 and the inclusion of an additional prior benefit year (that is, 2017) to recalibrate the 2024 benefit year models to dampen the impact of the 2020 benefit year data. We do not believe that such a broad dampening is necessary since the anomalous coefficient changes identified from the 2020 benefit year data were largely limited to the adult model age-sex coefficients and incorporating an

[24] These comments offered a variety of perspectives with some commenters stating that 2020 enrollee-level EDGE data should be used for model recalibration as normal, a few commenters suggesting that 2020 enrollee-level EDGE data should be excluded entirely, one commenter recommending that 2020 enrollee-level EDGE data should be used with a different weight assigned, and several commenters suggesting HHS release a technical paper on the use of 2020 enrollee-level EDGE data, with several suggesting HHS do a comparison of coefficients with and without the 2020 enrollee-level EDGE data to review relative changes in coefficients, and evaluate changes for clinical reasonability and consistency with 2018 and 2019 enrollee-level EDGE data. See 87 FR 27220 through 27221.

[25] The proposals related to the use of 2020 benefit year enrollee-level EDGE data in this rule for model recalibration purposes are focused on the 2024 benefit year models. Consistent with the approach finalized in part 2 of the 2022 Payment Notice (86 FR 24151 through 24155), any changes to the use of the 3 most recent consecutive years of enrollee-level EDGE data, including proposals related to the use of 2020 benefit year data, for recalibration of the 2025 and 2026 benefit year HHS risk adjustment models would be addressed and proposed in a future rulemaking.

[26] This is a similar approach to that taken in part 2 of the 2022 Payment Notice, where we only used 2016 and 2017 enrollee-level EDGE data for the limited purpose of developing the RXC 09 coefficients, RXC 09 HCC related coefficients, and RXC 09 interaction term coefficients for the 2022 benefit year adult models, given concerns regarding unrepresentative expenditures and off-label prescribing of hydroxychloroquine during the COVID–19 PHE relative to drugs that enrollees with HCC 048, 056, or 057 may take. See 86 FR 24180.

additional prior benefit year of data would dampen the impact of the 2020 benefit year data on other factors (for example, HCCs, RXCs, and interaction factors) and would prevent the models from reflecting changes in utilization and cost of care that are unrelated to the impact of the COVID–19 PHE. Furthermore, option 3 would use older data to fit the 2024 benefit year risk adjustment models than options 1 and 2 (that is, 2017 benefit year data), which may impact the risk adjustment models such that they reflect older cost and utilization trends than would be desirable.

We are similarly concerned about options 5 and 6, which would involve the complete exclusion of 2020 benefit year data. With respect to option 5, although using the same data years for 2024 benefit year model recalibration as 2023 benefit year model recalibration or using the 2023 benefit year models for the 2024 benefit year would likely yield the same or similar coefficients [27] to those published for the 2023 benefit year, thereby providing stability that issuers may find desirable, we are concerned this approach would also involve the use of older data as with option 3, which may not be the data set that would best reflect current utilization and spending trends including changes in drug prescribing patterns. In addition, our analyses of the 2020 benefit year enrollee-level EDGE recalibration data found that it was largely comparable with the 2019 benefit year data set and we did not identify other major anomalous trends in our comparison of the unconstrained HCC coefficients in the 2019 and 2020 enrollee-level EDGE recalibration data sets, which raises the question about whether there is a sufficient justification to completely exclude 2020 benefit year enrollee-level EDGE recalibration data in the recalibration of the risk adjustment models.

Option 6 has the same drawbacks as option 5—that is, it would not use the most recently available data for the applicable benefit year model recalibration, which may be the data set that would best reflect current utilization and spending trends, and raises the same question about whether there is a sufficient justification to completely exclude the 2020 benefit year data for model recalibration purposes. This option has the additional drawback of decreasing the stabilizing effect of using multiple years of data, as our goal in using multiple years of data for model calibration is to capture some degree of year-to-year cost shifting without over-relying on any factors unique to one particular year. When using 2 years of data, each year is weighted at 50 percent, but with 3 years of data, each year is weighted at 33.3 percent. As such, a change in a coefficient occurring in 1 year of the data that is actually included in recalibration would have a greater impact on the risk adjustment model coefficients if only using 2 years of data rather than 3 years, due to the increase in the reliance of the blended coefficients on the remaining 2 years of data.[28]

After consideration of these different options, we propose option 4—that is, maintain the current policy of using the 3 most recent consecutive benefit year data sets that are available at the time of publication of this proposed rule, with a narrowly tailored exception to exclude the 2020 benefit year data from the blending of the age-sex coefficients for the adult models. Under this proposal, we would determine coefficients for the 2024 benefit year based on a blend of separately solved coefficients from the 2018, 2019, and 2020 benefit years of enrollee-level EDGE recalibration data except for the coefficients for the adult age-sex factors, which would instead be based on a blend of separately solved coefficients from only the 2018 and 2019 benefit year enrollee-level EDGE recalibration. This approach preserves the current policy and use of the 3 most recent consecutive years of data available for the majority of the risk adjustment model coefficients, allowing for the use of the next available benefit year of data to recalibrate models that appears to be largely comparable with 2019 benefit year data to reflect changes in cost and utilization patterns for payment HCCs, RXCs, enrollment duration factors and interaction factors. At the same time, it includes an exception narrowly tailored to account for the observed anomalous decreases in the unconstrainted coefficients for the 2020 benefit year enrollee-level EDGE recalibration data for older adult enrollees, especially female enrollees. Thus, we believe that this offers a balanced approach to the use of 2020 benefit year enrollee-level EDGE recalibration data for model recalibration purposes while also addressing the limited observed anomalous trends in the 2020 benefit year enrollee-level EDGE recalibration data.

Our proposal to adopt option 4 is narrowly tailored to only address the observed trend in the unconstrained age-sex coefficients for the 2020 benefit year enrollee-level EDGE recalibration data for older adult enrollees, especially older adult female enrollees, which are likely due to decreases in discretionary spending among this age group in the 2020 benefit year. We are not proposing adjustments in response to the other trends observed in the 2020 benefit year enrollee-level EDGE recalibration data, such as the decrease in PMPM spending that occurred in March and April 2020,[29] because we generally found that the 2020 benefit year data and trends were otherwise largely comparable with the 2019 benefit year data and we did not identify other anomalous trends in our comparison of the unconstrained HCC coefficients in the 2019 and 2020 benefit year enrollee-level EDGE recalibration data sets. We further note that the coefficients fit by the risk adjustment models reflect the cost of treatment rather than the number of enrollees accessing treatment or when during the year the treatment is accessed. Therefore, even though there was some observed decreased utilization in the 2020 benefit year enrollee-level EDGE recalibration data, the lack of change in diagnosis-related coefficients between the models fit with prior years of enrollee-level EDGE recalibration data and the models fit with 2020 enrollee-level EDGE recalibration data indicates that when an enrollee was able to access care and a diagnosis was recorded on EDGE for the benefit year, the cost of treatment of their diagnosed conditions was similar to that experienced in previous benefit years. As such, we believe the 2020 enrollee-level EDGE recalibration data is sufficiently similar to prior years of enrollee level EDGE recalibration data to

[27] We expect that the trending of the prior benefit year data to reflect the anticipated costs and spending trends in the applicable future benefit year of risk adjustment that occurs as part of the annual model recalibration effort would impact the 2024 risk adjustment model coefficients.

[28] We do not have the same concerns with respect to using only 2 years of data for recalibration of the adult model age-sex coefficients because age-sex coefficients tend to contribute less to enrollees' risk scores than HCC, RXC, and interaction coefficients, so changes in a single age-sex coefficient in one of the remaining years of data is less likely to have an undue impact. Additionally, the age-sex coefficients are derived from substantially larger samples of enrollees and are therefore theoretically more stable than HCC, RXC, enrollment duration and interaction coefficients. Furthermore, the anomalies seen in the age-sex coefficients fit with the 2020 EDGE data systematically impact a wide range of enrollees. As such, we believe the risks of including 2020 EDGE data in blending of the age-sex coefficients outweighs the risks of only using the 2018 and 2019 benefit years of EDGE data to blend the age-sex coefficients for the 2024 benefit year adult models.

[29] As noted above, even though PMPM spending dropped substantially between March and April 2020, our analysis found that total PMPM spending in the 2020 benefit year was generally similar to the 2019 benefit year.

use in the fitting of coefficients for HCCs, RXCs, their interactions, and enrollment duration factors. We also do not believe that any 2020 enrollee-level EDGE recalibration data exceptions are needed for the child or infant risk adjustment models because among those models we did not observe anomalous trends between age-sex groups analogous to those trends observed that differentially impacted age-sex factors in the adult models. The draft coefficients listed in Tables 2 through 7 of this proposed rule reflect the use of 2018, 2019, and 2020 benefit year enrollee-level EDGE recalibration data, with an exception to exclude the 2020 benefit year data from the blending of the age-sex coefficients for the adult models, as well as the other risk adjustment model updates proposed in this proposed rule.[30]

To aid interested parties in their consideration of the proposed option, we are providing in Table 1 the values for the adult age-sex coefficients under option 1, which blends the age-sex coefficients using all three benefit years (2018, 2019 and 2020). Interested parties may compare the coefficients in Table 1 (reflecting option 1) to those in Table 2 (reflecting proposed option 4) to understand the impact of the 2020 enrollee-level EDGE data on the blended age-sex coefficients for the 2024 benefit year.

TABLE 1: Adult Risk Adjustment Age-Sex Coefficients[31] for the 2024 Benefit Year Using 2018, 2019 and 2020 Benefit Years of Enrollee-Level EDGE Data (Option 1)

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Age 21-24, Male	0.189	0.121	0.080	0.052	0.051
Age 25-29, Male	0.192	0.120	0.078	0.049	0.047
Age 30-34, Male	0.223	0.145	0.097	0.062	0.061
Age 35-39, Male	0.244	0.159	0.105	0.065	0.064
Age 40-44, Male	0.280	0.189	0.129	0.083	0.082
Age 45-49, Male	0.309	0.211	0.147	0.097	0.095
Age 50-54, Male	0.391	0.284	0.213	0.157	0.155
Age 55-59, Male	0.441	0.325	0.246	0.185	0.183
Age 60-64, Male	0.493	0.366	0.279	0.211	0.209
Age 21-24, Female	0.286	0.186	0.121	0.075	0.073
Age 25-29, Female	0.307	0.199	0.129	0.078	0.076
Age 30-34, Female	0.373	0.257	0.180	0.122	0.120
Age 35-39, Female	0.440	0.317	0.234	0.172	0.170
Age 40-44, Female	0.497	0.368	0.279	0.210	0.207
Age 45-49, Female	0.501	0.368	0.276	0.201	0.198
Age 50-54, Female	0.544	0.407	0.309	0.230	0.227
Age 55-59, Female	0.512	0.376	0.278	0.199	0.196
Age 60-64, Female	0.511	0.372	0.271	0.190	0.188

In addition to considering alternative options to recalibration in this section, we note that the coefficients could change if we identify an error after publication of this rule or if some or all of the proposed model changes are not finalized or are modified in response to comments. In addition, consistent with § 153.320(b)(1)(i), if we are unable to finalize the final coefficients in time for publication in the final rule, we would publish the final coefficients for the 2024 benefit year in guidance soon after the publication of the final rule.

We seek comment on the proposal to determine 2024 benefit year coefficients based on a blend of separately solved coefficients from the 2018, 2019, and 2020 enrollee-level EDGE recalibration data, with an exception to exclude the 2020 benefit year data from the blending of the age-sex coefficients for the adult models. We also seek comment on all of the alternative approaches outlined above.

b. Pricing Adjustment for the Hepatitis C Drugs

For the 2024 benefit year, we propose to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the risk adjustment models.[32] Since the 2020 benefit year risk adjustment models, we have been making a market pricing adjustment to the plan liability associated with Hepatitis C drugs to reflect future market pricing prior to solving for coefficients for the models.[33] The purpose of this market pricing adjustment is to account for significant pricing changes associated with the introduction of new and generic Hepatitis C drugs between the data years used for recalibrating the models and the applicable recalibration benefit year.[34]

We have committed to reassessing this pricing adjustment with additional years of enrollee-level EDGE data, as data become available. As part of the 2024 benefit year model recalibration, we reassessed the cost trend for Hepatitis C drugs using available

[30] Similar to recalibration of the 2023 risk adjustment adult models and consistent with the policies adopted in the 2023 Payment Notice, the draft factors in this rule also reflect the removal of the mapping of hydroxychloroquine sulfate to RXC 09 (Immune Suppressants and Immunomodulators) and the related RXC 09 interactions (RXC 09 × HCC056 or 057 and 048 or 041; RXC 09 × HCC056; RXC 09 × HCC 057; RXC 09 × HCC048, 041) from the 2018 and 2019 benefit year enrollee-level EDGE data sets for purposes of recalibrating the 2024 benefit year adult models. See 87 FR 27232 through 27235. Additionally, the draft factors for the adult models reflect the use of the final, fourth quarter (Q4) RXC mapping document that was applicable for each benefit year of data included in the current year's model recalibration (except under extenuating circumstances that can result in targeted changes to RXC mappings). See 87 FR at 27231 through 27232.

[31] All coefficients in Table 2 except for the adult age-sex factors are blended using all three benefit years of enrollee-level EDGE data (2018, 2019, and 2020). Option 1 and proposed option 4 only differ in the values of the adult age-sex coefficients. As such, in Table 1, we only provide the adult age-sex coefficients for option 1.

[32] See for example, 84 FR 17463 through 17466.

[33] The Hepatitis C drugs market pricing adjustment to plan liability is applied for all enrollees taking Hepatitis C drugs in the data used for recalibration.

[34] Silseth, S., & Shaw, H. (2021). Analysis of prescription drugs for the treatment of hepatitis C in the United States. Milliman White Paper. *https://www.milliman.com/-/media/milliman/pdfs/2021-articles/6-11-21-analysis-prescription-drugs-treatment-hepatitis-c-us.ashx.*

enrollee-level EDGE data (including 2020 benefit year data) to consider whether the adjustment was still needed and if it is still needed, whether it should be modified. We found that the data for the Hepatitis C RXC that would be used for the 2024 benefit year recalibration [35] still do not account for the significant pricing changes due to the introduction of new Hepatitis C drugs, and therefore, do not precisely reflect the average cost of Hepatitis C treatments applicable to the benefit year in question.

Specifically, generic Hepatitis C drugs did not become available on the market until 2019, and we propose to use 2018 benefit year EDGE data in the 2024 benefit year model recalibration.[36] Due to the lag between the data years used to recalibrate the risk adjustment models and the applicable benefit year of risk adjustment, as well as the expectation that the costs for Hepatitis C drugs will not increase at the same rate as other drug costs between the data year and the applicable benefit year of risk adjustment, we do not believe that the trends used to reflect growth in the cost of prescription drugs due to inflation and related factors for recalibrating the models will appropriately reflect the average cost of Hepatitis C treatments expected in the 2024 benefit year. Therefore, we continue to believe a market pricing adjustment specific to Hepatitis C drugs in our models for the 2024 benefit year is necessary to account for the significant pricing changes associated with the introduction of new and generic Hepatitis C drugs between the data years used for recalibrating the models and the applicable recalibration benefit year. We intend to continue to assess this pricing adjustment in future benefit year recalibrations using additional years of enrollee-level EDGE data.

We seek comment on our proposal to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs for the 2024 benefit year.

c. Request for Information: Payment HCC for Gender Dysphoria

HHS requests information on adding a payment HCC for gender dysphoria to the HHS-operated risk adjustment models for future benefit years. As part of the ongoing assessment of improvements to the HHS-operated risk adjustment program, HHS considers whether adjustments are needed to the payment HCCs in the risk adjustment models.[37] In light of Executive Order (E.O.) 13985 ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' [38] E.O. 13988 ''Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation,'' [39] and a comment received in response to the 2023 Payment Notice proposed rule, HHS is soliciting comment on whether to consider adding a new payment HCC for gender dysphoria to the risk adjustment models for future benefit years.

In considering the inclusion of a new payment HCC for gender dysphoria, we evaluated this potential payment HCC against the 10 Principles of HHS-Operated Risk Adjustment and determined that a new payment HCC for gender dysphoria would satisfy some but not all of these principles (77 FR 73128).

To further consider whether we should add a payment HCC for gender dysphoria to the HHS-operated risk adjustment models, we request feedback on the following questions:

- The implications of using the changing clinical concepts and labels from the ICD–10–CM diagnosis of ''gender identity disorder'' compared to the draft ICD–11–CM diagnosis of ''gender incongruence'' [40] for the naming and inclusion of this diagnosis or payment HCC in the HHS risk adjustment models.
- Whether a gender dysphoria HCC should be a separate and standalone payment HCC, or if gender dysphoria could be combined with any other diagnoses to form a broader payment HCC.[41]
- Any other factors HHS should consider when determining whether to add a gender dysphoria HCC to the HHS risk adjustment models as a payment HCC.

While we are not proposing to add a payment HCC for gender dysphoria to the HHS risk adjustment models at this time, we solicit comments to inform our continued consideration of potential risk adjustment model updates for future benefit years.

d. List of Factors To Be Employed in the Risk Adjustment Models (§ 153.320)

The proposed 2024 benefit year risk adjustment model factors resulting from the equally weighted (averaged) blended factors from separately solved models using the 2018, 2019, and 2020 enrollee-level EDGE data, with an exception to exclude the 2020 data from recalibration of the age-sex factors for the adult models, are shown in Tables 1 through 6. The adult, child, and infant models have been truncated to account for the high-cost risk pool payment parameters by removing 60 percent of costs above the $1 million threshold.[42] Table 2 contains factors for each adult model, including the age-sex, HCCs, RXCs, RXC–HCC interactions, interacted HCC counts, and enrollment duration coefficients. Table 3 contains the factors for each child model, including the age-sex, HCCs, and interacted HCC counts coefficients. Table 4 lists the HHS–HCCs selected for the interacted HCC counts factors that apply to the adult and child models. Table 5 contains the factors for each infant model. Tables 6 and 7 contain the HCCs included in the infant models' maturity and severity categories, respectively.

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[35] As detailed above, we propose to use 2018, 2019 and 2020 enrollee-level EDGE data for recalibration of the 2024 benefit year HHS risk adjustment models, with an exception to exclude 2020 data from recalibration of the age-sex factors for the adult models. However, for purposes of assessing whether this pricing adjustment was still needed and, if so, if it should be modified, we also assessed 2017 enrollee-level EDGE data in the event one of the alternative proposals regarding use of 2020 enrollee-level EDGE data is adopted.

[36] See Miligan, J, (2018). A perspective from our CEO: Gilead Subsidiary to Launch Authorized Generics to Treat HCV. Gilead. *https://www.gilead.com/news-and-press/company-statements/authorized-generics-for-hcv.* See also AbbVie. (2017). AbbVie Receives U.S. FDA Approval of MAVYRET™ (glecaprevir/pibrentasvir) for the Treatment of Chronic Hepatitis C in All Major Genotypes (GT 1–6) in as Short as 8 Weeks. Abbvie. *https://news.abbvie.com/news/abbvie-receives-us-fda-approval-mavyret-glecaprevirpibrentasvir-for-treatment-chronic-hepatitis-c-in-all-major-genotypes-gt-1-6-in-as-short-as-8-weeks.htm.*

[37] See, for example, the 2019 White Paper. *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Potential-Updates-to-HHS-HCCs-HHS-operated-Risk-Adjustment-Program.pdf.*

[38] 86 FR 7009.

[39] 86 FR 7023.

[40] World Health Organization. (n.d.). Gender incongruence and transgender health in the ICD. *https://www.who.int/standards/classifications/frequently-asked-questions/gender-incongruence-and-transgender-health-in-the-icd.*

[41] Gender dysphoria codes are currently mapped to HCC 93 Other Psychiatric Disorders, a non-payment HCC that is not currently included in the HHS-operated risk adjustment models.

[42] We are not proposing changes to the high-cost risk pool parameters for the 2024 benefit year. Therefore, we would maintain the $1 million threshold and 60 percent coinsurance rate.

TABLE 2: Proposed Adult Risk Adjustment Model Factors for the 2024 Benefit Year

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors						
	Age 21-24, Male	0.187	0.120	0.079	0.050	0.049
	Age 25-29, Male	0.190	0.121	0.079	0.049	0.047
	Age 30-34, Male	0.222	0.146	0.097	0.062	0.060
	Age 35-39, Male	0.245	0.161	0.106	0.065	0.063
	Age 40-44, Male	0.282	0.191	0.130	0.083	0.081
	Age 45-49, Male	0.311	0.214	0.147	0.096	0.094
	Age 50-54, Male	0.398	0.292	0.218	0.161	0.159
	Age 55-59, Male	0.450	0.333	0.252	0.188	0.186
	Age 60-64, Male	0.509	0.382	0.293	0.221	0.219
	Age 21-24, Female	0.286	0.188	0.124	0.077	0.075
	Age 25-29, Female	0.308	0.203	0.133	0.082	0.080
	Age 30-34, Female	0.380	0.264	0.187	0.128	0.125
	Age 35-39, Female	0.453	0.329	0.246	0.181	0.179
	Age 40-44, Female	0.510	0.381	0.291	0.219	0.216
	Age 45-49, Female	0.515	0.382	0.287	0.209	0.206
	Age 50-54, Female	0.561	0.424	0.324	0.241	0.238
	Age 55-59, Female	0.532	0.395	0.294	0.212	0.209
	Age 60-64, Female	0.542	0.400	0.296	0.212	0.209
Diagnosis Factors						
HCC001	HIV/AIDS	0.610	0.495	0.426	0.382	0.380
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	9.632	9.382	9.265	9.203	9.202
HCC003	Central Nervous System Infections, Except Viral Meningitis	8.965	8.831	8.747	8.678	8.675

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC004	Viral or Unspecified Meningitis	8.914	8.769	8.675	8.592	8.589
HCC006	Opportunistic Infections	8.576	8.501	8.427	8.333	8.329
HCC008	Metastatic Cancer	24.525	24.081	23.916	23.899	23.899
HCC009	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	13.190	12.873	12.733	12.672	12.670
HCC010	Non-Hodgkin Lymphomas and Other Cancers and Tumors	6.042	5.834	5.716	5.631	5.628
HCC011	Colorectal, Breast (Age < 50), Kidney, and Other Cancers	3.876	3.663	3.536	3.439	3.436
HCC012	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	2.622	2.463	2.358	2.273	2.271
HCC013	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.054	0.935	0.827	0.717	0.714
HCC018 43	Pancreas Transplant Status	7.002	6.831	6.765	6.687	6.672
HCC019	Diabetes with Acute Complications	0.295	0.237	0.189	0.146	0.144
HCC020	Diabetes with Chronic Complications	0.295	0.237	0.189	0.146	0.144
HCC021	Diabetes without Complication	0.295	0.237	0.189	0.146	0.144
HCC022	Type 1 Diabetes Mellitus, add-on to Diabetes HCCs 19-21	0.380	0.339	0.303	0.234	0.231
HCC023	Protein-Calorie Malnutrition	11.879	11.731	11.645	11.587	11.585
HCC026	Mucopolysaccharidosis	27.187	26.955	26.857	26.834	26.834
HCC027	Lipidoses and Glycogenosis	27.187	26.955	26.857	26.834	26.834
HCC029	Amyloidosis, Porphyria, and Other Metabolic Disorders	6.954	6.830	6.758	6.702	6.700
HCC030	Adrenal, Pituitary, and Other Significant Endocrine Disorders	1.446	1.351	1.278	1.204	1.201
HCC034	Liver Transplant Status/Complications	6.481	6.531	6.579	6.647	6.649
HCC035_1 44	Acute Liver Failure/Disease, Including Neonatal Hepatitis	7.706	7.500	7.402	7.365	7.367
HCC035_2	Chronic Liver Failure/End-Stage Liver Disorders	2.506	2.315	2.223	2.167	2.166
HCC036	Cirrhosis of Liver	0.706	0.607	0.537	0.466	0.463
HCC037_1	Chronic Viral Hepatitis C	0.528	0.451	0.389	0.324	0.322
HCC037_2	Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.528	0.451	0.389	0.324	0.322
HCC041	Intestine Transplant Status/Complications	11.558	11.539	11.535	11.546	11.546
HCC042	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	11.889	11.691	11.610	11.582	11.581
HCC045	Intestinal Obstruction	5.323	5.085	4.970	4.891	4.890
HCC046	Chronic Pancreatitis	2.842	2.639	2.547	2.497	2.497
HCC047	Acute Pancreatitis	2.842	2.624	2.517	2.427	2.425
HCC048	Inflammatory Bowel Disease	0.469	0.365	0.266	0.146	0.142
HCC054	Necrotizing Fasciitis	9.611	9.426	9.345	9.332	9.332
HCC055	Bone/Joint/Muscle Infections/Necrosis	5.113	4.911	4.827	4.805	4.804

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC056	Rheumatoid Arthritis and Specified Autoimmune Disorders	1.073	0.964	0.876	0.795	0.792
HCC057	Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.467	0.376	0.280	0.173	0.168
HCC061	Osteogenesis Imperfecta and Other Osteodystrophies	2.273	2.113	2.012	1.922	1.919
HCC062	Congenital/Developmental Skeletal and Connective Tissue Disorders	2.273	2.113	2.012	1.922	1.919
HCC063	Cleft Lip/Cleft Palate	1.395	1.258	1.174	1.102	1.100
HCC066	Hemophilia	74.006	73.673	73.537	73.513	73.514
HCC067	Myelodysplastic Syndromes and Myelofibrosis	12.434	12.293	12.226	12.181	12.177
HCC068	Aplastic Anemia	12.434	12.293	12.226	12.181	12.177
HCC069	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	12.434	12.293	12.226	12.181	12.177
HCC070	Sickle Cell Anemia (Hb-SS)	2.115	2.003	1.925	1.852	1.849
HCC071	Beta Thalassemia Major	2.115	2.003	1.925	1.852	1.849
HCC073	Combined and Other Severe Immunodeficiencies	4.051	3.941	3.879	3.832	3.831
HCC074	Disorders of the Immune Mechanism	4.051	3.941	3.879	3.832	3.831
HCC075	Coagulation Defects and Other Specified Hematological Disorders	2.211	2.111	2.041	1.976	1.974
HCC081	Drug Use with Psychotic Complications	1.844	1.675	1.544	1.399	1.394
HCC082	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications	1.844	1.675	1.544	1.399	1.394
HCC083	Alcohol Use with Psychotic Complications	1.046	0.902	0.803	0.704	0.701
HCC084	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications	1.046	0.902	0.803	0.704	0.701
HCC087_1	Schizophrenia	2.423	2.222	2.100	1.990	1.988
HCC087_2	Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis	2.407	2.208	2.086	1.969	1.966
HCC088	Major Depressive Disorder, Severe, and Bipolar Disorders	1.097	0.972	0.866	0.752	0.748
HCC090	Personality Disorders	0.777	0.675	0.568	0.452	0.448
HCC094	Anorexia/Bulimia Nervosa	2.296	2.160	2.060	1.969	1.965
HCC096	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	8.822	8.772	8.724	8.674	8.671
HCC097	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.212	1.128	1.063	1.003	1.001
HCC102	Autistic Disorder	0.871	0.770	0.669	0.571	0.567
HCC103	Pervasive Developmental Disorders, Except Autistic Disorder	0.777	0.675	0.568	0.452	0.448
HCC106	Traumatic Complete Lesion Cervical Spinal Cord	9.999	9.801	9.692	9.611	9.609
HCC107	Quadriplegia	9.999	9.801	9.692	9.611	9.609
HCC108	Traumatic Complete Lesion Dorsal Spinal Cord	7.110	6.939	6.841	6.758	6.756
HCC109	Paraplegia	7.110	6.939	6.841	6.758	6.756
HCC110	Spinal Cord Disorders/Injuries	5.642	5.424	5.314	5.240	5.238

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	5.761	5.574	5.459	5.348	5.345
HCC112	Quadriplegic Cerebral Palsy	0.915	0.782	0.690	0.593	0.590
HCC113	Cerebral Palsy, Except Quadriplegic	0.603	0.508	0.433	0.350	0.347
HCC114	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.376	1.266	1.184	1.094	1.091
HCC115	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	5.550	5.444	5.393	5.365	5.364
HCC117	Muscular Dystrophy	1.561	1.445	1.353	1.252	1.248
HCC118	Multiple Sclerosis	1.790	1.656	1.563	1.474	1.471
HCC119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	1.561	1.445	1.353	1.252	1.248
HCC120	Seizure Disorders and Convulsions	1.167	1.050	0.963	0.871	0.868
HCC121	Hydrocephalus	10.740	10.618	10.534	10.464	10.461
HCC122	Coma, Brain Compression/Anoxic Damage	11.024	10.847	10.738	10.657	10.654
HCC123	Narcolepsy and Cataplexy	4.582	4.419	4.310	4.218	4.215
HCC125	Respirator Dependence/Tracheostomy Status	21.711	21.476	21.356	21.292	21.293
HCC126	Respiratory Arrest	8.925	8.681	8.560	8.492	8.491
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	8.925	8.681	8.560	8.492	8.491
HCC128	Heart Assistive Device/Artificial Heart	19.352	19.182	19.086	19.034	19.039
HCC129	Heart Transplant Status/Complications	19.352	19.182	19.086	19.034	19.039
HCC130	Heart Failure	2.114	2.006	1.943	1.890	1.889
HCC131	Acute Myocardial Infarction	5.710	5.437	5.334	5.318	5.319
HCC132	Unstable Angina and Other Acute Ischemic Heart Disease	4.333	4.076	3.969	3.906	3.906
HCC135	Heart Infection/Inflammation, Except Rheumatic	9.550	9.428	9.336	9.245	9.241
HCC137	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	2.354	2.242	2.159	2.087	2.085
HCC138	Major Congenital Heart/Circulatory Disorders	2.354	2.242	2.159	2.087	2.085
HCC139	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	2.354	2.242	2.159	2.087	2.085
HCC142	Specified Heart Arrhythmias	2.068	1.940	1.846	1.747	1.749
HCC145	Intracranial Hemorrhage	11.501	11.303	11.199	11.134	11.132
HCC146	Ischemic or Unspecified Stroke	1.589	1.449	1.381	1.325	1.324
HCC149	Cerebral Aneurysm and Arteriovenous Malformation	2.506	2.361	2.270	2.182	2.178
HCC150	Hemiplegia/Hemiparesis	3.702	3.558	3.501	3.483	3.483
HCC151	Monoplegia, Other Paralytic Syndromes	2.759	2.625	2.548	2.482	2.481
HCC153	Atherosclerosis of the Extremities with Ulceration or Gangrene	8.513	8.338	8.287	8.310	8.312
HCC154	Vascular Disease with Complications	5.876	5.705	5.617	5.563	5.561

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC156	Pulmonary Embolism and Deep Vein Thrombosis	8.158	8.045	7.945	7.831	7.827
HCC158	Lung Transplant Status/Complications	11.241	11.061	10.970	10.928	10.928
HCC159	Cystic Fibrosis	4.651	4.456	4.346	4.270	4.268
HCC160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.708	0.610	0.518	0.424	0.420
HCC161_1	Severe Asthma	0.708	0.610	0.518	0.424	0.420
HCC161_2	Asthma, Except Severe	0.708	0.610	0.518	0.424	0.420
HCC162	Fibrosis of Lung and Other Lung Disorders	1.669	1.555	1.476	1.396	1.394
HCC163	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	6.800	6.776	6.772	6.785	6.786
HCC174	Exudative Macular Degeneration	1.410	1.250	1.133	1.006	1.002
HCC183 45	Kidney Transplant Status/Complications	7.002	6.831	6.765	6.687	6.672
HCC184	End Stage Renal Disease	22.616	22.143	22.091	22.024	21.952
HCC187	Chronic Kidney Disease, Stage 5	0.754	0.654	0.624	0.599	0.588
HCC188	Chronic Kidney Disease, Severe (Stage 4)	0.754	0.654	0.624	0.599	0.588
HCC203	Ectopic and Molar Pregnancy	2.101	1.869	1.688	1.453	1.446
HCC204	Miscarriage with Complications	0.735	0.627	0.487	0.297	0.289
HCC205	Miscarriage with No or Minor Complications	0.735	0.627	0.487	0.297	0.289
HCC207	Pregnancy with Delivery with Major Complications	4.112	3.743	3.511	3.184	3.177
HCC208	Pregnancy with Delivery with Complications	4.112	3.743	3.511	3.184	3.177
HCC209	Pregnancy with Delivery with No or Minor Complications	2.959	2.685	2.452	2.035	2.021
HCC210	(Ongoing) Pregnancy without Delivery with Major Complications	0.925	0.787	0.614	0.411	0.403
HCC211	(Ongoing) Pregnancy without Delivery with Complications	0.602	0.498	0.349	0.200	0.194
HCC212	(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.045	0.011	0.000	0.000	0.000
HCC217	Chronic Ulcer of Skin, Except Pressure	1.673	1.557	1.495	1.449	1.448
HCC218	Extensive Third-Degree Burns	24.045	23.796	23.670	23.616	23.615
HCC219	Major Skin Burn or Condition	3.002	2.852	2.759	2.688	2.686
HCC223	Severe Head Injury	19.211	19.023	18.906	18.816	18.812
HCC226	Hip and Pelvic Fractures	8.717	8.433	8.321	8.299	8.299
HCC228	Vertebral Fractures without Spinal Cord Injury	4.629	4.430	4.311	4.209	4.206
HCC234	Traumatic Amputations and Amputation Complications	5.579	5.388	5.310	5.282	5.280
HCC251	Stem Cell, Including Bone Marrow, Transplant Status/Complications	19.317	19.299	19.253	19.203	19.204
HCC253	Artificial Openings for Feeding or Elimination	6.278	6.141	6.079	6.051	6.051

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC254	Amputation Status, Upper Limb or Lower Limb	1.275	1.144	1.078	1.030	1.028
Interacted HCC Counts Factors						
	Severe illness, 1 payment HCC	-6.481	-6.531	-6.579	-6.647	-6.649
	Severe illness, 2 payment HCCs	-5.980	-6.064	-6.100	-6.138	-6.138
	Severe illness, 3 payment HCCs	-4.874	-4.919	-4.880	-4.800	-4.797
	Severe illness, 4 payment HCCs	-4.038	-4.010	-3.884	-3.675	-3.667
	Severe illness, 5 payment HCCs	-3.255	-3.127	-2.917	-2.600	-2.589
	Severe illness, 6 payment HCCs	-2.821	-2.566	-2.271	-1.865	-1.850
	Severe illness, 7 payment HCCs	-2.043	-1.611	-1.209	-0.711	-0.695
	Severe illness, 8 payment HCCs	-1.976	-1.496	-1.066	-0.544	-0.526
	Severe illness, 9 payment HCCs	0.766	1.457	2.004	2.616	2.636
	Severe illness, 10 or more payment HCCs	8.825	9.947	10.723	11.493	11.519
	Transplant severe illness, 4 payment HCCs	4.029	3.981	3.935	3.854	3.847
	Transplant severe illness, 5 payment HCCs	8.160	8.097	8.057	7.989	7.980
	Transplant severe illness, 6 payment HCCs	15.312	15.232	15.196	15.140	15.128
	Transplant severe illness, 7 payment HCCs	18.743	18.632	18.584	18.522	18.511
	Transplant severe illness, 8 or more payment HCCs	36.031	36.054	36.081	36.066	36.056
Enrollment Duration Factors						
	Enrolled for 1 month, at least one payment HCC	10.880	9.150	8.099	7.149	7.117
	Enrolled for 2 months, at least one payment HCC	5.224	4.342	3.782	3.305	3.288
	Enrolled for 3 months, at least one payment HCC	3.367	2.788	2.400	2.080	2.070
	Enrolled for 4 months, at least one payment HCC	2.219	1.818	1.536	1.309	1.301
	Enrolled for 5 months, at least one payment HCC	1.636	1.339	1.121	0.944	0.938
	Enrolled for 6 months, at least one payment HCC	1.088	0.869	0.701	0.561	0.556
Prescription Drug Factors						
RXC 01	Anti-HIV Agents	5.647	5.055	4.669	4.306	4.296
RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	8.662	8.116	7.936	7.952	7.956
RXC 0346	Antiarrhythmics	0.091	0.083	0.075	0.058	0.035
RXC 04	Phosphate Binders	1.008	1.204	1.125	1.295	1.411
RXC 05	Inflammatory Bowel Disease Agents	1.467	1.314	1.155	0.930	0.920
RXC 06	Insulin	1.429	1.215	1.022	0.841	0.834
RXC 07	Anti-Diabetic Agents, Except Insulin and Metformin Only	0.789	0.673	0.549	0.375	0.369
RXC 08	Multiple Sclerosis Agents	16.266	15.334	14.880	14.547	14.531

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC 0947	Immune Suppressants and Immunomodulators	12.396	11.784	11.558	11.525	11.527
RXC 10	Cystic Fibrosis Agents	15.054	14.632	14.479	14.440	14.440
RXC 01 x HCC001	Additional effect for enrollees with RXC 01 and HCC 001	2.048	2.149	2.376	2.748	2.761
RXC 02 x HCC037_1, 036, 035_2, 035_1, 034	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034)	-0.528	-0.451	-0.389	-0.324	-0.322
RXC 03 x HCC142	Additional effect for enrollees with RXC 03 and HCC 142	0.000	0.000	0.000	0.000	0.000
RXC 04 x HCC184, 183, 187, 188	Additional effect for enrollees with RXC 04 and (HCC 184 or 183 or 187 or 188)	0.000	0.000	0.000	0.000	0.000
RXC 05 x HCC048, 041	Additional effect for enrollees with RXC 05 and (HCC 048 or 041)	-0.469	-0.365	-0.266	-0.146	-0.142
RXC 06 x HCC018, 019, 020, 021	Additional effect for enrollees with RXC 06 and (HCC 018 or 019 or 020 or 021)	0.434	0.492	0.567	0.578	0.580
RXC 07 x HCC018, 019, 020, 021	Additional effect for enrollees with RXC 07 and (HCC 018 or 019 or 020 or 021)	-0.295	-0.237	-0.189	-0.146	-0.144
RXC 08 x HCC118	Additional effect for enrollees with RXC 08 and HCC 118	0.947	1.380	1.709	2.146	2.168
RXC 09 x HCC056 or 057 and 048 or 041	Additional effect for enrollees with RXC 09 and (HCC 048 or 041) and (HCC 056 or 057)	0.287	0.347	0.387	0.425	0.426
RXC 09 x HCC056	Additional effect for enrollees with RXC 09 and HCC 056	-1.073	-0.964	-0.876	-0.795	-0.792
RXC 09 x HCC057	Additional effect for enrollees with RXC 09 and HCC 057	-0.467	-0.376	-0.280	-0.173	-0.168
RXC 09 x HCC048, 041	Additional effect for enrollees with RXC 09 and (HCC 048 or 041)	2.454	2.573	2.695	2.872	2.877
RXC 10 x HCC159, 158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	41.353	41.406	41.472	41.618	41.623

TABLE 3: Proposed Child Risk Adjustment Model Factors for the 2024 Benefit Year

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2-4, Male	0.288	0.195	0.146	0.109	0.108
Age 5-9, Male	0.213	0.132	0.093	0.069	0.068
Age 10-14, Male	0.236	0.156	0.115	0.092	0.091
Age 15-20, Male	0.271	0.186	0.135	0.101	0.100
Age 2-4, Female	0.233	0.151	0.113	0.088	0.087
Age 5-9, Female	0.160	0.087	0.056	0.037	0.036
Age 10-14, Female	0.227	0.149	0.110	0.087	0.086
Age 15-20, Female	0.314	0.210	0.145	0.099	0.097
Diagnosis Factors					
HIV/AIDS	4.490	3.999	3.762	3.617	3.615
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	14.897	14.669	14.536	14.439	14.437
Central Nervous System Infections, Except Viral Meningitis	13.638	13.470	13.360	13.293	13.291
Viral or Unspecified Meningitis	11.963	11.850	11.768	11.643	11.642
Opportunistic Infections	17.169	17.088	16.997	16.907	16.904
Metastatic Cancer	33.749	33.464	33.322	33.262	33.261
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	9.374	9.094	8.929	8.808	8.804
Non-Hodgkin Lymphomas and Other Cancers and Tumors	7.293	7.065	6.911	6.777	6.772
Colorectal, Breast (Age < 50), Kidney, and Other Cancers	4.615	4.450	4.331	4.221	4.217
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	4.615	4.450	4.331	4.221	4.217
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.171	1.037	0.925	0.806	0.802
Pancreas Transplant Status	11.106	11.020	10.974	10.939	10.937
Diabetes with Acute Complications	2.624	2.312	2.075	1.754	1.745
Diabetes with Chronic Complications	2.624	2.312	2.075	1.754	1.745
Diabetes without Complication	2.624	2.312	2.075	1.754	1.745
Protein-Calorie Malnutrition	19.295	19.163	19.078	19.037	19.035
Mucopolysaccharidosis	39.965	39.679	39.551	39.501	39.500
Lipidoses and Glycogenosis	39.965	39.679	39.551	39.501	39.500
Congenital Metabolic Disorders, Not Elsewhere Classified	4.830	4.698	4.609	4.541	4.538
Amyloidosis, Porphyria, and Other Metabolic Disorders	4.830	4.698	4.609	4.541	4.538
Adrenal, Pituitary, and Other Significant Endocrine Disorders	5.553	5.285	5.146	5.079	5.078
Liver Transplant Status/Complications	11.106	11.020	10.974	10.939	10.937
Acute Liver Failure/Disease, Including Neonatal Hepatitis	9.767	9.619	9.551	9.525	9.524
Chronic Liver Failure/End-Stage Liver Disorders	9.286	9.131	9.047	8.983	8.980
Cirrhosis of Liver	4.128	3.990	3.907	3.848	3.849
Chronic Viral Hepatitis C	1.186	1.046	0.961	0.917	0.917
Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.197	0.169	0.142	0.111	0.110
Intestine Transplant Status/Complications	13.858	13.756	13.667	13.582	13.579

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	17.886	17.459	17.325	17.276	17.275
Intestinal Obstruction	4.767	4.582	4.446	4.332	4.329
Chronic Pancreatitis	11.778	11.601	11.522	11.476	11.476
Acute Pancreatitis	5.360	5.102	4.953	4.826	4.823
Inflammatory Bowel Disease	9.915	9.478	9.266	9.139	9.135
Necrotizing Fasciitis	3.684	3.449	3.308	3.207	3.204
Bone/Joint/Muscle Infections/Necrosis	3.684	3.449	3.308	3.207	3.204
Rheumatoid Arthritis and Specified Autoimmune Disorders	4.733	4.456	4.296	4.195	4.192
Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.746	0.619	0.500	0.376	0.372
Osteogenesis Imperfecta and Other Osteodystrophies	1.389	1.262	1.168	1.085	1.082
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.389	1.262	1.168	1.085	1.082
Cleft Lip/Cleft Palate	1.174	1.006	0.881	0.756	0.752
Hemophilia	67.994	67.478	67.248	67.166	67.164
Myelodysplastic Syndromes and Myelofibrosis	13.130	12.957	12.863	12.801	12.800
Aplastic Anemia	13.130	12.957	12.863	12.801	12.800
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	13.130	12.957	12.863	12.801	12.800
Sickle Cell Anemia (Hb-SS)	3.851	3.643	3.511	3.411	3.408
Beta Thalassemia Major	3.851	3.643	3.511	3.411	3.408
Combined and Other Severe Immunodeficiencies	4.918	4.760	4.660	4.582	4.580
Disorders of the Immune Mechanism	4.918	4.760	4.660	4.582	4.580
Coagulation Defects and Other Specified Hematological Disorders	4.218	4.082	3.982	3.897	3.894
Drug Use with Psychotic Complications	2.517	2.331	2.202	2.065	2.061
Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications	2.517	2.331	2.202	2.065	2.061
Alcohol Use with Psychotic Complications	1.203	1.031	0.894	0.740	0.734
Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications	1.203	1.031	0.894	0.740	0.734
Schizophrenia	3.991	3.694	3.511	3.350	3.346
Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis	3.395	3.122	2.941	2.760	2.755
Major Depressive Disorder, Severe, and Bipolar Disorders	2.638	2.413	2.243	2.082	2.077
Personality Disorders	0.378	0.270	0.155	0.042	0.038
Anorexia/Bulimia Nervosa	2.453	2.277	2.147	2.034	2.030
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	11.637	11.535	11.450	11.378	11.376
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	0.982	0.842	0.742	0.642	0.638
Autistic Disorder	2.638	2.413	2.243	2.082	2.077
Pervasive Developmental Disorders, Except Autistic Disorder	0.404	0.314	0.222	0.146	0.144
Traumatic Complete Lesion Cervical Spinal Cord	11.137	10.900	10.779	10.704	10.702
Quadriplegia	11.137	10.900	10.779	10.704	10.702
Traumatic Complete Lesion Dorsal Spinal Cord	11.047	10.807	10.695	10.627	10.625

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Paraplegia	11.047	10.807	10.695	10.627	10.625
Spinal Cord Disorders/Injuries	4.782	4.560	4.404	4.246	4.240
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	50.056	49.780	49.630	49.543	49.540
Quadriplegic Cerebral Palsy	0.913	0.651	0.525	0.440	0.439
Cerebral Palsy, Except Quadriplegic	0.274	0.128	0.061	0.017	0.015
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.770	1.630	1.533	1.437	1.434
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	11.126	10.941	10.858	10.829	10.829
Muscular Dystrophy	6.190	6.018	5.902	5.793	5.790
Multiple Sclerosis	9.870	9.439	9.256	9.199	9.200
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	6.190	6.018	5.902	5.793	5.790
Seizure Disorders and Convulsions	1.667	1.509	1.368	1.223	1.218
Hydrocephalus	11.086	11.068	11.036	11.016	11.015
Coma, Brain Compression/Anoxic Damage	10.655	10.694	10.708	10.737	10.737
Narcolepsy and Cataplexy	4.295	4.102	3.955	3.821	3.816
Respirator Dependence/Tracheostomy Status	27.170	26.905	26.769	26.706	26.705
Respiratory Arrest	16.066	15.761	15.608	15.522	15.520
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	16.066	15.761	15.608	15.522	15.520
Heart Assistive Device/Artificial Heart	13.858	13.756	13.667	13.582	13.579
Heart Transplant Status/Complications	13.858	13.756	13.667	13.582	13.579
Heart Failure	4.738	4.612	4.524	4.454	4.452
Acute Myocardial Infarction	1.087	1.045	1.017	0.993	0.993
Unstable Angina and Other Acute Ischemic Heart Disease	1.087	1.045	1.017	0.993	0.993
Heart Infection/Inflammation, Except Rheumatic	16.465	16.330	16.226	16.134	16.130
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	4.201	4.021	3.874	3.748	3.744
Major Congenital Heart/Circulatory Disorders	1.119	1.001	0.878	0.777	0.774
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	0.691	0.583	0.488	0.415	0.413
Specified Heart Arrhythmias	3.278	3.106	2.985	2.886	2.883
Intracranial Hemorrhage	12.842	12.667	12.542	12.440	12.435
Ischemic or Unspecified Stroke	1.680	1.505	1.397	1.293	1.290
Cerebral Aneurysm and Arteriovenous Malformation	1.745	1.547	1.416	1.288	1.283
Hemiplegia/Hemiparesis	5.876	5.734	5.649	5.574	5.571
Monoplegia, Other Paralytic Syndromes	3.202	3.050	2.948	2.842	2.838
Atherosclerosis of the Extremities with Ulceration or Gangrene	10.987	10.723	10.584	10.490	10.488
Vascular Disease with Complications	7.360	7.213	7.130	7.077	7.077
Pulmonary Embolism and Deep Vein Thrombosis	19.940	19.772	19.662	19.581	19.579
Lung Transplant Status/Complications	13.858	13.756	13.667	13.582	13.579
Cystic Fibrosis	46.375	45.821	45.593	45.555	45.556
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	1.807	1.629	1.497	1.375	1.372
Severe Asthma	1.269	1.080	0.919	0.762	0.757
Asthma, Except Severe	0.347	0.258	0.172	0.104	0.102
Fibrosis of Lung and Other Lung Disorders	1.474	1.310	1.170	1.039	1.035

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	10.655	10.694	10.708	10.737	10.737
Kidney Transplant Status/Complications	11.106	11.020	10.974	10.939	10.937
End Stage Renal Disease	37.125	36.898	36.806	36.786	36.783
Chronic Kidney Disease, Stage 5	0.266	0.200	0.150	0.093	0.091
Chronic Kidney Disease, Severe (Stage 4)	0.266	0.200	0.150	0.093	0.091
Ectopic and Molar Pregnancy	1.605	1.396	1.203	1.035	1.028
Miscarriage with Complications	0.597	0.466	0.325	0.183	0.178
Miscarriage with No or Minor Complications	0.597	0.466	0.325	0.183	0.178
Pregnancy with Delivery with Major Complications	3.535	3.159	2.880	2.439	2.424
Pregnancy with Delivery with Complications	3.535	3.159	2.880	2.439	2.424
Pregnancy with Delivery with No or Minor Complications	2.619	2.338	2.064	1.572	1.553
(Ongoing) Pregnancy without Delivery with Major Complications	0.553	0.406	0.236	0.129	0.125
(Ongoing) Pregnancy without Delivery with Complications	0.553	0.406	0.236	0.129	0.125
(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.365	0.249	0.135	0.060	0.057
Chronic Ulcer of Skin, Except Pressure	2.144	2.023	1.933	1.863	1.861
Extensive Third-Degree Burns	22.431	22.185	22.041	21.957	21.952
Major Skin Burn or Condition	2.195	2.007	1.877	1.757	1.753
Severe Head Injury	22.431	22.185	22.041	21.957	21.952
Hip and Pelvic Fractures	4.771	4.510	4.344	4.242	4.239
Vertebral Fractures without Spinal Cord Injury	4.693	4.459	4.289	4.124	4.119
Traumatic Amputations and Amputation Complications	3.506	3.260	3.106	2.949	2.943
Stem Cell, Including Bone Marrow, Transplant Status/Complications	13.858	13.756	13.667	13.582	13.579
Artificial Openings for Feeding or Elimination	6.435	6.241	6.156	6.110	6.110
Amputation Status, Upper Limb or Lower Limb	3.506	3.260	3.106	2.949	2.943
Interacted HCC Counts Factors					
Severe illness, 1 payment HCC	-10.655	-10.694	-10.708	-10.737	-10.737
Severe illness, 2 payment HCCs	-10.570	-10.647	-10.680	-10.723	-10.724
Severe illness, 3 payment HCCs	-8.365	-8.447	-8.418	-8.359	-8.355
Severe illness, 4 payment HCCs	-7.724	-7.718	-7.590	-7.404	-7.396
Severe illness, 5 payment HCCs	-4.948	-4.829	-4.600	-4.291	-4.279
Severe illness, 6 or 7 payment HCCs	-0.619	-0.297	0.075	0.521	0.537
Severe illness, 8 or more payment HCCs	20.186	21.065	21.786	22.505	22.529
Transplant severe illness, 4 or more payment HCCs	16.793	16.848	16.877	16.897	16.899

TABLE 4: HCCs Selected for the Proposed HCC Interacted Counts Variables for the Adult and Child Models for the 2024 Benefit Year

Payment HCC	Severity Illness Indicator	Transplant Indicator
HCC 2 Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	X	
HCC 3 Central Nervous System Infections, Except Viral Meningitis	X	
HCC 4 Viral or Unspecified Meningitis	X	
HCC 6 Opportunistic Infections	X	
HCC 23 Protein-Calorie Malnutrition	X	
HCC 34 Liver Transplant Status/Complications	X	X
HCC 41 Intestine Transplant Status/Complications	X	X
HCC 42 Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	X	
HCC 96 Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	X	
HCC 121 Hydrocephalus	X	
HCC 122 Coma, Brain Compression/Anoxic Damage	X	
HCC 125 Respirator Dependence/Tracheostomy Status	X	
HCC 135 Heart Infection/Inflammation, Except Rheumatic	X	
HCC 145 Intracranial Hemorrhage	X	
HCC 156 Pulmonary Embolism and Deep Vein Thrombosis	X	
HCC 158 Lung Transplant Status/Complications	X	X
HCC 163 Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	X	
HCC 218 Extensive Third-Degree Burns	X	
HCC 223 Severe Head Injury	X	
HCC 251 Stem Cell, Including Bone Marrow, Transplant Status/Complications	X	X
G13 (Includes HCC 126 Respiratory Arrest and HCC 127 Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes)	X	
G14 (Includes HCC 128 Heart Assistive Device/Artificial Heart and HCC 129 Heart Transplant Status/Complications)	X	X
G24 (Includes HCC 18 Pancreas Transplant Status and HCC 183 Kidney Transplant Status/Complications)48	X	X

TABLE 5: Proposed Infant Risk Adjustment Model Factors for the 2024 Benefit Year

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	225.754	224.102	223.390	223.190	223.189
Extremely Immature * Severity Level 4	162.909	161.046	160.171	159.788	159.782
Extremely Immature * Severity Level 3	36.950	35.414	34.671	34.338	34.330
Extremely Immature * Severity Level 2	36.950	35.414	34.671	34.338	34.330
Extremely Immature * Severity Level 1 (Lowest)	36.950	35.414	34.671	34.338	34.330
Immature * Severity Level 5 (Highest)	127.417	125.708	124.964	124.729	124.726
Immature * Severity Level 4	75.684	73.973	73.203	72.924	72.919
Immature * Severity Level 3	36.950	35.414	34.671	34.338	34.330
Immature * Severity Level 2	36.950	35.414	34.671	34.338	34.330
Immature * Severity Level 1 (Lowest)	28.369	26.894	26.146	25.745	25.734
Premature/Multiples * Severity Level 5 (Highest)	115.509	114.050	113.404	113.199	113.198
Premature/Multiples * Severity Level 4	32.082	30.557	29.821	29.460	29.453
Premature/Multiples * Severity Level 3	15.009	13.884	13.202	12.641	12.623
Premature/Multiples * Severity Level 2	8.402	7.557	6.909	6.201	6.175
Premature/Multiples * Severity Level 1 (Lowest)	6.306	5.569	4.951	4.366	4.346
Term * Severity Level 5 (Highest)	86.920	85.564	84.906	84.586	84.580
Term * Severity Level 4	17.039	15.909	15.237	14.692	14.677
Term * Severity Level 3	6.250	5.550	4.948	4.333	4.311
Term * Severity Level 2	3.964	3.368	2.784	2.177	2.155
Term * Severity Level 1 (Lowest)	2.042	1.592	1.108	0.790	0.781
Age1 * Severity Level 5 (Highest)	70.542	69.775	69.404	69.235	69.232
Age1 * Severity Level 4	13.870	13.286	12.950	12.711	12.704
Age1 * Severity Level 3	3.079	2.756	2.528	2.344	2.337
Age1 * Severity Level 2	2.039	1.758	1.531	1.324	1.317
Age1 * Severity Level 1 (Lowest)	0.611	0.499	0.443	0.406	0.405
Age 0 Male	0.634	0.590	0.557	0.494	0.491
Age 1 Male	0.103	0.086	0.069	0.049	0.048

TABLE 6: HHS HCCs Included in Infant Model Maturity Categories

Maturity Category	HCC/Description
Extremely Immature	Extremely Immature Newborns, Birth weight < 500 Grams
Extremely Immature	Extremely Immature Newborns, Including Birth weight 500-749 Grams
Extremely Immature	Extremely Immature Newborns, Including Birth weight 750-999 Grams
Immature	Premature Newborns, Including Birth weight 1000-1499 Grams
Immature	Premature Newborns, Including Birth weight 1500-1999 Grams
Premature/Multiples	Premature Newborns, Including Birth weight 2000-2499 Grams
Premature/Multiples	Other Premature, Low Birth weight, Malnourished, or Multiple Birth Newborns
Term	Term or Post-Term Singleton Newborn, Normal or High Birth weight
Age 1	All age 1 infants

TABLE 7: HHS HCCs Included in Infant Model Severity Categories

Severity Category	HCC/Description
Severity Level 5 (Highest)	Metastatic Cancer
Severity Level 5	Pancreas Transplant Status
Severity Level 5	Liver Transplant Status/Complications
Severity Level 5	Intestine Transplant Status/Complications
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis
Severity Level 5	Respirator Dependence/Tracheostomy Status
Severity Level 5	Heart Assistive Device/Artificial Heart
Severity Level 5	Heart Transplant Status/Complications
Severity Level 5	Heart Failure
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders
Severity Level 5	Lung Transplant Status/Complications
Severity Level 5	Kidney Transplant Status/Complications
Severity Level 5	End Stage Renal Disease
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia
Severity Level 4	Mucopolysaccharidosis
Severity Level 4	Adrenal, Pituitary, and Other Significant Endocrine Disorders
Severity Level 4	Acute Liver Failure/Disease, Including Neonatal Hepatitis
Severity Level 4	Chronic Liver Failure/End-Stage Liver Disorders
Severity Level 4	Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age < 2
Severity Level 4	Myelodysplastic Syndromes and Myelofibrosis
Severity Level 4	Aplastic Anemia
Severity Level 4	Combined and Other Severe Immunodeficiencies
Severity Level 4	Traumatic Complete Lesion Cervical Spinal Cord
Severity Level 4	Quadriplegia
Severity Level 4	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease
Severity Level 4	Quadriplegic Cerebral Palsy
Severity Level 4	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy
Severity Level 4	Coma, Brain Compression/Anoxic Damage
Severity Level 4	Respiratory Arrest
Severity Level 4	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes
Severity Level 4	Acute Myocardial Infarction
Severity Level 4	Heart Infection/Inflammation, Except Rheumatic
Severity Level 4	Major Congenital Heart/Circulatory Disorders
Severity Level 4	Intracranial Hemorrhage
Severity Level 4	Ischemic or Unspecified Stroke
Severity Level 4	Vascular Disease with Complications
Severity Level 4	Pulmonary Embolism and Deep Vein Thrombosis
Severity Level 4	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections
Severity Level 4	Chronic Kidney Disease, Stage 5
Severity Level 4	Artificial Openings for Feeding or Elimination
Severity Level 3	HIV/AIDS
Severity Level 3	Central Nervous System Infections, Except Viral Meningitis
Severity Level 3	Opportunistic Infections
Severity Level 3	Non-Hodgkin Lymphomas and Other Cancers and Tumors
Severity Level 3	Colorectal, Breast (Age < 50), Kidney and Other Cancers
Severity Level 3	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors

Severity Category	HCC/Description
Severity Level 3	Lipidoses and Glycogenosis
Severity Level 3	Intestinal Obstruction
Severity Level 3	Necrotizing Fasciitis
Severity Level 3	Bone/Joint/Muscle Infections/Necrosis
Severity Level 3	Osteogenesis Imperfecta and Other Osteodystrophies
Severity Level 3	Cleft Lip/Cleft Palate
Severity Level 3	Hemophilia
Severity Level 3	Disorders of the Immune Mechanism
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders
Severity Level 3	Drug Use with Psychotic Complications
Severity Level 3	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications
Severity Level 3	Alcohol Use with Psychotic Complications
Severity Level 3	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications
Severity Level 3	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes
Severity Level 3	Traumatic Complete Lesion Dorsal Spinal Cord
Severity Level 3	Paraplegia
Severity Level 3	Spinal Cord Disorders/Injuries
Severity Level 3	Cerebral Palsy, Except Quadriplegic
Severity Level 3	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies
Severity Level 3	Muscular Dystrophy
Severity Level 3	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders
Severity Level 3	Hydrocephalus
Severity Level 3	Unstable Angina and Other Acute Ischemic Heart Disease
Severity Level 3	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders
Severity Level 3	Specified Heart Arrhythmias
Severity Level 3	Cerebral Aneurysm and Arteriovenous Malformation
Severity Level 3	Hemiplegia/Hemiparesis
Severity Level 3	Cystic Fibrosis
Severity Level 3	Extensive Third-Degree Burns
Severity Level 3	Severe Head Injury
Severity Level 3	Hip and Pelvic Fractures
Severity Level 3	Vertebral Fractures without Spinal Cord Injury
Severity Level 2	Viral or Unspecified Meningitis
Severity Level 2	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors
Severity Level 2	Diabetes with Acute Complications
Severity Level 2	Diabetes with Chronic Complications
Severity Level 2	Diabetes without Complication
Severity Level 2	Protein-Calorie Malnutrition
Severity Level 2	Congenital Metabolic Disorders, Not Elsewhere Classified
Severity Level 2	Amyloidosis, Porphyria, and Other Metabolic Disorders
Severity Level 2	Cirrhosis of Liver
Severity Level 2	Chronic Pancreatitis
Severity Level 2	Acute Pancreatitis
Severity Level 2	Inflammatory Bowel Disease
Severity Level 2	Rheumatoid Arthritis and Specified Autoimmune Disorders
Severity Level 2	Systemic Lupus Erythematosus and Other Autoimmune Disorders
Severity Level 2	Congenital/Developmental Skeletal and Connective Tissue Disorders
Severity Level 2	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn
Severity Level 2	Sickle Cell Anemia (Hb-SS)
Severity Level 2	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital

Severity Category	HCC/Description
	Malformation Syndromes
Severity Level 2	Seizure Disorders and Convulsions
Severity Level 2	Monoplegia, Other Paralytic Syndromes
Severity Level 2	Atherosclerosis of the Extremities with Ulceration or Gangrene
Severity Level 2	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis
Severity Level 2	Severe Asthma
Severity Level 2	Fibrosis of Lung and Other Lung Disorders
Severity Level 2	Chronic Kidney Disease, Severe (Stage 4)
Severity Level 2	Chronic Ulcer of Skin, Except Pressure
Severity Level 2	Major Skin Burn or Condition
Severity Level 1 (Lowest)	Chronic Viral Hepatitis C
Severity Level 1	Chronic Hepatitis, Except Chronic Viral Hepatitis C
Severity Level 1	Beta Thalassemia Major
Severity Level 1	Autistic Disorder
Severity Level 1	Pervasive Developmental Disorders, Except Autistic Disorder
Severity Level 1	Multiple Sclerosis
Severity Level 1	Asthma, Except Severe
Severity Level 1	Traumatic Amputations and Amputation Complications
Severity Level 1	Amputation Status, Upper Limb or Lower Limb

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e. CSR Adjustments[43] [44] [45] [46] [47] [48]

We propose to continue including an adjustment for the receipt of CSRs in the risk adjustment models in all 50 States and the District of Columbia. While we continue to study and explore a range of options to update the CSR adjustments to improve prediction for CSR enrollees and whether changes are needed to the risk adjustment transfer formula to account for CSR plans,[49] to maintain stability and certainty for issuers for the 2024 benefit year, we are proposing to maintain the CSR adjustment factors finalized in the 2019, 2020, 2021, 2022, and 2023 Payment Notices.[50] See Table 8. We also propose to continue to use a CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans in the risk adjustment plan liability risk score calculation, as all of Massachusetts' cost-sharing plan variations have AVs above 94 percent (81 FR 12228).

We seek comment on these proposals.

[43] Starting with the 2024 risk adjustment adult models, HHS will group HCC 18 Pancreas Transplant Status and HCC 183 Kidney Transplant Status/Complications to reflect that these transplants frequently co-occur for clinical reasons and to reduce volatility of coefficients across benefit years due to the small sample size of HCC 18. This change will also be reflected in the DIY Software for the 2024 benefit year.

[44] HCC numbers that appear with an underscore in this document will appear without the underscore in the DIY software. For example, HCC 35_1 in this table will appear as HCC 351 in the DIY software.

[45] Starting with the 2024 risk adjustment adult models, HHS will group HCC 18 Pancreas Transplant Status and HCC 183 Kidney Transplant Status/Complications to reflect that these transplants frequently co-occur for clinical reasons and to reduce volatility of coefficients across benefit years due to the small sample size of HCC 18. This change will also be reflected in the DIY Software for the 2024 benefit year.

[46] As a note, we constrain RXC 03 to be equal to average plan liability for RXC 03 drugs, RXC 04 to be equal to the average plan liability for RXC 04 drugs, and we constrain RXC 03 x HCC142 and RXC 04 x HCC184, 183, 187, 188 to be equal to 0. See CMS. (2016, March 24). March 2016 Risk Adjustment Methodology Discussion Paper. *https://www.cms.gov/cciio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf* (where we previously discussed the use of constraints in the risk adjustment models).

[47] Similar to recalibration of the 2023 risk adjustment adult models and consistent with the final policies adopted in the 2023 Payment Notice, the draft factors in this rule reflect the removal of the mapping of hydroxychloroquine sulfate to RXC 09 (Immune Suppressants and Immunomodulators) and the related RXC 09 interactions (RXC 09 x HCC056 or 057 and 048 or 041; RXC 09 x HCC056; RXC 09 x HCC 057; RXC 09x HCC048, 041) from the 2018 and 2019 benefit year enrollee-level EDGE data sets for purposes of recalibrating the 2024 benefit year adult models. See 87 FR 27232 through 27235. Additionally, the draft factors for the adult models reflect the use of the final, fourth quarter (Q4) RXC mapping document that was applicable for each benefit year of data included in the current year's model recalibration (except under extenuating circumstances that can result in targeted changes to RXC mappings), while continuing to engage in annual and quarterly review processes. See 87 FR 27231 through 27232.

[48] Starting with the 2024 risk adjustment adult models, HHS will group HCC 18 Pancreas Transplant Status and HCC 183 Kidney Transplant Status/Complications to reflect that these transplants frequently co-occur for clinical reasons and to reduce volatility of coefficients across benefit years due to the small sample size of HCC 18. This change will also be reflected in the DIY Software for the 2024 benefit year and will be applied to the adult models only. In the child models, HCC 18 and HCC 183 are subject to an *a priori* constraint (S1) with HCC 34, also for sample size reasons. See Section 4.2.2 of the 2019 White Paper. (June 17, 2019.) *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Potential-Updates-to-HHS-HCCs-HHS-operated-Risk-Adjustment-Program.pdf.* Nevertheless, in both the adult and child models, the presence of one of these HCCs either alone or in a group will trigger a severity illness indicator and/or a transplant indicator for the interacted counts model specification depending on the total number of HCCs the enrollee has.

[49] See CMS. (2021, October 26). HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. Appendix A. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.* We are also considering a letter recently published by the American Academy of Actuaries regarding accounting for the receipt of CSRs in risk adjustment and plan rating and are continuing to monitor changes related to these issues. Bohl, J., Novak, D., & Karcher, J. (2022, September 8). *Comment Letter on Cost-Sharing Reduction Premium Load Factors.* American Academy of Actuaries. *https://www.actuary.org/sites/default/files/202209/Academy_CSR_Load_Letter_09.08.22.pdf.*

[50] See 83 FR 16930 at 16953; 84 FR 17478 through 17479; 85 FR 29190; 86 FR 24181; and 87 FR 27235 through 27236.

TABLE 8: Cost-Sharing Reduction Adjustment Factors

Household Income	Plan AV	Adjustment Factor
Silver Plan Variant Recipients		
100-150% of Federal Poverty Line (FPL)	Plan Variation 94%	1.12
150-200% of FPL	Plan Variation 87%	1.12
200-250% of FPL	Plan Variation 73%	1.00
>250% of FPL	Standard Plan 70%	1.00
Zero Cost Sharing Recipients		
<300% of FPL	Platinum (90%)	1.00
<300% of FPL	Gold (80%)	1.07
<300% of FPL	Silver (70%)	1.12
<300% of FPL	Bronze (60%)	1.15
Limited Cost Sharing Recipients		
>300% of FPL	Platinum (90%)	1.00
>300% of FPL	Gold (80%)	1.07
>300% of FPL	Silver (70%)	1.12
>300% of FPL	Bronze (60%)	1.15

f. Model Performance Statistics

Each benefit year, to evaluate risk adjustment model performance, we examine each model's R-squared statistic and predictive ratios (PRs). The R-squared statistic, which calculates the percentage of individual variation explained by a model, measures the predictive accuracy of the model overall. The PR for each of the HHS risk adjustment model is the ratio of the weighted mean predicted plan liability for the model sample population to the weighted mean actual plan liability for the model sample population. The PR represents how well the model does on average at predicting plan liability for that subpopulation.

A subpopulation that is predicted perfectly would have a PR of 1.0. For each of the current and proposed HHS risk adjustment models, the R-squared statistic and the PRs are in the range of published estimates for concurrent risk adjustment models.[51] Because we propose to blend the coefficients from separately solved models based on the 2018, 2019, and 2020 benefit years' enrollee-level EDGE data, with an exception to exclude 2020 benefit year data from the recalibration of the age-sex factors for the adult models, we are publishing the R-squared statistic for each model separately to verify their statistical validity. The R-squared statistics for the proposed 2024 benefit models are shown in Table 9.

TABLE 9: R-Squared Statistic for the Proposed HHS Risk Adjustment Models

Models	2018 Enrollee-Level EDGE Data	2019 Enrollee-Level EDGE Data	2020 Enrollee-Level EDGE Data
Platinum Adult	0.4411	0.4441	0.4347
Gold Adult	0.4348	0.4379	0.4278
Silver Adult	0.4310	0.4341	0.4237
Bronze Adult	0.4277	0.4309	0.4204
Catastrophic Adult	0.4276	0.4307	0.4203
Platinum Child	0.3614	0.3569	0.3420
Gold Child	0.3583	0.3536	0.3381
Silver Child	0.3558	0.3510	0.3352
Bronze Child	0.3531	0.3483	0.3325
Catastrophic Child	0.3530	0.3482	0.3323
Platinum Infant	0.3130	0.3166	0.2898
Gold Infant	0.3093	0.3130	0.2858
Silver Infant	0.3072	0.3109	0.2835
Bronze Infant	0.3055	0.3094	0.2817
Catastrophic Infant	0.3055	0.3094	0.2816

[51] Hileman, G., & Steele, S. (2016). Accuracy of Claims-Based Risk Scoring Models. Society of Actuaries. *https://www.soa.org/4937b5/globalassets/assets/files/research/research-2016-accuracy-claims-based-risk-scoring-models.pdf.*

3. Overview of the HHS Risk Adjustment Methodology (§ 153.320)

In part 2 of the 2022 Payment Notice (86 FR 24183 through 24186), we finalized the proposal to continue to use the State payment transfer formula finalized in the 2021 Payment Notice for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking. We explained that under this approach, we will no longer republish these formulas in future annual HHS notice of benefit and payment parameter rules unless changes are being proposed. We are not proposing any changes to the formula in this rule, and therefore, are not republishing the formulas in this rule. We would continue to apply the formula as finalized in the 2021 Payment Notice (86 FR 24183 through 24186) [52] in the States where HHS operates the risk adjustment program in the 2024 benefit year. Additionally, as finalized in the 2020 Payment Notice (84 FR 17466 through 17468), we will maintain the high-cost risk pool parameters for the 2020 benefit year and beyond, unless amended through notice-and-comment rulemaking. We are not proposing any changes to the high-cost risk pool parameters for the 2024 benefit year; therefore, we would maintain the $1 million threshold and 60 percent coinsurance rate.

4. Repeal of Risk Adjustment State Flexibility To Request a Reduction in Risk Adjustment State Transfers (§ 153.320(d))

We propose to repeal the flexibility under § 153.320(d) for States to request reductions of risk adjustment State transfers under the State payment transfer formula in all State market risk pools, including those prior participant States that previously requested a reduction,[53] for the 2025 benefit year and beyond. We also solicit comment on Alabama's requests to reduce risk adjustment State transfers in the individual (including the catastrophic and non-catastrophic risk pools) and small group markets for the 2024 benefit year.

a. Repeal of State Flexibility To Request Transfer Reductions

We propose to amend § 153.320(d) to repeal the ability for any State to request a reduction in risk adjustment State transfers beginning with the 2025 benefit year. As part of this repeal, we propose conforming amendments to the introductory text of § 153.320(d), which currently provides that prior participant States may request to reduce risk adjustment transfers in all State market risk pools by up to 50 percent beginning with the 2024 benefit year, to remove this flexibility for the 2025 benefit year and beyond and limit the timeframe available for prior participants to request reductions to the 2024 benefit year only. Similarly, we propose conforming amendments to paragraphs (d)(1)(iv) and (d)(4)(i)(B), which describe the conditions for a prior participant State to request a reduction beginning with the 2024 benefit year, to also limit these requests to the 2024 benefit year only and to eliminate the ability for prior participant States to request a reduction for the 2025 benefit year and beyond.

In the 2019 Payment Notice (83 FR 16955 through 16960), we amended § 153.320 to add paragraph (d) to provide States the flexibility to request a reduction to the applicable risk adjustment State transfers calculated by HHS using the State payment transfer formula for the State's individual (catastrophic or non-catastrophic risk pools), small group, or merged market risk pool by up to 50 percent in States where HHS operates the risk adjustment program to more precisely account for differences in actuarial risk in the applicable State's markets beginning with the 2020 benefit year. We finalized that any requests we received would be published in the applicable benefit year's proposed HHS notice of benefit and payment parameters, and the supporting evidence provided by the State in support of its request would be made available for public comment.[54]

In the 2023 Payment Notice (87 FR 27236), HHS limited this flexibility by finalizing amendments to § 153.320(d) that repealed the State flexibility framework for States to request reductions in risk adjustment State transfer payments for the 2024 benefit year and beyond, with an exception for prior participants.[55] We also limited the options for prior participants to request reductions by finalizing that beginning with the 2024 benefit year, States submitting reduction requests must demonstrate that the requested reduction satisfies the de minimis standard—that is, the premium increase necessary to cover the affected issuer's or issuers' reduced risk adjustment payments does not exceed 1 percent in the relevant State market risk pool.[56] In the 2023 Payment Notice (87 FR 27239 through 27241), we also finalized the conforming amendments to the HHS approval framework in § 153.320(d)(4) to reflect the changes to the applicable criteria (that is, only retaining the de minimis criterion) beginning with the 2024 benefit year, and we finalized the proposed definition of ''prior participant'' in § 153.320(d)(5). In addition, HHS indicated our intention to propose in future rulemaking to repeal the exception for prior participants beginning with the 2025 benefit year.[57]

Since finalizing the ability for States to request a reduction of risk adjustment transfers in the 2019 Payment Notice (83 FR 16955 through 16960), we received public comments on subsequent proposed rulemakings requesting that HHS repeal this policy, with several commenters noting that reducing risk adjustment transfers to plans with higher-risk enrollees could create incentives for issuers to avoid enrolling high-risk enrollees in the future by distorting plan offerings and designs, including by avoiding broad network plans, not offering platinum plans at all, and only offering limited gold plans. Commenters further stated that issuers could also distort plan designs by excluding coverage or imposing high cost-sharing for certain drugs or services. For example, one commenter stated that the risk adjustment State payment transfer formula already adjusts for differences in types of individuals enrolled in different States and aggregate differences in prices and utilization by using the Statewide average premium as a scaling factor, so State flexibility to account for State-specific factors is unnecessary.[58] In addition, since establishing this framework, we have observed a lack of

[52] Discussion provided an illustration and further details on the State payment transfer formula.

[53] Alabama is the only State that has previously requested a reduction in risk adjustment transfers through this flexibility and therefore is the only State considered a ''prior participant State''.

[54] If the State requests that HHS not make publicly available certain supporting evidence and analysis because it contains trade secrets or confidential commercial or financial information within the meaning of HHS' Freedom of Information Act regulations at 45 CFR 5.31(d), HHS will only make available on the CMS website the supporting evidence submitted by the State that is not a trade secret or confidential commercial or financial information by posting a redacted version of the State's supporting evidence. See § 153.320(d)(3).

[55] Section 153.320(d)(5) defines prior participants as States that submitted a State reduction request in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool in the 2020, 2021, 2022, or 2023 benefit year.

[56] 87 FR 27239 through 27241. See also 83 FR 16957.

[57] 87 FR 27239 through 27241. See also 83 FR 16957.

[58] See Fielder, M, & Layton, T. (2020, December 30). *Comment Letter on 2022 Payment Notice Proposed Rule.* Brookings. *https://www.brookings.edu/wp-content/uploads/2020/12/FiedlerLaytonCommentLetterNBPP2022.pdf.*

interest from States in using this policy. Only one State (Alabama) has exercised this flexibility and requested reductions to transfers in its individual and/or small group markets.[59]

HHS believes this proposal to completely repeal the option for States to request reductions in risk adjustment State transfers would align HHS policy with Section 1 of E.O. 14009 (86 FR 7793), which prioritizes protecting and strengthening the ACA and making high-quality health care accessible and affordable for all individuals. Section 3 of E.O. 14009 directs HHS, and the heads of all other executive departments and agencies with authorities and responsibilities related to Medicaid and the ACA, to review all existing regulations, orders, guidance documents, policies, and any other similar agency actions to determine whether they are inconsistent with policy priorities described in Section 1 of E.O. 14009. Consistent with this directive, HHS reviewed the risk adjustment State flexibility under § 153.320(d) and determined it is inconsistent with policies described in sections 1 and 3 of E.O. 14009. We believe that a complete repeal of § 153.320(d) would prevent the potential negative outcomes of risk adjustment State flexibility identified through public comment, including the possibility of risk selection, market destabilization, increased premiums, smaller networks, and less-comprehensive plan options, the prevention of which would protect and strengthen the ACA and make health care more accessible and affordable. For all of these reasons, we propose to amend § 153.320(d) to fully repeal the flexibility for States, including prior participants, to request reductions of risk adjustment State transfers calculated by HHS under the State payment transfer formula in all State market risk pools beginning with the 2025 benefit year. If these amendments are finalized, no State would be able to request a reduction in risk adjustment transfers calculated by HHS under the State payment transfer formula starting with the 2025 benefit year.

We seek comment on this proposal.

b. Requests To Reduce Risk Adjustment Transfers for the 2024 Benefit Year

In accordance with § 153.320(d)(2), beginning with the 2020 benefit year, States requesting a reduction in the transfers calculated by HHS under the State payment transfer formula must submit their requests with the supporting evidence and analysis outlined under § 153.320(d)(1) by August 1 of the calendar year that is 2 calendar years prior to the beginning of the applicable benefit year. As finalized in the 2023 Payment Notice (87 FR 27239 through 27241), under § 153.320(d)(1)(iv), State requests for a reduction to transfers must include a justification for the reduction requested demonstrating the requested reduction would have de minimis impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments beginning with the 2024 benefit year. In accordance with § 153.320(d)(4)(i)(B), HHS will approve State reduction requests if HHS determines, based on the review of the information submitted as part of the State's request, along with other relevant factors, including the premium impact of the transfer reduction for the State market risk pool, and relevant public comments, that the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments beginning with the 2024 benefit year. In addition, pursuant to § 153.320(d)(4)(ii), HHS may approve a reduction amount that is lower than the amount requested by the State if the supporting evidence and analysis do not fully support the requested reduction amount. If approved by HHS, State reduction requests are applied to the plan PMPM payment or charge State payment transfer amount (Ti in the State payment transfer formula).

For the 2024 benefit year, HHS received requests from Alabama to reduce risk adjustment State transfers for its individual[60] and small group markets by 50 percent. As Alabama has stated in previous years, Alabama asserts that the HHS-operated risk adjustment program does not work precisely in the Alabama market, clarifying that they do not assert that the risk adjustment formula is flawed, only that it produces imprecise results in Alabama which has an ''extremely unbalanced market share.'' The State reports that its review of the issuers' 2021 financial data suggested that any premium increase resulting from a reduction of 50 percent to the 2024 benefit year risk adjustment payments for the individual market would not exceed one percent, the *de minimis* premium increase threshold set forth in § 153.320(d)(1)(iv) and (d)(4)(i)(B). Additionally, the State reports that its review of the issuers' 2021 financial data also suggested that any premium increase resulting from a 50 percent reduction to risk adjustment payments in the small group market for the 2024 benefit year would not exceed the *de minimis* threshold of one percent.

At this time, to make HHS's approval determination under § 153.320(d)(4), we seek comment on Alabama's requests to reduce risk adjustment State transfers in their individual and small group markets by 50 percent for the 2024 benefit year. The request and additional documentation submitted by Alabama are posted under the ''State Flexibility Requests'' heading at *https://www.cms.gov/cciio/programs-and-initiatives/premium-stabilization-programs.*

5. Risk Adjustment Issuer Data Requirements (§§ 153.610, 153.700, and 153.710)

We propose, beginning with the 2023 benefit year, to collect and extract from issuers' EDGE servers through issuers' EDGE Server Enrollment Submission (ESES) files and risk adjustment recalibration enrollment files a new data element, a QSEHRA indicator. We also propose to extract plan ID and rating area data elements issuers have submitted to their EDGE servers from certain benefit years prior to 2021.

45 CFR 153.610(a) requires that health insurance issuers of risk adjustment covered plans submit or make accessible all required risk adjustment data in accordance with the data collection approach established by HHS[61] in States where HHS operates the program on behalf of a State.[62] In the 2014 Payment Notice (78 FR 15497 through 15500; § 153.720), HHS established an approach for obtaining the necessary data for risk adjustment calculations in States where HHS operates the program

[59] For the 2020 and 2021 benefit years, Alabama submitted a 50 percent risk adjustment transfer reduction request for its small group market, which HHS approved in the 2020 Payment Notice (84 FR 17454) and in the 2021 Payment Notice (85 FR 29164). For the 2022 and 2023 benefit years, Alabama submitted 50 percent risk adjustment transfer reduction requests for its individual and small group markets. HHS approved the State's requests for the 2022 benefit year in part 2 of the 2022 Payment Notice final rule (86 FR 24140) and approved a 25 percent reduction for Alabama's individual market State transfers (including the catastrophic and non-catastrophic risk pools) and a 10 percent reduction for the State's small group market transfers for the 2023 benefit year in the 2023 Payment Notice (87 FR 27208).

[60] Alabama's individual market request is for a 50 percent reduction to risk adjustment transfers for its individual market non-catastrophic and catastrophic risk pools.

[61] Also see 45 CFR 153.700–153.740.

[62] The full list of required data elements can be found in Appendix A of OMB Control Number 0938–1155/CMS–10401. (2022, May 26). Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment. *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10401.*

through a distributed data collection model that prevented the transfer of individuals' personally identifiable information (PII). Then, in several subsequent rulemakings,[63] we finalized policies for the extraction and use of enrollee-level EDGE data. The purpose of collecting and extracting enrollee-level data is to provide HHS with more granular data to use for recalibrating the HHS risk adjustment models, informing updates to the AV Calculator, conducting policy analysis, and calibrating HHS programs in the individual and small group (including merged) markets and the PHS Act requirements enforced by HHS that are applicable market-wide,[64] as well as informing policy and improving the integrity of other HHS Federal health-related programs.[65] The use of enrollee-level data extracted from issuers' EDGE servers and summary level reports produced from remote command and ad hoc queries enhances HHS' ability to develop and set policy and limits the need to pursue alternative burdensome data collections from issuers. We also previously finalized policies related to creating on an annual basis an enrollee-level EDGE Limited Data Set (LDS) using masked enrollee-level data submitted to EDGE servers by issuers of risk adjustment covered plans in the individual and small group (including merged) markets and making this LDS available to requestors who seek the data for research purposes.[66] [67]

a. Collection and Extraction of the QSEHRA Indicator

In the 2023 Payment Notice (87 FR 27241 through 27252), we finalized that we will collect and extract an individual coverage Health Reimbursement Arrangement (ICHRA) indicator and that we will make this indicator available in the enrollee-level EDGE LDS beginning with the 2023 benefit year. The primary purpose of collecting and extracting ICHRA indicator data is to allow HHS to conduct analyses to examine whether there are any unique actuarial characteristics of the ICHRA population (such as the health status of enrollees with ICHRAs), and to investigate what impact (if any) ICHRA enrollment is having on State individual and small group (or merged) market risk pools. The additional information collected through the ICHRA indicator will be used to further analyze if any refinements to the HHS risk adjustment methodology should be examined or proposed through notice and comment rulemaking, and similarly may also be used to inform policy analysis and potential updates to the AV Calculator, other HHS individual or small group (including merged) market programs, or other HHS Federal health-related programs.

Since finalizing the collection of the ICHRA indicator as part of the enrollee-level EDGE data extracted from issuers' EDGE servers, we determined that also collecting and extracting a QSEHRA indicator would provide a more thorough picture of the actuarial characteristics of the Health Reimbursement Arrangement (HRA) population and how or whether HRA enrollment is impacting State individual and small group (including merged) market risk pools. HHS needs QSEHRA data in order to conduct a comprehensive assessment of the HRA markets. A QSEHRA indicator would also allow HHS to investigate whether the risk profile of enrollees in QSEHRAs, which differ from ICHRAs with respect to standards related to employer eligibility, employee eligibility, restrictions on allowance amounts, and eligibility for PTCs, differ from enrollees in ICHRAs.[68] While we acknowledge that FFEs, SBE–FPs, and SBEs collect information about the provision of QSEHRAs, we note that adding a QSEHRA indicator to the required risk adjustment EDGE data submissions would provide more uniform and comprehensive information than what is submitted by Exchange enrollees, as it would capture information on both Exchange and non-Exchange enrollment. It also would provide HHS the ability to extract and aggregate the QSEHRA indicator alongside other claims and enrollment data accessible through issuers' EDGE servers, which would not be possible with the data collection from consumers through other processes since the EDGE data is masked [69] and therefore cannot be linked with other enrollment data sources.[70]

We therefore propose that, beginning with the 2023 benefit year, issuers would be required to collect and submit a QSEHRA indicator as part of the required risk adjustment data that issuers make accessible to HHS from their respective EDGE servers in States where HHS operates the risk adjustment program. This new data element would be included as part of the enrollee-level EDGE data extracted from issuers' EDGE servers and summary level reports produced from remote command and ad hoc queries beginning with the 2023 benefit year.[71] We also propose to include this indicator in the enrollee-level EDGE LDS made available to qualified researchers upon request once available (that is, beginning with 2023 benefit year data).

In the 2023 Payment Notice (87 FR at 27248), we acknowledged that ICHRA information is collected by HHS from FFE or SBE–FP enrollees through the eligibility application process and from SBE enrollees through the State Exchange enrollment and payment files, as well as collected directly by issuers and their affiliated agents and brokers. We also noted the ICHRA indicator was intended to capture whether a particular enrollee's health care coverage involves (or does not involve) an ICHRA and that we would structure this data element for EDGE data submissions similar to current collections, where possible. Additionally, we explained that the collection and extraction of an ICHRA indicator as part of the required risk adjustment data submissions issuers make accessible to HHS through their respective EDGE servers provides more uniform and comprehensive information than what is submitted by FFE and SBE–FP enrollees on a QHP application and by SBE enrollees through enrollment and payment files, as it would capture both on and off Exchange enrollees.

The same is also true for QSEHRA information and we therefore propose to apply the same approach for the QSEHRA indicator. Currently, the FFEs and SBE–FPs collect information about

[63] See the 2018 Payment Notice, 81 FR 94101; the 2020 Payment Notice, 84 FR 17488; and the 2023 Payment Notice, 87 FR 27241.

[64] See, for example, 42 U.S.C. 300gg–300gg–28.

[65] As detailed in the 2023 Payment Notice, the finalized policies related to the permitted uses of EDGE data and reports make clear that HHS can use this information to inform policy analyses and improve the integrity of other HHS Federal health-related programs outside the commercial individual and small group (including merged) markets, such as the programs in certain States to provide wrap-around QHP coverage through Exchanges to Medicaid expansion populations and coverage offered by non-Federal Governmental plans. See 87 FR 27243; 87 FR 630 through 631.

[66] See the 2020 Payment Notice, 84 FR 17486 through 17490 and the 2023 Payment Notice, 87 FR 27243. Also see CMS. (2022, August 15). Enrollee-Level External Data Gathering Environment (EDGE) Limited Data Set (LDS). *https://www.cms.gov/research-statistics-data-systems/limited-data-set-lds-files/enrollee-level-external-data-gathering-environment-edge-limited-data-set-lds.*

[67] As explained in the 2020 Payment Notice, we do not currently make the EDGE LDS available to requestors for public health or health care operation activities. See 84 FR 17488.

[68] Rosso, R. (2022, May 7). Health Reimbursement Arrangements (HRAs): Overview and Related History. Congressional Research Service. *https://crsreports.congress.gov/product/pdf/R/R47041.*

[69] 45 CFR 153.720.

[70] For information on the challenges associated with linking the extracted enrollee-level EDGE data to other sources, see 87 FR 631 through 632.

[71] The deadline for submission of 2023 benefit year risk adjustment data is April 30, 2024. See 45 CFR 153.730.

QSEHRA provision from all applicants to determine whether they are eligible for a special enrollment period (SEP), as individuals and their dependents who become newly eligible for a QSEHRA may be eligible for a SEP. SBEs also collect similar information from their applicants to determine SEP eligibility. This data may also be provided directly to issuers by consumers who seek to enroll in coverage directly with the issuer. In addition, an issuer may currently have or collect information that could be used to populate the QSEHRA indicator in situations where the issuer is being paid directly by the employer through the QSEHRA for the individual market coverage. We therefore propose to generally permit issuers to populate the required QSEHRA indicator with information from the FFE or SBE–FP enrollees or enrollees through SBEs, or from other sources for collecting this information. The QSEHRA indicator would be used to capture whether a particular enrollee's health care coverage involves (or does not involve) a QSEHRA, and we propose to structure this data element for EDGE data submissions similar to current collections, where possible. Beginning with the 2023 benefit year, HHS would provide additional operational and technical guidance on how issuers should submit this new data element to HHS through issuer EDGE servers via the applicable benefit year's EDGE Server Business Rules and the EDGE Server Interface Control Document, as may be necessary.

We are also proposing, similar to the transitional approach for the ICHRA indicator finalized in the 2023 Payment Notice (87 FR 27241 through 27252), a transitional approach for the collection and extraction of the QSEHRA indicator. For the 2023 and 2024 benefit years, issuers would be required to populate the QSEHRA indicator using only data they already collect or have accessible regarding their enrollees. For example, when an FFE enrollee is using an SEP, information about QSEHRA provision is collected by the FFE, and the FFE may make these data available to issuers. In addition, as noted above, there may be situations where an issuer has or collects information that could be used to populate the QSEHRA indicator. Then, beginning with the 2025 benefit year, we propose that the transitional approach would end, and issuers would be required to populate the QSEHRA field using available sources (for example, information from Exchanges, and requesting information directly from enrollees) and, in the absence of an existing source for particular enrollees, to make a good faith effort to ensure collection and submission of the QSEHRA indictor for these enrollees. HHS would provide additional details on what constitutes a good faith effort to ensure collection and submission of the QSEHRA indicator in the future. HHS intends to seek input from issuers and other interested parties to inform development of the good faith standard and determine the most feasible methods for issuers to collect the information used to populate this data field.[72]

We believe this transitional approach is necessary as the burden associated with the collection of this data would be similar to that of the collection of the ICHRA indicator, as finalized in the 2023 Payment Notice (87 FR 27241 through 27252). Much like the ICHRA indicator data, we believe that some issuers already collect the relevant QSEHRA data. However, we do not believe the information to populate the QSEHRA indicator is routinely collected by all issuers at this time; therefore, we anticipate that there may be administrative burden for some issuers in developing processes for collection, validation, and submission of this new data element. In recognition of the burden that collection of this new data element potentially would pose for some issuers, we propose to adopt a transitional approach for the 2023 and 2024 benefit years. This transitional approach for the QSEHRA indicator would be the same as the approach finalized for the ICHRA indicator in the 2023 Payment Notice and is also similar to how we have handled other new data collection requirements.[73] Further details regarding the estimated burden may be found below in the *ICRs Regarding Risk Adjustment Issuer Data Submission Requirements (§§ 153.610, 153.700, and 153.710).*

Consistent with the policy adopted in the 2020 Payment Notice (84 FR 17488 through 17490) regarding HHS' use of data and reports extracted from issuers EDGE servers (including data reports and ad hoc query reports), and the policy adopted in the 2023 Payment Notice (87 FR 27243) to expand the permissible uses of such data and reports, beyond the risk adjustment program, we would also use the QSEHRA indicator once it is available to conduct policy analysis; operationalize and calibrate other HHS programs in the individual and small group (including merged) markets; and to inform policy analysis and improve the integrity of other HHS Federal health-related programs to the extent such use is otherwise authorized by, required under, or not inconsistent with applicable Federal law. We would not use the QSEHRA indicator or any analysis that relied upon the indictor to pursue changes to our policies until we conduct data quality checks and ensure the response rate is adequate to support any analytical conclusions. These data quality and reliability checks would generally be consistent with other data standard checks that HHS performs related to data collected through issuers' EDGE servers.

In conjunction with the proposal to collect and extract this new data element, we also propose to include the QSEHRA indicator in the LDS containing enrollee-level EDGE data that HHS makes available to qualified researchers upon request once the QSEHRA indicator is available, beginning with the 2023 benefit year. We propose to include the new indicator as part of the LDS because it would enhance the usefulness of the data set for qualified researchers by making available additional data to increase understanding of these markets, particularly the impact QSEHRA provision may have on the individual and small group (including merged) markets, and contribute to greater transparency. We further note that similar to the ICHRA indicator, the proposed QSEHRA indicator would not be a direct identifier that must be excluded from an LDS under the HIPAA Privacy Rule and thus would not add to the risk of enrollees being identified. As noted in the 2023 Payment Notice (87 FR at 27245), only an LDS of certain masked enrollee-level EDGE data elements is made available and this LDS is available only to qualified researchers if they meet the requirements for access to such file(s), including entering into a data use agreement that establishes the permitted uses or disclosures of the information and prohibits the recipient from identifying the information.[74] [75] In

[72] If the burden estimate for collection of QSEHRA indicator changes beginning with the 2025 benefit year (after the transitional approach ends), the information collection under OMB control number 0938–1155 would be revised accordingly and interested parties would be provided the opportunity to comment through that process.

[73] For example, HHS did not penalize issuers for temporarily submitting a default value for the in/out-of-network indictor for the 2018 benefit year in order to give issuers time to make the necessary changes to their operations and systems to comply with the new data collection requirement, but required issuers to provide full and accurate information for the in/out-of-network indicator beginning with the 2019 benefit year.

[74] See CMS. (2020, June). Data Use Agreement. (Form CMS–R–0235L).*https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/*

addition, consistent with how we created the LDS in prior years, HHS will continue to exclude data from the LDS that could lead to identification of certain enrollees.[76]

b. Extracting Plan ID and Rating Area

Finally, in addition to collecting and extracting a QSEHRA indicator, we propose to extract the plan ID[77] and rating area data elements from the 2017, 2018, 2019 and 2020 benefit year data submissions that issuers already made accessible to HHS. In the 2023 Payment Notice (87 FR 27249), we finalized the proposal to extract these data elements beginning with the 2021 benefit year. However, HHS has determined that to aid in annual model recalibration, as well as HHS' analyses of risk adjustment data, it would be beneficial to also include these two data elements as part of the enrollee-level EDGE data and reports extracted from issuers' EDGE servers for the 2017, 2018, 2019 and 2020 benefit years. Inclusion of plan ID and rating area in extractions of these additional benefit year data sets would also support analysis of other HHS individual and small group (including merged) market programs, as well as other HHS Federal health-related programs.

Moreover, since finalizing the 2023 Payment Notice, we have found that the analysis of risk adjustment data would be more valuable if we could compare historical trends, and access to these data elements for past years would further our ability to analyze and improve the risk adjustment program. For example, in assessing the 2020 enrollee-level EDGE data set for inclusion in the 2024 benefit year model recalibration, having access to plan ID and rating area would have allowed us to consider the different patterns of utilization and costs at a more granular level (for example, the State market risk pool level). Since issuers already collected and made available these data elements to HHS for the 2017, 2018, 2019 and 2020 benefit years,[78] we do not believe that this proposal would increase burden on issuers. We are also not proposing any changes to the accompanying policies finalized in the 2023 Payment Notice with respect to these data elements and the enrollee-level EDGE LDS. Although we recognize that including plan ID and rating area would enhance the usefulness of the LDS, we continue to believe it is appropriate to exclude these data elements from the LDS to mitigate the risk that entities that receive the LDS file could identify issuers based on these identifiers, particularly in areas with a small number of issuers. As such, HHS would not include these data elements (plan ID and rating area) in the LDS files made available to qualified researchers upon request.

We seek comment on these proposals.

6. Risk Adjustment User Fee for 2024 Benefit Year (§ 153.610(f))

We propose a risk adjustment user fee for the 2024 benefit year of $0.21 PMPM. Under § 153.310, if a State is not approved to operate, or chooses to forgo operating, its own risk adjustment program, HHS will operate risk adjustment on its behalf. As noted previously in this proposed rule, for the 2024 benefit year, HHS will operate the risk adjustment program in every State and the District of Columbia. As described in the 2014 Payment Notice (78 FR 15416 through 15417), HHS' operation of risk adjustment on behalf of States is funded through a risk adjustment user fee. Section 153.610(f)(2) provides that, where HHS operates a risk adjustment program on behalf of a State, an issuer of a risk adjustment covered plan must remit a user fee to HHS equal to the product of its monthly billable member enrollment in the plan and the PMPM risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

OMB Circular No. A–25 established Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.[79] The HHS-operated risk adjustment program provides special benefits as defined in section 6(a)(1)(B) of OMB Circular No. A–25 to issuers of risk adjustment covered plans because it mitigates the financial instability associated with potential adverse risk selection.[80] The risk adjustment program also contributes to consumer confidence in the health insurance industry by helping to stabilize premiums across the individual, merged, and small group markets.

In the 2023 Payment Notice (87 FR 27252), we calculated the Federal administrative expenses of operating the risk adjustment program for the 2023 benefit year to result in a risk adjustment user fee rate of $0.22 PMPM based on our estimated costs for risk adjustment operations and estimated BMM for individuals enrolled in risk adjustment covered plans. For the 2024 benefit year, HHS proposes to use the same methodology to estimate our administrative expenses to operate the risk adjustment program. These costs cover development of the models and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, interested parties training, operational support, and administrative and personnel costs dedicated to risk adjustment program activities. To calculate the risk adjustment user fee, we divided HHS' projected total costs for administering the risk adjustment program on behalf of States by the expected number of BMM in risk adjustment covered plans in States where the HHS-operated risk adjustment program will apply in the 2024 benefit year.

We estimate that the total cost for HHS to operate the risk adjustment program on behalf of States for the 2024 benefit year will be approximately $60 million, which remains stable with the approximately $60 million estimated for the 2023 benefit year. We also project higher enrollment than our prior estimates in the individual and small group (including merged) markets in the 2023 and 2024 benefit years based on the increased enrollment between the 2020 and 2021 benefit years, likely due to the increased PTC subsidies provided for in the American Rescue Plan Act of 2021 (ARP).[81] [82] In light of the passage

CMS-R-0235L.pdf. See also 84 FR 17486 through 17490.

[75] CMS. (2020, June). Data Use Agreement. (Form CMS–R–0235L). *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS-R-0235L.pdf.*

[76] See, for example, CMS. (2021, August 25). Creation of the 2019 Benefit Year Enrollee-Level EDGE Limited Data Sets: Methods, Decisions and Notes on Data Use. *https://www.cms.gov/files/document/2019-data-use-guide.pdf.*

[77] For details on the plan ID and its components, see p. 42 of the following: CMS. (2013, March 22). *CMS Standard Companion Guide Transaction Information: Instructions related to the ASC X12 Benefit Enrollment and Maintenance (834) transaction, based on the 005010X220 Implementation Guide and its associated 005010X220A1 addenda for the FFE. https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/companion-guide-for-ffe-enrollment-transaction-v15.pdf.*

[78] As detailed in the 2023 Payment Notice, issuers have been required to submit these two data elements as part of the required risk adjustment data submissions to their respective EDGE servers to support HHS' calculation of risk adjustment transfers since the 2014 benefit year. See 87 FR 27243.

[79] OMB. (1993). *OMB Circular No. A–25 Revised, Transmittal Memorandum No. https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf.*

[80] Ibid.

[81] ARP. Public Law 117–2 (2021).

Continued

of the Inflation Reduction Act of 2022 (IRA), in which Section 12001 extended the enhanced PTC subsidies in section 9661 of the ARP through the 2025 benefit year, we project increased 2021 enrollment levels to remain steady through the 2025 benefit year.[83] Because this provision of the IRA is expected to continue higher enrollment, we propose a slightly lower risk adjustment user fee of $0.21 PMPM.

We seek comment on the proposed risk adjustment user fee for the 2024 benefit year.

7. Risk Adjustment Data Validation Requirements When HHS Operates Risk Adjustment (HHS–RADV) (§§ 153.350 and 153.630)

HHS will conduct risk adjustment data validation under §§ 153.350 and 153.630 in any State where HHS is operating risk adjustment on a State's behalf.[84] The purpose of risk adjustment data validation is to ensure issuers are providing accurate high-quality information to HHS, which is crucial for the proper functioning of the HHS-operated risk adjustment program. HHS–RADV also ensures that risk adjustment transfers reflect verifiable actuarial risk differences among issuers, rather than risk score calculations that are based on poor quality data, thereby helping to ensure that the HHS-operated risk adjustment program assesses charges to issuers with plans with lower-than-average actuarial risk while making payments to issuers with plans with higher-than-average actuarial risk. HHS–RADV consists of an initial validation audit (IVA) and a second validation audit (SVA). Under § 153.630, each issuer of a risk adjustment covered plan must engage an independent initial validation audit entity. The issuer provides demographic, enrollment, and medical record documentation for a sample of enrollees selected by HHS to its initial validation auditor for data validation. Each issuer's IVA is followed by an SVA, which is conducted by an entity HHS retains to verify the accuracy of the findings of the IVA. Based on the findings from the IVA, or SVA (as applicable), HHS conducts error estimation to calculate an HHS–RADV error rate. The HHS–RADV error rate is then applied to adjust the plan liability risk scores of outlier issuers, as well as the risk adjustment transfers calculated under the State payment transfer formula for the applicable State market risk pools, for the benefit year being audited.

a. Materiality Threshold for Risk Adjustment Data Validation

Beginning with 2022 benefit year HHS–RADV, we propose to change the HHS–RADV materiality threshold definition, first implemented in the 2018 Payment Notice (81 FR 94104 through 94105), from $15 million in total annual premiums Statewide to 30,000 total BMM Statewide, calculated by combining an issuer's enrollment in a State's individual non-catastrophic, catastrophic, small group, and merged markets, as applicable, in the benefit year being audited.[85] Consistent with the application of the current materiality threshold definition and accompanying exemption under § 153.630(g)(2), issuers that fall below the new proposed materiality threshold would not be subject to the annual IVA (and SVA) audit requirements, but may be selected to participate in a given benefit year of HHS–RADV based on random sampling or targeted sampling due to the identification of any risk-based triggers that warrant more frequent audits.

In the 2020 Payment Notice (84 FR 17508 through 17511), HHS established § 153.630(g) to codify exemptions to HHS–RADV requirements, including an exemption for issuers that fell below a materiality threshold, as defined by HHS, to ease the burden of annual audit requirements for smaller issuers of risk adjustment covered plans that do not materially impact risk adjustment transfers.[86] This materiality threshold was first implemented and defined in the 2018 Payment Notice (81 FR 94104 through 94105), where HHS finalized a policy that issuers with total annual premiums at or below $15 million (calculated based on the Statewide premiums of the benefit year being validated) would not be subject to annual IVA requirements, but would still be subject to random and targeted sampling.[87] Under this approach, issuers below the materiality threshold are subject to an IVA approximately every 3 years, barring any risk-based triggers that would warrant more frequent audits.

We implemented the materiality threshold based on an evaluation of the burden associated with HHS–RADV, particularly the fixed costs associated with hiring an initial validation auditor and submitting IVA results to HHS on an annual basis, which may be a large portion of some issuers' administrative costs.[88] To ease the burden of annual audit requirements for smaller issuers of risk adjustment covered plans that do not materially impact risk adjustment transfers, we finalized a threshold of $15 million in total annual premiums Statewide—a threshold at which 1 percent of an issuer's premiums would cover the estimated $150,000 cost of the IVA.[89] When defining this threshold, we also considered the impact of the exemption on risk adjustment transfers and data validation activities, and estimated issuers above this threshold represented approximately 98.5 percent of enrollment in risk adjustment covered plans nationally. As such, we determined the annual audit of issuers at or below the threshold of total annual premiums Statewide of $15 million was not material.[90] We committed to continue to monitor this threshold and further noted we may propose adjustments in the future to maintain this balance.[91]

Since we established the materiality threshold definition, the estimated costs to complete the IVA have increased, especially with the addition of prescription drug categories to the adult models starting with the 2018 benefit year, and our current estimate of the cost of the IVA is approximately $170,000 per an issuer. To maintain the same general framework and effectively limit the proportion of an issuer's premiums that would be used to cover IVA costs to 1 percent, we would need to adjust the current materiality threshold definition and increase it to

[82] CMS. (2022, July 19). *Summary Report on Permanent Risk Adjustment Transfers for the 2021 Benefit Year.* (p. 9). *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2021.pdf.*

[83] Inflation Reduction Act. Public Law 1217–169 (2022).

[84] HHS has operated the risk adjustment program in all 50 States the District of Columbia since the 2017 benefit year.

[85] Activities related to the 2022 benefit year of HHS–RADV will generally begin in March 2023, when issuers can start selecting their IVA entity, and IVA entities can start electing to participate in HHS–RADV for the 2022 benefit year. See, for example, the 2021 Benefit Year HHS–RADV Activities Timeline (May 3, 2022), available at: *https://regtap.cms.gov/uploads/library/HRADV_2021Timeline_5CR_050322.pdf.*

[86] Additionally, in the 2019 Payment Notice (83 FR 16966), we finalized an exemption from HHS–RADV for issuers with 500 or fewer BMM Statewide in the benefit year being audited. This very small issuer exemption is codified at 45 CFR 153.630(g)(1). Issuers with 500 or fewer BMM Statewide are not subject to random or targeted sampling.

[87] While the 2018 Payment Notice (81 FR 94104 through 94105) provided an applicability date for the materiality threshold that began with the 2017 benefit year of HHS–RADV, we postponed the application of the materiality threshold to the 2018 benefit year in the 2019 Payment Notice (83 FR 16966 through 16967).

[88] See 81 FR 94104 through 94105. Also see 81 FR 61490.

[89] See 81 FR 94104 through 94105.

[90] See 81 FR 94104 through 94105. Also see 81 FR 61490.

[91] See 81 FR 94105.

$17 million in total annual premiums Statewide. We estimate that 30,000 BMM Statewide translates to approximately $17 million in total annual premiums Statewide on average across markets, and this proposed threshold would maintain that issuers of risk adjustment covered plans below this threshold would represent no more than 1.5 percent of enrollment in risk adjustment covered plans nationally. We therefore propose to change the HHS definition of the materiality threshold under § 153.630(g)(2) to 30,000 BMM Statewide in the benefit year being audited beginning with the 2022 benefit year of HHS–RADV.

We propose shifting the exemption from a dollar threshold to BMM threshold because a BMM threshold would continue to exempt small issuers that face a disproportionally higher burden even in situations where PMPM premiums grow overtime. Shifting the materiality threshold under § 153.630(g)(2) to a BMM basis would also align with the threshold established in § 153.630(g)(1), which exempts issuers with 500 or fewer BMM Statewide in the benefit year being audited from HHS–RADV requirements, including random and targeted sampling. We do not anticipate that this proposal would change the current estimated burdens of the annual HHS–RADV requirements on issuers as the pool of issuers falling below a 30,000 BMM Statewide threshold does not significantly differ from the pool of issuers falling below a $15 million total annual premiums Statewide threshold. On average, between the 2017 and 2021 benefit years, there were 197 issuers of risk adjustment covered plans with total annual premiums Statewide below $15 million and 201 issuers of risk adjustment covered plans with total BMM Statewide below 30,000. The proposed changes should also have a minimal impact on data validation activities as issuers of risk adjustment covered plans below this proposed threshold are estimated to represent no more than 1.5 percent of enrollment in risk adjustment covered plans nationally. We continue to believe that setting this 1.5 percent of enrollment threshold promotes the goals of the HHS–RADV process, while also considering the burden of the process on smaller plans, and therefore represents the appropriate balance.

We are not proposing any changes to the regulatory text at § 153.630(g)(2) or to the other accompanying policies. As such, beginning with the 2022 benefit year of HHS–RADV, issuers below the proposed 30,000 BMM Statewide threshold would be exempt from participating in the annual HHS–RADV IVA and SVA requirements if not otherwise selected by HHS to participate under random and targeted sampling conducted approximately every 3 years (barring any risk-based triggers based on experience that would warrant more frequent audits). To determine whether an issuer falls under the materiality threshold, its BMM would be calculated Statewide, that is, by combining an issuer's enrollment in a State's individual non-catastrophic, catastrophic, small group, and merged markets, as applicable, in the benefit year being audited. Issuers that qualify for the exemption under § 153.630(g)(2) from HHS–RADV requirements for a particular benefit year must continue to maintain their risk adjustment documents and records consistent with § 153.620(b) and may be required to make those documents and records available for review or to comply with an audit by the Federal Government.[92] We further note that if an issuer of a risk adjustment covered plan that falls within the materiality threshold is not exempt from HHS–RADV for a given benefit year (that is, the issuer is selected as part of random or targeted sampling), and fails to engage an IVA or submit IVA results to HHS, the issuer would be subject to the default data validation charge in accordance with § 153.630(b)(10) and may be subject to other enforcement action. Lastly, we affirm that an issuer that qualifies for an exemption under § 153.630(g)(2) from HHS–RADV requirements for a particular benefit year would not have its risk scores and State transfers adjusted due to its own risk score error rate(s), but its risk scores and State transfers could be adjusted if other issuers in the applicable State market risk pools were outliers in that benefit year of HHS–RADV.

We solicit comments on this proposal as well as comments on whether we should increase the materiality threshold to $17 million in total annual premiums Statewide instead of switching to 30,000 BMM Statewide and on the applicability date for when a new HHS–RADV materiality threshold should begin to apply.

b. HHS–RADV Adjustments for Issuers That Have Exited the Market

Beginning with 2021 benefit year HHS–RADV, we propose to remove the policy to only apply an exiting issuer's HHS–RADV results if that issuer is a positive error rate outlier.[93] We are proposing to change this policy because it is no longer necessary to treat exiting issuers differently from non-exiting issuers when they are negative error rate outliers in the applicable benefit year's HHS–RADV given the transition to the concurrent application of HHS–RADV results for all issuers.

Consistent with 45 CFR 153.350(b) and (c), adjustments are made to risk scores and risk adjustment State transfers based on the errors discovered in HHS–RADV. In the 2015 Payment Notice (79 FR 13768 through 13769), HHS established a prospective approach to adjust risk scores and risk adjustment State transfers based on the results of HHS–RADV. Under the prospective approach, an issuer's HHS–RADV error rate for a given benefit year is applied to the following benefit year's risk scores and risk adjustment State transfers. However, an issuer that exits all market risk pools in the State during or at the end of the benefit year being audited would not have risk scores and State transfers to adjust in the next applicable benefit year. As such, the 2019 Payment Notice (83 FR 16965 through 16966) created an exception to the prospective approach for exiting issuers that provides for the concurrent application of HHS–RADV results for exiting issuers identified as outliers. Under this exception, the HHS–RADV error rate of an outlier exiting issuer is used to adjust the exiting issuer's prior year risk scores and State transfers for the applicable State market risk pool(s). Due to the budget neutral nature of the HHS-operated risk adjustment program, including HHS–RADV, the application of an outlier exiting issuer's HHS–RADV error rate would also impact other issuers in the applicable State market risk pool(s). Recognizing the impact on non-exiting issuers, we further refined the exiting issuer HHS–RADV policies in the 2020 Payment Notice (84 FR 17503 through 17504) to limit the re-opening of risk pools to make HHS–RADV adjustments to non-exiting issuers' risk adjustment State transfers in certain situations. More specifically, HHS finalized a policy to only make risk score and risk adjustment State transfer adjustments to reflect an exiting issuer's HHS–RADV results if that issuer is a

[92] See 45 CFR 153.620(b) and (c).

[93] To qualify as an exiting issuer, an issuer must exit all of the market risk pools in the State (that is, not selling or offering any new plans in the State). If an issuer only exits some markets or risk pools in the State, but continues to sell or offer new plans in others, it is not considered an exiting issuer. A small group market issuer with off-calendar year coverage who exits the market but has only carry-over coverage that ends in the next benefit year (that is, carry-over of run out claims for individuals or groups enrolled in the previous benefit year, with no new coverage being offered or sold) is considered an exiting issuer. See the 2020 Payment Notice, 84 FR 17503 through 17504.

positive error rate outlier in the benefit year being audited, beginning with the 2018 benefit year.[94] This policy makes adjustments for positive error rate outliers because those HHS–RADV results indicate there was an undercharge or overpayment in the initial calculation of the exiting issuer's State transfer amount(s).[95] Adjustments were not made if an exiting issuer was found to be a negative error rate outlier.[96] This policy was designed to ensure that other issuers in a State market risk pool are made whole when an issuer with a positive error rate exits the State and to remove the additional burden of having transfers adjusted (including the potential for additional charges to be assessed to other issuers) for a prior benefit year when a negative error rate outlier exits the State.

Subsequently, in the 2020 HHS–RADV Amendments Rule (85 FR 76979), HHS finalized a transition to the concurrent application of HHS–RADV results for all issuers, including non-exiting issuers, beginning with the 2020 benefit year HHS–RADV, and has continued the policy to only make risk scores and risk adjustment State transfers adjustments for exiting issuers if they are positive error rate outliers. However, in light of this shift to the concurrent application of HHS–RADV adjustments for all issuers, there is no longer a reason to treat exiting issuers differently than non-exiting issuers. We therefore propose, beginning with 2021 HHS–RADV, to modify this policy and apply HHS–RADV results to adjust the plan liability risk scores of the benefit year being audited for all positive and negative error rate outlier issuers.[97]

We are not proposing any other changes to the policies regarding HHS–RADV adjustments for issuers that exit the market and therefore would maintain the existing framework for determining whether an issuer is an exiting issuer. As such, the issuer would have to exit all of the market risk pools in the State (that is, not selling or offering any new plan in the State) to be considered an exiting issuer. If an issuer only exits some of the markets or risk pools in the State, but continues to sell or offer new plans in others, it would not be considered an exiting issuer. We also affirm that small group market issuers with off-calendar year coverage who exit the market and only have carry-over coverage that ends in the next benefit year (that is, carry-over of run out claims for individuals enrolled in the previous benefit year, with no new coverage being offered or sold) would be considered an exiting issuer and would be exempt from HHS–RADV under § 153.630(g)(4). Individual market issuers offering or selling any new individual market coverage in the subsequent benefit year would be required to participate in HHS–RADV, unless another exemption applies.

We solicit comments on this proposal.

c. Discontinue Lifelong Permanent Conditions List and Use of Non-EDGE Claims in HHS–RADV

We seek comment on discontinuing the use of the Lifelong Permanent Conditions (LLPC) list[98] and the use of non-EDGE claims starting with the 2022 benefit year of HHS–RADV.

The LLPC list was developed for HHS–RADV medical record abstraction purposes beginning with the 2016 benefit year, when issuers were first learning the HHS–RADV protocols and still gaining experience with EDGE data submissions.[99] The intention of the LLPC list was to balance the burdens and costs of HHS–RADV with the program integrity goals of validating the actuarial risk of enrollees in risk adjustment covered plans to ensure that the HHS-operated risk adjustment program accurately assesses charges to issuers with plans with lower-than-average actuarial risk while making payments to issuers with plans with higher-than-average actuarial risk. The LLPC list was designed to ease the burden of medical record retrieval for lifelong conditions by simplifying and standardizing coding abstraction for IVA and SVA entities that may have different interpretations of standard coding guidelines. Conditions on the LLPC list can be abstracted by IVA and SVA entities and validated in HHS–RADV if present anywhere on an enrollee's valid and authenticated medical record, even if the associated diagnosis is not present on a claim that meets EDGE server data submission requirements for the applicable benefit year.[100] The associated diagnoses for the health conditions selected by HHS are considered to be lifelong, permanent conditions which last for multiple years, require ongoing medical attention, and are typically unresolved once diagnosed.[101]

While the LLPC list was developed for HHS–RADV medical record abstraction purposes, the EDGE Server Business Rules for risk adjustment EDGE data submissions direct that EDGE server data submissions are claim-based and follow standard coding principles and guidelines. EDGE Server Business Rules require that diagnoses codes submitted to the EDGE server be related to medical services performed during the patient's visit, be performed by a State licensed medical provider, be associated with a paid claim submitted to the issuer's EDGE server, and be associated with an active enrollment period with the issuer for the applicable risk adjustment benefit year.[102] Some issuers have raised concerns that the LLPC list may incentivize issuers to submit EDGE supplemental diagnosis files containing LLPC diagnoses even though those diagnoses may not have been addressed in the claim submitted to the EDGE server for that encounter. While we allowed the use of the LLPC list for the last several years of HHS–RADV, we continued to consider these issues and

[94] In adjusting exiting issuers with positive error rates, HHS collects funds (either increasing the charge amount or reducing the payment amount) from the exiting issuer and redistributes these funds to the other issuers who participated in that State market risk pool in the prior benefit year. See 84 FR 17503 through 17504.

[95] A positive error rate generally has the effect of decreasing an issuer's risk score and thereby decreasing its risk adjustment State transfer payment amount or increasing its risk adjustment State transfer charge amount.

[96] A negative error rate generally has the effect of increasing an issuer's risk score and thereby increasing its risk adjustment State transfer payment amount or decreasing its risk adjustment State transfer charge amount.

[97] Due to the budget neutral nature of the HHS-operated risk adjustment program, including HHS–RADV, the application of an outlier issuer's HHS–RADV error rate would also impact other issuers in the applicable State market risk pool(s). As such, non-outlier and exempt issuers may also see their State transfers adjusted as a result of the application of HHS–RADV results if there are one or more outliers in the State market risk pool(s).

[98] See, for example, Appendix C: Lifelong Permanent Conditions in the 2021 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (November 9, 2022) available at *https://regtap.cms.gov/uploads/library/HRADV_2021_Benefit_Year_Protocols_5CR_110922.pdf.* Also see, for example, Appendix E: Lifelong Permanent Conditions in the 2018 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (June 24, 2019) available at *https://regtap.cms.gov/uploads/library/HRADV_2018Protocols_070319_RETIRED_5CR_070519.pdf.*

[99] CMS first published the ''Chronic Condition HCCs'' list in the 2016 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (October 20, 2017) available at *https://regtap.cms.gov/uploads/library/HRADV_2016Protocols_v1_5CR_052218.pdf.* Beginning with 2018 benefit year, CMS has provided the ''Lifelong Permanent Conditions'' list, a simplified list of health conditions which share similar characteristics as those on the ''Chronic Condition HCCs'' list. See supra note 93.

[100] Ibid.

[101] See, for example, Appendix C: Lifelong Permanent Conditions in the 2021 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (August 17, 2022) available at *https://regtap.cms.gov/uploads/library/HRADV_2021_Benefit_Year_Protocols_v1_5CR_081722.pdf.*

[102] See, for example, Section 8.1 Guidance on Diagnosis Code(s) Derived from Health Assessments of the EDGE Server Business Rules (ESBR) (November 1, 2022) available at *https://regtap.cms.gov/uploads/library/DDC-ESBR-110122-5CR-110122.pdf.*

are now soliciting comments on the discontinuance of the use of the LLPC list beginning with the 2022 benefit year of HHS–RADV.

We believe that discontinuing the use of the LLPC list in HHS–RADV, beginning with the 2022 benefit year, would better align HHS–RADV guidance with the EDGE Server Business Rules and would eliminate some situations where an issuer may receive risk score credit for conditions that did not require treatment during an active enrollment period with the issuer for the applicable risk adjustment benefit year. In addition, we also believe that issuers have now gained sufficient experience with the EDGE data submission process and HHS–RADV protocols that it may not be necessary to continue use of the LLPC list. For example, while nearly half the States subject to the HHS-operated risk adjustment program for the 2015 benefit year [103] were not eligible to receive an interim risk adjustment summary report,[104] this trend has not continued. In fact, all States have received an interim risk adjustment summary report since the 2017 benefit year of the HHS-operated risk adjustment program [105] and only one State where HHS was responsible for operating the risk adjustment program failed to receive an interim risk adjustment summary report for the 2016 benefit year.[106] Further, after several pilot years of HHS–RADV, issuers also have now gained several years of experience with HHS–RADV and HHS–RADV protocols.[107] Therefore, we solicit comment on all aspects of this potential change, including the applicability date for the discontinuance of the LLPC list. We also request comment on the extent that issuers and their IVA entities have relied on the LLPC list to document diagnoses when official coding guidance was unclear or the medical record lacked documentation to support diagnosis of a lifelong, permanent condition.

Similarly, we seek comments on discontinuing the current policy that permits the use of non-EDGE claims in HHS–RADV beginning with the 2022 HHS–RADV benefit year. Under § 153.630(b)(6), issuers are required to provide their IVA entity with all relevant claims data and medical record documentation for the enrollees selected for audit. HHS currently allows issuers to submit medical records to their IVA entity for which no claim was accepted into the EDGE server in certain situations.[108] Under the non-EDGE claims protocol, if issuers identify medical records with no associated EDGE server claim in HHS–RADV, they must demonstrate that a non-EDGE claim meets risk adjustment eligibility criteria. Issuers must also allow the IVA entity to view the associated non-EDGE claim, and IVA entities must record their validation results in their IVA Entity Audit Results Submission.[109] This protocol was also adopted during the early years of HHS–RADV when issuers were gaining experience with HHS–RADV protocols and some may have experienced challenges submitting claims to the EDGE server. However, as explained above, issuers have consistently met data integrity criteria for their EDGE data submissions for multiple consecutive benefit years such that we are now examining the non-EDGE claims protocol and considering whether it should be discontinued. Thus, as part of our ongoing effort to examine ways to better align HHS–RADV guidance and the EDGE Server Business Rules, and in recognition of the experience issuers have gained with HHS–RADV and EDGE data submissions, we solicit comments on discontinuing this protocol. If this change is adopted, beginning with the 2022 benefit year of HHS–RADV, issuers would no longer be able to submit non-EDGE claims to their IVA entities to supplement EDGE claims reviewed during HHS–RADV. We solicit comment on all aspects of this potential protocol change, including the applicability date. We also request comment on the extent that issuers and their IVA entities have relied on the current non-EDGE claims protocol and on how this potential change would impact issuers.

d. HHS–RADV Discrepancy and Administrative Appeals Process

We propose to shorten the window to confirm the findings of the SVA (if applicable),[110] or file a discrepancy report, to within 15 calendar days of the notification by HHS, beginning with the 2022 benefit year of HHS–RADV. Under § 153.630(d)(2), issuers currently have 30 calendar days to confirm the findings

[103] See the Interim Summary Report on Risk Adjustment for the 2015 Benefit Year (March 18, 2016), available at: *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/InterimRAReport_BY2015_5CR_032816.pdf.*

[104] Since the 2015 benefit year of the HHS-operated risk adjustment program, in order for a State to receive the interim risk adjustment summary report, all issuers with 0.5 percent of market share must successfully submit at least 90 percent of full year enrollment and 90 percent of three quarters of medical claims to their EDGE servers by the applicable deadline, as well as pass EDGE quality checks. Details of EDGE quantity and quality assessment can be found in the ''Evaluation of EDGE Data Submissions'' guidance published every year. See, for example, the Evaluation of EDGE Data Submissions for 2015 Benefit Year EDGE Server Data Bulletin (March 18, 2016), available at: *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Part-2-EDGE-Q_Q-Guidance_03182016.pdf.* Also see, for example, the Evaluation of EDGE Data Submissions for 2022 Benefit Year EDGE Server Data Bulletin (October 25, 2022), available at: *https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/edge_2022_qq_guidance.pdf.*

[105] See the Interim Summary Report on Risk Adjustment for the 2017 Benefit Year (April 27, 2018), available at: *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/Interim-RA-Report-BY2017.pdf.* Also see, for example, the Interim Summary Report on Risk Adjustment for the 2018 Benefit Year (March 22, 2019), available at: *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/Interim-RA-Report-BY2018.pdf.* Also see, for example, the Interim Summary Report on Risk Adjustment for the 2019 Benefit Year (March 25, 2020), available at: *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/Interim-RA-Report-BY2019.pdf.* Also see, for example, the Interim Summary Report on Risk Adjustment for the 2020 Benefit Year (March 31, 2021), available at: *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/Interim-RA-Report-BY2020.pdf.* Also see, for example, the Interim Summary Report on Risk Adjustment for the 2021 Benefit Year (March 22, 2022), available at: *https://www.cms.gov/files/document/interim-ra-report-by2021.pdf.*

[106] See the Interim Summary Report on Risk Adjustment for the 2016 Benefit Year (April 11, 2017), available at: *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/InterimRAReport_BY2016_5CR_033117.pdf.*

[107] CMS conducted two (2) pilot years for HHS–RADV for the 2015 and 2016 benefit years. The results of 2015 and 2016 benefit year HHS–RADV were not applied to adjust plan liability risk scores or risk adjustment transfers. In addition, 2017 benefit year HHS–RADV was a pilot year for Massachusetts issuers; therefore, these issuers' 2017 benefit year HHS–RADV results were not applied to risk scores or transfers. Except for Massachusetts issuers, the 2017 benefit year was the first non-pilot year where HHS–RADV results were used to adjust risk scores and risk adjustment transfers. See 84 FR at 17508 (April 25, 2019). Also see the Summary Report of 2017 Benefit Year HHS–RADV Adjustments to Risk Adjustment Transfers (August 1, 2019), available at: *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/BY2017-HHSRADV-Adjustments-to-RA-Transfers-Summary-Report.pdf.*

[108] See, for example, Section 9.2.6.5: Documentation of Claims Not Accepted in EDGE of the 2021 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (August 17, 2022) available at *https://regtap.cms.gov/uploads/library/HRADV_2021_Benefit_Year_Protocols_v1_5CR_081722.pdf.*

[109] The non-EDGE claim must be risk adjustment eligible paid/positively adjudicated within the benefit year for the specified sampled enrollee. Although the non-EDGE claim would have been accepted to EDGE had it met the EDGE submission deadline, diagnoses associated with non-EDGE claim s are not included in the risk adjustment risk score calculations in the June 30th Summary Report on Permanent Risk Adjustment Transfers. Diagnoses associated with non-EDGE claims are only used as an option for HCC validation purposes in HHS–RADV when the applicable criteria are met.

[110] Only those issuers who have insufficient pairwise agreement between the IVA and SVA receive SVA findings. See 84 FR 17495. Also see 86 FR 24201.

of the SVA, or file a discrepancy report, in the manner set forth by HHS, to dispute those SVA findings. We propose the shorter attestation and discrepancy reporting window for SVA findings to improve HHS' ability to finalize SVA findings results prior to release of the applicable benefit year HHS Risk Adjustment Data Validation (RADV) Results Memo and the Summary Report of Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers for the applicable benefit year, which are time-sensitive publications because information on HHS–RADV adjustments is used by issuers for medical loss ratio (MLR) reporting.[111]

We do not propose to shorten the 30-calendar-day window set forth in § 153.630(d)(2) to confirm the risk score error rate, or file a discrepancy, as the same timing considerations do not extend to the risk score error rate attestation and discrepancy reporting window. In addition, all issuers who participate in HHS–RADV for the applicable benefit year must complete the risk score error rate attestation and discrepancy reporting process, whereas the SVA findings attestation and discrepancy reporting process is limited to the small number of issuers that have insufficient pairwise agreement between the IVA and SVA.

In prior rulemakings, we proposed shortening the attestation and discrepancy reporting window for the SVA findings, but did not finalize these proposals in response to comments suggesting that we revisit this proposal once issuers had more experience with HHS–RADV after the first non-pilot year.[112] Since issuers now have more than 4 years of experience with HHS–RADV, including several non-pilot years, HHS believes it is appropriate to revisit the proposal to shorten the reporting window to confirm the findings of the SVA, or file a discrepancy report, and that any disadvantages of this shortened reporting window would be outweighed by the benefits of timely resolution of any discrepancies before the release of the applicable benefit year HHS Risk Adjustment Data Validation (RADV) Results Memo and the Summary Report of Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers for the applicable benefit year. Specifically, based on our experience, we found that few issuers have insufficient pairwise agreement between the IVA and SVA that results in receiving SVA findings, and therefore, few issuers would even have the option to file an SVA discrepancy.[113] Of these issuers, even fewer of them will actually file a discrepancy, and therefore, based on this experience, HHS believes only a very small number of issuers will receive SVA findings and file discrepancies in future years of HHS–RADV.

More importantly, without this timing change, we are concerned about HHS' continued ability to release the applicable benefit year HHS Risk Adjustment Data Validation (RADV) Results Memo and Summary Report of Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers on a timely basis. Specifically, this proposal would improve our ability to follow the HHS–RADV timeline as described in part 2 of the 2022 Payment Notice,[114] which provides for release of the Summary Report of Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers in early summer of 2 calendar years after the applicable benefit year. This schedule was developed to support timely reporting of HHS–RADV adjustment amounts in the MLR reports [115] due by July 31st of the same calendar year in which the results are released.[116] The SVA findings need to be finalized to begin the HHS–RADV error estimation process, publish the HHS–RADV Results Memo (which is released alongside issuer's HHS–RADV results reports), and prepare the Summary Report of Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers for publication. Shortening the current 30-calendar-day attestation and discrepancy reporting window for SVA findings (if applicable) to 15 calendar days would better allow HHS to finalize SVA findings results and timely release the Summary Report of Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers in summer, which would support timely reporting of the HHS–RADV adjustments to risk adjustment State transfers in issuers' MLR reports.

We further note that a 15-calendar-day attestation and discrepancy reporting window is consistent with the IVA sample and EDGE attestation and discrepancy reporting windows at §§ 153.630(d)(1) and 153.710(d), respectively. At the conclusion of the SVA for a given benefit year, we distribute SVA findings to issuers that have insufficient agreement between their IVA and SVA results during the pairwise means analysis, and use the SVA findings for the risk score error rate calculation.[117] Under this proposal, a 15-calendar-day window to confirm the findings or file a discrepancy, in the manner set forth by HHS, would begin when the SVA finding reports are issued.

To effectuate this proposed amendment, we propose the following four revisions to § 153.630(d). First, we propose to revise § 153.630(d)(2) to remove the reference to the calculation of the risk score error rate as a result of HHS–RADV. Second, we propose to revise § 153.630(d)(2) to establish that the attestation and discrepancy reporting window for the SVA findings (if applicable) would be within 15 calendar days of the notification by HHS of the SVA findings (if applicable), rather than the current 30-calendar-day reporting window. Third, we propose to redesignate current paragraph (d)(3) as paragraph (d)(4), to maintain the existing provision which explains that an issuer may appeal findings of an SVA (if applicable) or the calculation of a risk score error rate as a result HHS–RADV, under the process set forth in § 156.1220. Fourth, we propose to add a new § 153.630(d)(3) to maintain the current attestation and discrepancy reporting window for the calculation of the risk score error rate. This new regulatory subsection would provide that within 30 calendar days of the notification by HHS of the calculation of the risk score error rate, in the manner set forth by HHS, an issuer must either confirm or file a discrepancy report to dispute the calculation of the risk score error rate as a result of HHS–RADV.

In addition, we propose to make corresponding amendments to the cross-references to § 153.630(d)(2) that appear in §§ 153.710(h)(1) and 156.1220(a)(4)(ii). Section 153.630(d)(2) currently sets forth the attestation and discrepancy reporting window for both SVA findings (if applicable) and the calculation of the risk score error rate as a result of HHS–RADV. Under this proposal, the attestation and discrepancy reporting window for SVA

[111] Section 2718 of the PHS Act, as added by the ACA generally requires health insurance issuers to submit an annual MLR report to HHS and provide rebates to enrollees if the issuers do not achieve specified MLR thresholds. See 42 U.S.C. 300gg–18 and 45 CFR part 158. Also see 45 CFR 153.710(h).

[112] See 84 FR 17495 and 86 FR 24201.

[113] Only those issuers who have insufficient pairwise agreement between the IVA and SVA receive SVA findings. See, for example, 84 FR 17495 and 86 FR 24201.

[114] 86 FR 24198 through 24201.

[115] Issuer MLRs are calculated using a 3-year average. See 45 CFR 158.220(b).

[116] See 45 CFR 158.110(b). Also see 45 CFR 153.710(h)(1)(v).

[117] If sufficient pairwise means agreement is achieved, the IVA findings will be used for purposes of the risk score error rate calculation. Issuers with sufficient pairwise means agreement are only permitted to file a discrepancy or appeal the risk score error rate calculation. See 78 FR 72334 through 72337 and 79 FR 13761 through 13768.

findings (if applicable) and the calculation of the risk score error rate as a result of HHS–RADV would be set forth in separate paragraphs, § 153.630(d)(2) and (d)(3), respectively. As such, we propose to amend the existing cross-reference to § 153.630(d)(2) in §§ 153.710(h)(1) and 156.1220(a)(4)(ii) to add a reference to paragraph (d)(3).

We seek comment on this proposal and the accompanying conforming amendments.

8. EDGE Discrepancy Materiality Threshold (§ 153.710)

We propose to amend the EDGE discrepancy materiality threshold set forth at § 153.710(e) to align it with the final policy adopted in preamble in part 2 of the 2022 Payment Notice.[118] We also propose a conforming amendment to § 153.710(h)(1) to add a reference to new proposed § 153.630(d)(3).

An issuer of a risk adjustment covered plan must provide to HHS, through their EDGE server,[119] access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data as specified by HHS for a benefit year.[120] Consistent with § 153.730, to be considered for risk adjustment payments and charges, issuers of risk adjustment covered plans must submit their respective EDGE data by April 30th of the year following the applicable benefit year or, if such date is not a business day, the next applicable business day. At the end of the EDGE data submission process, HHS issues final EDGE server reports [121] which reflect an issuer's data that was successfully submitted by the data submission deadline. Within 15 calendar days of the date of these final EDGE server reports, the issuer must confirm to HHS that the information in the final EDGE server reports accurately reflect the data to which the issuer has provided access to HHS through its EDGE server for the applicable benefit year by submitting an attestation; or the issuer must describe to HHS any discrepancies it identifies in the final EDGE server reports.[122]

In part 2 of the 2022 Payment Notice (86 FR 24194 through 24195), we codified at § 153.710(e) a materiality threshold for EDGE discrepancies reported under § 153.710(d)(2) that the amount in dispute must equal or exceed $100,000 or one percent of the applicable payment or charge payable to or due from the issuer for the benefit year, whichever is less. However, in preamble, we explained the final policy was intended to establish that the amount in dispute must equal or exceed $100,000 or one percent of the total estimated transfer amount in the applicable State market risk pool, whichever is less.[123] That is, the preamble uses one percent of the total estimated transfer amount in the applicable State market risk pool while the regulation uses one percent of the applicable payment or charge payable to or due from the issuer. As explained in the preamble in part 2 of the 2022 Payment Notice, the intended threshold is $100,000 or one percent of the total estimated transfer amount in the applicable State market risk pool because HHS generally only takes action on reported material EDGE discrepancies that harm other issuers in the same State market risk pool and, based on HHS' experience with prior benefit years, EDGE discrepancies that are less than a fraction of total State market risk pool transfers are unlikely to materially impact other issuers. We therefore propose to amend § 153.710(e) to revise the materiality threshold for EDGE discrepancies to reflect that the amount in dispute must equal or exceed $100,000 or one percent of the total estimated transfer amount in the applicable State market risk pool, whichever is less.

Finally, as discussed in section III.A.7.d of this preamble (HHS–RADV Discrepancy and Administrative Appeals Process), we also propose amendments to § 153.710(h)(1) to add a reference to new proposed § 153.630(d)(3). As discussed in the HHS–RADV Discrepancy and Administrative Appeals Process section of this proposed rule, under new proposed § 153.630(d)(3), we would retain the 30-calendar-day window to confirm, or file a discrepancy, regarding the calculation of the risk score error rate as a result of HHS–RADV. Under this proposal, the cross-reference to § 153.630(d)(2) in § 153.710(h)(1) would be maintained and would capture the new proposed 15-calendar-day window to confirm, or file a discrepancy, for SVA findings (if applicable).

We seek comment on the proposed amendment to § 153.710 and the accompanying policies.

B. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

1. Exchange Blueprint Approval Timelines (§ 155.106)

We propose a change to address the Exchange Blueprint approval timelines for States transitioning from either a Federally-facilitated Exchange (FFE) to a State-based Exchange on the Federal Platform (SBE–FP) or to a State-based Exchange (SBE), or from an SBE–FP to an SBE. At § 155.106(a)(3) (for FFE or SBE–FP to SBE transitions) and § 155.106(c)(3) (for FFE to SBE–FP transitions), we propose to revise the current timelines by which a State must have an approved or conditionally approved Exchange Blueprint to require that States gain approval prior to the date on which the Exchange proposes to begin open enrollment either as an SBE or SBE–FP. The current regulatory timeline by which a State must have an approved or conditionally approved Exchange Blueprint was finalized in the 2017 Payment Notice (81 FR 12203, 12241 through 12242). Based on our experience with Exchange transitions since then, we believe the current timeline by which a State must gain Exchange Blueprint approval does not sufficiently support States' need to work with HHS to finalize and submit an approvable Exchange Blueprint.

Section 155.106 requires States to have an approved or conditionally approved Exchange Blueprint 14 months prior to an SBE–FP to SBE transition in accordance with paragraph (a)(3) and three months prior to a FFE to SBE–FP transition in accordance with paragraph (c)(3). The submission and approval of Exchange Blueprints is an iterative process that generally takes place over the course of 15 months prior to a State's first open enrollment with an SBE, or three to six months prior to a State's first open enrollment with an SBE–FP. The Exchange Blueprint serves as a vehicle for a State to document its progress toward implementing its intended Exchange operational model. HHS' review and approval of the Exchange Blueprint involves providing

[118] See 86 FR 24194 through 24195.

[119] This is also known as the dedicated distributed data collection environment.

[120] 45 CFR 153.710(a) through (c).

[121] These reports are: Enrollee (Without) Claims Summary (ECS), Enrollee (Without) Claims Detail (ECD), Frequency Report by Data Element for Medical Accepted Files (FDEMAF), Frequency Report by Data Element for Pharmacy Accepted Files (FDEPAF), Frequency Report by Data Element for Supplemental Accepted Files (FDESAF), Frequency Report by Data Element for Enrollment Accepted Files (FDEEAF), Claim and Enrollee Frequency Report (CEFR), High Cost Risk Pool Summary (HCRPS), High Cost Risk Pool Detail Enrollee (HCRPDE), Risk Adjustment Claims Selection Summary (RACSS), Risk Adjustment Claims Selection Detail (RACSD), Risk Adjustment Transfer Elements Extract (RATEE), Risk Adjustment Risk Score Summary (RARSS), Risk Adjustment Risk Score Detail (RARSD), Risk Adjustment Data Validation Population Summary Statistics (RADVPS), Risk Adjustment Payment Hierarchical Condition Category Enrollee (RAPHCCER), Risk Adjustment User Fee (RAUF).

[122] 45 CFR 153.710(d).

[123] See 86 FR 24194 through 24195. Also see 85 FR 78604 through 78605.

substantial technical assistance to States as they design, finalize, and implement their Exchange operations. The transition from a FFE or SBE–FP to SBE, or SBE–FP to SBE, involves significant collaboration between HHS and States to develop plans and document readiness for the State to transition from one Exchange operational model and information technology infrastructure to another. These activities include the State completing key milestones, meeting established deadlines, and implementing contingency measures.

Our proposal to require Exchange Blueprint approval or conditional approval prior to an Exchange's first open enrollment period would allow States the additional time and flexibility if needed, that, in HHS' experience, is necessary to support the development and finalization of an approvable Exchange Blueprint, as well as for completion of the myriad activities necessary to transition QHP enrollees in the State to a new Exchange model and operator. HHS is of the view that the more generous proposed timeline is appropriate and necessary to support a State's submission of an approvable Exchange Blueprint. The proposed timeline is more protective of the significant investments of personnel time and State tax dollars a State must make to stand up a new Exchange, by providing the State a more generous timeline to develop an approvable Exchange Blueprint that shows the Exchange will be ready to support the State's current and future QHP enrollees and applicants for QHP enrollment.

We seek comment on this proposal, including comments related to how transitioning SBEs could provide greater transparency to consumers regarding the Exchange Blueprint approval process.

2. Navigator, Non-Navigator Assistance Personnel, and Certified Application Counselor Program Standards (§§ 155.210, 155.215, and 155.225)

a. Repeal of Prohibitions on Door-to-Door and Other Direct Contacts

HHS proposes to repeal the provisions that currently prohibit Navigators, certified application counselors, non-Navigator assistance personnel in FFEs, and non-Navigator assistance personnel in certain State Exchanges funded with section 1311(a) Exchange Establishment grants (collectively, Assisters) from going door-to-door or using other unsolicited means of direct contact to provide enrollment assistance to consumers. This proposal would eliminate barriers to coverage access by maximizing pathways to enrollment.

Sections 1311(d)(4)(K) and 1311(i) of the ACA direct all Exchanges to establish a Navigator program. Navigator duties and requirements for all Exchanges are set forth in section 1311(i) of the ACA and § 155.210. Section 1321(a)(1) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA, with respect to, among other things, the establishment and operation of Exchanges. Pursuant to section 1321(a)(1) of the ACA, the Secretary issued § 155.205(d) and (e), which authorizes Exchanges to perform certain consumer service functions in addition to the Navigator program, such as the establishment of a non-Navigator assistance personnel program. Section 155.215 establishes standards for non-Navigator assistance personnel in FFEs and in State Exchanges if they are funded with section 1311(a) Exchange Establishment grant funds.[124] Section 155.225 establishes the certified application counselor program as a consumer assistance function of the Exchange, separate from and in addition to the functions described in §§ 155.205(d) and (e), 155.210, and 155.215.

Assisters are certified and trusted community partners who provide free and impartial enrollment assistance to consumers. They conduct outreach and education to raise awareness about the Exchanges and other coverage options. Their mission focuses on assisting the uninsured and other underserved communities to prepare applications, establish eligibility and enroll in coverage through the Exchanges, among many other things. The regulations governing these Assisters prohibit Assisters from soliciting any consumer for application or enrollment assistance by going door-to-door or through other unsolicited means of direct contact, including calling a consumer to provide application or enrollment assistance without the consumer initiating the contact, unless the individual has a pre-existing relationship with the individual Assister or designated organization and other applicable State and Federal laws are otherwise complied with. HHS has interpreted this prohibition in the 2015 Market Standards final rule (79 FR 30240, 30284 through 30285) as still permitting door-to-door and other unsolicited contacts to conduct for general consumer education or outreach, including to let the community know that the Assister's organization is available to provide application and enrollment assistance services to the public.

The existing regulations prohibiting Navigators (at § 155.210(d)(8)), non-Navigator assistance personnel (through the cross-reference to § 155.210(d) in § 155.215(a)(2)(i)), and certified application counselors (at § 155.225(g)(5)) were initially finalized in the 2015 Market Standards final rule (79 FR 30240). At the time that HHS proposed and finalized the 2015 Market Standards rule in 2014, the Exchanges were still in their infancy. At the time, we believed that prohibiting door-to-door solicitation and other unsolicited means of direct consumer contact by an Assister for application or enrollment assistance would ensure that Assisters' practices were sufficiently protective of the privacy and security interests of the consumers they served. We also believed that prohibiting unsolicited means of direct contacts initiated by Assisters was necessary to provide important guidance and peace of mind to consumers, especially when they were faced with questions or concerns about what to expect in their interactions with individuals offering Exchange assistance.[125]

However, under existing regulations, Navigators and other non-Navigator assistance personnel in FFE States are permitted to conduct outreach to consumers using consumer information provided to them by an FFE. The Health Insurance Exchanges (HIX) System of Records Notice,[126] Routine Use No. 1 provides that the FFEs may share consumer information with CMS grantees, including Navigators and other non-Navigator assistance personnel in FFE States, who have been engaged by CMS to assist in an FFE authorized function, which includes conducting outreach to persons who have been redetermined ineligible for Medicaid/CHIP. In this limited circumstance, an FFE may share with Navigators and other non-Navigator assistance personnel in FFE States consumer information that the FFE receives from Medicaid/CHIP agencies once a consumer has been redetermined ineligible for Medicaid/CHIP in order for the Navigators and other non-Navigator assistance personnel to conduct outreach to such consumers regarding opportunities for coverage through the FFEs.

Since finalizing the 2015 Market Standards final rule, HHS has enacted a number of measures designed to ensure that Assisters are properly safeguarding

[124] At this time, no State Exchanges are funded with section 1311(a) Exchange Establishment grant funds.

[125] 79 FR 30240.

[126] 78 FR 63211, 63215.

the personally identifiable information of all consumers they assist. As part of their annual certification training, HHS requires Assisters to complete a course on privacy, security, and fraud prevention standards. Further, we require Assisters to obtain a consumer's consent before discussing or accessing their personal information (except in the limited circumstance described above) and to only create, collect, disclose, access, maintain, store and/or use consumer personally identifiable information to perform the functions that they are authorized to perform as Assisters in accordance with §§ 155.210(b)(2)(iv) and (c)(1)(v), 155.225(d)(3), and 155.215(b)(2), as applicable. In addition, now that the Exchanges and their Assister programs have been in operation for almost 10 years, Assisters have more name recognition and consumer trust within the communities the Assisters serve. Accordingly, HHS believes that its previous concerns related to consumers' privacy and security interests and consumers not knowing what to expect when interacting with Assisters have been sufficiently mitigated with the measures HHS has enacted such that a blanket prohibition on unsolicited direct contact of consumers by Assisters for application or enrollment assistance is no longer necessary.

The prohibition on door-to-door enrollment places additional burden on consumers and Assisters to make subsequent appointments to facilitate enrollment, which creates access barriers for consumers to receive timely and relevant enrollment assistance. Additionally, this prohibition could impede the Exchanges' potential to reach a broader consumer base in a timely manner, reduce uninsured rates, and increase access to health care. We believe it is important to be able to increase access to coverage for those whose ability to travel is impeded due to mobility, sensory or other disabilities, who are immunocompromised, and who are limited by a lack of transportation.

Consistent with the proposal to remove the general prohibition on door-to-door and other direct outreach by Navigators, we propose to delete § 155.210(d)(8). If finalized, the repeal of § 155.210(d)(8) would remove the general prohibition on door-to-door and other direct outreach by non-Navigator assistance personnel in FFEs and in State Exchanges if funded with section 1311(a) Exchange Establishment grants, as § 155.215(a)(2)(i) requires such entities to comply with the prohibitions on Navigator conduct set forth at § 155.210(d). Likewise, we propose to repeal § 155.225(g)(5), which currently imposes the general prohibition against door-to-door and other direct contacts on certified application counselors.

As we explained earlier in this preamble, HHS is now of the view that repealing restrictions on an Exchange's ability to allow Navigators, non-Navigator assistance personnel, and certified application counselors to offer application or enrollment assistance by going door-to-door or through other unsolicited means of direct contact is a positive step that would enable Assisters to reach a broader consumer base in a timely manner—helping to reduce uninsured rates and health disparities by removing underlying barriers to accessing health coverage.

We seek comment on this proposal.

3. Ability of States To Permit Agents and Brokers and Web-Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220)

Section 1312(e) of the ACA directs the Secretary to establish procedures under which a State may permit agents and brokers to enroll individuals and employers in QHPs through an Exchange and to assist individuals in applying for financial assistance for QHPs sold through an Exchange. In addition, section 1313(a)(5)(A) of the ACA directs the Secretary to provide for the efficient and non-discriminatory administration of Exchange activities and to implement any measure or procedure the Secretary determines is appropriate to reduce fraud and abuse. Under § 155.220, we established procedures to support the State's ability to permit agents, brokers, and web-brokers to assist individuals, employers, or employees with enrollment in QHPs offered through an Exchange, subject to applicable Federal and State requirements. This includes processes under § 155.220(g) and (h) for HHS to suspend or terminate an agent's, broker's, or web-broker's Exchange agreement(s) in circumstances that involve fraud of abusive conduct or where there are sufficiently severe findings of non-compliance. We also established FFE standards of conduct under § 155.220(j) for agents and brokers that assist consumers in enrolling in coverage through the FFEs to protect consumers and ensure the proper administration of the FFEs. Consistent with § 155.220(l), agents, brokers and web-brokers that assist with or facilitate enrollment in States with SBE–FPs must comply with all applicable FFE standards, including the requirements in § 155.220. In this rule, we propose to build on this foundation with new proposed procedures and additional consumer protection standards for agents, brokers, and web-brokers that assist consumers with enrollments through FFEs and SBE–FPs.

a. Extension of Time To Review Suspension Rebuttal Evidence and Termination Reconsideration Requests (§ 155.220(g) and (h))

We propose to allow HHS up to an additional 15 or 30 calendar days to review evidence submitted by agents, brokers, or web-brokers to rebut allegations that led to suspension of their Exchange agreement(s) or to request reconsideration of termination of their Exchange agreement(s), respectively. This proposal would provide HHS a total of up to 45 or 60 calendar days to review such rebuttal evidence or reconsideration request and notify the submitting agents, brokers, or web-brokers of HHS' determination regarding the suspension of their Exchange agreement(s) or reconsideration decision related to the termination of their Exchange agreement(s), respectively. In the 2017 Payment Notice, we added paragraph (5) to § 155.220(g) to address the temporary suspension or immediate termination of an agent's or broker's agreements with the FFEs in cases involving fraud or abusive conduct.[127] Consistent with section 1313(a)(5)(A) of the ACA, we added these procedures to give HHS authority to act quickly in these situations to prevent further harm to consumers and to support the efficient and effective administration of Exchanges on the Federal platform. Under § 155.220(g)(5)(i)(A), if HHS reasonably suspects that an agent, broker, or web-broker may have engaged in fraud or abusive conduct using personally identifiable information of Exchange applicants or enrollees or in connection with an Exchange enrollment or application, HHS may temporarily suspend the agent's, broker's or web-broker's Exchange agreement(s) for up to 90 calendar days, with the suspension effective as of the date of the notice to the agent, broker, or web-broker. This temporary suspension is effective immediately and prohibits the agent, broker, or web-broker from assisting with or facilitating enrollment in coverage in a manner that constitutes enrollment through the Exchange, including participating in the Classic DE and EDE Pathways, during this 90-day period.[128] [129] As previously

[127] See 81 FR at 12258–12264. Also see 80 FR at 75525–75526.

[128] 45 CFR 155.220(g)(5)(iii).

[129] The agent, broker, or web-broker must continue to protect any personally identifiable

Continued

explained, immediate suspension is critical in these circumstances to stop additional potentially fraudulent enrollments through the FFEs and SBE–FPs.[130] Consistent with § 155.220(g)(5)(i)(B), the agent, broker, or web-broker can submit evidence to HHS to rebut the allegations that they have engaged in fraud or abusive conduct that led to a temporary suspension by HHS of their Exchange agreement(s) at any time during 90-day period. If such rebuttal evidence is submitted, HHS will review it and make a determination as to whether a suspension should be lifted within 30 days of receipt of such evidence.[131] If HHS determines that the agent, broker, or web-broker satisfactorily addresses the concerns at issue, HHS will lift the temporary suspension and notify the agent, broker, or web-broker. If the rebuttal evidence does not persuade HHS to lift the suspension, HHS may terminate the agent's, broker's, or web-broker's Exchange agreement(s) for cause.[132] [133]

HHS also previously established a framework for termination of an agent's, broker's, or web-broker's Exchange agreement(s) for cause in situations where, in HHS' determination, a specific finding of noncompliance or pattern of noncompliance is sufficiently severe.[134] This framework provides HHS the ability to terminate an agent's, broker's, or web-broker's Exchange agreement(s) for cause to protect consumers and the efficient and effective operation of Exchanges in cases of sufficiently severe violations or patterns of violations. In these situations, HHS provides the agent, broker, or web-broker, an advance 30-day notice and an opportunity to cure and address the non-compliance finding(s).[135] [136] More specifically, upon identification of a sufficiently severe violation, HHS notifies the agent, broker, or web-broker of the specific finding(s) of noncompliance or pattern of noncompliance. The agent, broker, or web-broker then has a period of 30 days from the date of the notice to correct the noncompliance to HHS' satisfaction. If after 30 days the noncompliance is not addressed to HHS' satisfaction, HHS may terminate the Exchange agreement(s) for cause. Once their Exchange agreement(s) are terminated for cause under § 155.220(g)(3), the agent, broker, or web-broker is no longer registered with the FFE, is not permitted to assist with or facilitate enrollment of a qualified individual, qualified employer, or qualified employee in coverage in a manner that constitutes enrollment through the Exchange, and is not permitted to assist individuals in applying for APTC and CSRs for QHPs.[137] [138] Consistent with § 155.220(h)(1), an agent, broker, or web-broker whose Exchange agreement(s) are terminated can request reconsideration of such action. Section 155.220(h)(2) provides the agent, broker, or web-broker with 30 calendar days to submit their request (including any rebuttal evidence or information) and § 155.220(h)(3) requires HHS to provide agents, brokers, or web-brokers with written notice of HHS' reconsideration decision within 30 calendar days of receipt of the request for reconsideration.

Our experience reviewing evidence and other information submitted by agents, brokers, or web-brokers to rebut allegations that led to the suspension of their Exchange agreement(s) or to request reconsideration of the termination of their Exchange agreement(s), found that the process, especially in more complex situations, often requires significant resources and time. The review process can involve parsing complex technical information and data, as well as revisiting consumer complaints or conducting outreach to consumers. The amount of time it takes for the review process is largely dependent on the particular situation at hand (for example, the number of alleged violations and impacted consumers, how much and what type of information an agent, broker, or web-broker submits, the amount of time it takes for consumers to locate and provide documentation related to their complaints, and the number of concurrent submissions in need of review). Given the large number of factors involved, we believe that allowing HHS additional time to complete the review would be beneficial.

We are cognizant that this additional time could delay the ability of agents, brokers, and web-brokers to conduct business, which may be particularly burdensome to those who have compelling evidence to rebut allegations of noncompliance. Given the critical role that agents, brokers, and web-brokers serve in enrolling consumers in plans on the Exchanges, it is our intention to minimize the burden imposed on agents, brokers, and web-brokers to the greatest extent possible while also ensuring that HHS has additional time (if necessary) to review any submitted rebuttal evidence. As stated above, this additional time is warranted to accommodate particularly complex situations that require significant resources and time. We expect that not all reviews are so complex that they would require the use of this additional time; in cases where agents, brokers, and web-brokers present compelling evidence to rebut allegations of noncompliance, we expect to be able to resolve the vast majority of those reviews without the use of this additional time.

We believe that the proposal to allow HHS a total of up to 45 calendar days to review rebuttal evidence is warranted given that agents, brokers, and web-brokers have up to 90 days to submit rebuttal evidence to HHS during their suspension period, while HHS currently only has 30 days to review, consider, and make determinations based on that evidence. It does not seem unreasonable to increase this combined maximum 120-day time period[139] to 135 days.[140]

We believe that this is not an unreasonable maximum timeframe,

information accessed during the term of their Exchange agreements. See, *e.g.,* 45 CFR 155.220(g)(5)(iii) and 155.260.

[130] See, *e.g.,* 81 FR at 12258–12264.

[131] See 45 CFR 155.220(g)(5)(i)(B).

[132] See 45 CFR 155.220(g)(5)(i)(B).

[133] If the agent, broker, or web-broker fails to submit rebuttal information during this 90-day period, HHS may terminate their Exchange agreement(s) for cause. 45 CFR 155.220(g)(5)(i)(B).

[134] See 45 CFR 155.220(g)(1)–(4). Also see, *e.g.,* 78 FR at 37047 through 37048 and 78 FR at 54076 through 54081.

[135] See 45 CFR 155.220(g)(3)(i).

[136] The one exception is for situations where the agent, broker, or web-broker fails to maintain the appropriate license under applicable State law(s). See 45 CFR 155.220(g)(3)(ii). In these limited situations, HHS may immediately terminate the agent, broker, or web-broker's Exchange agreement(s) for cause without any further opportunity to resolve the matter upon providing notice to the agent, broker, or web-broker. Ibid.

[137] 45 CFR 155.220(g)(4).

[138] The agent, broker, or web-broker must continue to protect any PII accessed during the term of their Exchange agreements. See, *e.g.,* 45 CFR 155.220(g)(4) and 155.260.

[139] As noted above, an agent, broker, or web-broker whose Exchange agreement(s) are temporarily suspended can submit rebuttal evidence at any time during the 90-day suspension period, thus triggering the start of the HHS review period and limiting the length of the suspension period. For example, under this proposal, if an agent were to submit rebuttal evidence within seven days of receiving the suspension notice and HHS were to respond on the last day of the proposed new review period (day 45) and lift the suspension, that would mean the agent's Exchange agreement(s) would have been suspended for only 52 days.

[140] For example, under this proposal, if an agent whose Exchange agreement(s) were temporarily suspended were to submit rebuttal evidence to rebut allegations that led to the suspension of their Exchange agreement(s) on the final day of the suspension period (day 90), pursuant to § 155.220(g)(5)(i)(B), and HHS were to respond on the final day of the proposed new review period (day 45) and lift the suspension, that agent's Exchange agreement(s) would be suspended for a maximum of 135 days.

particularly where HHS has a reasonable suspicion the agent, broker, or web-broker engaged in fraud or abusive conduct that may cause imminent or ongoing consumer harm using personally identifiable information of an Exchange enrollee or applicant or in connection with an Exchange enrollment or application. As noted in the 2017 Payment Notice, there is a similar requirement for Medicare providers, as 42 CFR 405.371 provides HHS with the authority to suspend payment for at least 180 days if there is reliable information that an overpayment exists, or there is a credible allegation of fraud (81 FR 12262 through 12263). Under § 155.220(g)(5)(i)(A), HHS temporarily suspends an agent, broker or web-broker's Exchange agreement(s) only in situations in which there is sufficient evidence or other information such that HHS reasonably suspects the agent, broker or web-broker engaged in fraud, or in abusive conduct that may cause imminent or ongoing consumer harm using personally identifiable information of an Exchange enrollee or applicant or in connection with an Exchange enrollment or application. As such, HHS exercises this authority and sends suspension notices only in the limited situations where there may have been fraud or abusive conduct to stop further Exchange enrollment activity when the misconduct may cause imminent or ongoing harm to consumers or the effective and efficient administration of Exchanges. We also further emphasize that the proposed extension to allow for up to 45 days for HHS to review rebuttal evidence in these situations represents the maximum timeframe.[141] To the extent the situation at hand does not, for example, involve a large number of alleged violations or impacted consumers, HHS may not need the maximum timeframe to complete the review and notify the agent, broker, or web-broker whether the suspension is lifted.

Terminations of Exchange agreement(s) by HHS are also limited, but in a different way. As outlined above, § 155.220(g)(1) allows HHS to terminate an agent, broker, or web-brokers Exchange agreement for cause only when, in HHS' determination, a specific finding of noncompliance or pattern of noncompliance is sufficiently severe. Examples of specific findings of noncompliance that HHS might determine to be sufficiently severe to warrant termination of an agent's, broker's, or web-broker's Exchange agreement for cause under section § 155.220(g)(1) include, but are not limited to, violations of the Exchange privacy and security standards.[142] Patterns of noncompliance that HHS might determine to be sufficiently severe to warrant termination for cause include, for example, repeated violations of any of the applicable standards in § 155.220 or § 155.260(b) for which the agent or broker was previously found to be noncompliant.[143] As proposed, if HHS takes the total up to 60 calendar days to review rebuttal evidence submitted by the agent, broker, or web-broker whose Exchange agreement was terminated for cause, the maximum timeframe for the reconsideration process under § 155.220(h) would be 90 days. We believe this approach strikes the appropriate balance with respect to reviewing information submitted with a request to reconsider termination of their Exchange agreement(s) because it provides the agent, broker, or web-broker due process while also protecting consumers from potential harm. We are proposing a longer time period of 60 days for HHS review of information and evidence submitted by an agent, broker, or web-broker as part of their reconsideration request (versus 45 days for HHS review of rebuttal evidence and information submitted in response to a suspension determination) because the HHS reviews under § 155.220(h)(2) are part of the appeal process. As such, the agent, broker, or web-broker had an opportunity at an earlier stage of the suspension or termination process to rebut the allegations and/or findings, or otherwise take remedial steps to address the concerns identified by HHS, that led to suspension or termination of their Exchange agreement(s).[144] [145]

For these reasons, we propose to amend § 155.220(g)(5)(i)(B) to provide HHS with up to 45 calendar days to review evidence and other information submitted by agents, brokers, or web-brokers to rebut allegations that led to suspension of their Exchange agreement(s) and make a determination of whether to lift the suspension. We also propose to amend § 155.220(h)(3) to provide HHS with up to 60 days to review evidence and other information submitted by agents, brokers, or web-brokers to rebut allegations that led to termination of their Exchange agreement(s) and provide written notice of HHS' reconsideration decision.

We seek comment on this proposal.

b. Providing Correct Information to the FFEs (§ 155.220(j))

We propose to amend § 155.220(j)(2)(ii) to require agents, brokers, or web-brokers assisting with and facilitating enrollment through FFEs and SBE–FPs or assisting an individual with applying for APTC and CSRs for QHPs to document that eligibility application information has been reviewed by and confirmed to be accurate by the consumer or their authorized representative designated in compliance with § 155.227, prior to application submission. We propose that such documentation would be created by the assisting agent, broker, or web-broker and would require the consumer or their authorized representative to take an action, such as providing a signature or a recorded verbal confirmation, that produces a record that can be maintained by the agent, broker, or web-broker and produced to confirm the submitted eligibility application information was reviewed and confirmed to be accurate by the consumer or their authorized representative. In addition, we propose that the documentation must include the date the information was reviewed, the name of the consumer or their authorized representative, an explanation of the attestations at the end of the eligibility application, and the name of the agent, broker, or web-broker providing assistance. Lastly, we propose that the documentation must be maintained by the agent, broker, or web-broker for a minimum of 10 years and produced upon request in response to monitoring, audit, and enforcement activities conducted consistent with § 155.220(c)(5), (g), (h) and (k). These proposed changes would require amending § 155.220(j)(2)(ii), creating new paragraph § 155.220(j)(2)(ii)(A), and redesignating current § 155.220(j)(2)(ii)(A), § 155.220(j)(2)(ii)(B),

[141] Further, as detailed above, the agent, broker, or web-broker whose Exchange agreement(s) are suspended has an opportunity to limit the overall length of the suspension period with the timely submission of rebuttal evidence.

[142] As outlined in § 155.220(g)(2), an agent, broker, or web-broker may be determined noncompliant if HHS finds that the agent, broker, or web-broker violated any standard specified in § 155.220; any term or condition of their Exchange agreement(s); any State law applicable to agents, brokers, or web-brokers; or any Federal law applicable to agents, brokers, or web-brokers.

[143] Ibid.

[144] See 45 CFR 155.220(g)(5)(i)(B) (providing an opportunity to rebut allegations of fraud or abusive conduct) and 45 CFR 155.220(g)(3)(i) (providing advance notice and an opportunity to correct the noncompliance).

[145] The one exception is for immediate terminations for cause due to the lack of appropriate State licensure under 45 CFR 155.220(g)(3)(ii). In these situations, however, the maximum timeframe between the agent, broker, or web-broker receiving the termination notice and the issuance of the HHS reconsideration decision would be 90 days.

§ 155.220(j)(2)(ii)(C) and § 155.220(j)(2)(ii)(D) without change as § 155.220(j)(2)(ii)(B), § 155.220(j)(2)(ii)(C), § 155.220(j)(2)(ii)(D), and § 155.220(j)(2)(ii)(E), respectively.

Agents, brokers and web-brokers are among those who play a critical role in educating consumers about Exchanges and insurance affordability programs, and in helping consumers complete and submit applications for eligibility determinations, compare plans, and enroll in coverage. Consistent with section 1312(e) of the ACA, § 155.220 establishes the minimum standards for the process by which an agent, broker, or web-broker may help enroll an individual in a QHP in a manner that constitutes enrollment through the Exchange and to assist individuals in applying for PTC and CSRs. This process and minimum standards require the applicant's completion of an eligibility verification and enrollment application and the agent's, broker's, or web-broker's submission of the eligibility application information through the Exchange website or an Exchange-approved web service.[146] While agents, brokers, and web-brokers can assist a consumer with completing the Exchange application, the consumer is the individual with the knowledge to confirm the accuracy of the information provided on the application.[147]

Section 155.220(j)(2) sets forth the standards of conduct for agents, brokers, or web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through an FFE or SBE–FP or that assist individuals in applying for APTC and CSRs for QHPs sold through an FFE or SBE–FP. As explained in the 2017 Payment Notice proposed rule (81 FR 12258 through 12264), these standards are designed to protect against agent, broker, and web-broker conduct that is harmful towards consumers or prevents the efficient operation of the FFEs and SBE–FPs. Under § 155.220(j)(2)(ii), agents, brokers, or web-brokers must provide the FFEs and SBE–FPs with ''correct information under section 1411(b) of the Affordable Care Act.''

Section 1411(h) of the ACA provides for the imposition of civil penalties if any person fails to provide correct information under section 1411(b) to the Exchange. Consistent with § 155.220(l), agents, brokers and web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees in States with SBE–FPs must comply with all applicable FFE standards. This includes, but is not limited to, compliance with the FFE standards of conduct in § 155.220(j).

Currently, § 155.220(j)(2)(ii) requires that agents, brokers, and web-brokers provide the FFEs and SBE–FPs with correct information under section 1411(b) of the ACA, but it does not explicitly require agents, brokers, or web-brokers assisting consumers with completing eligibility applications through the FFEs and SBE–FPs to confirm with those consumers the accuracy of the information entered on their applications prior to application submission or document the consumer has reviewed and confirmed the information to be accurate. HHS has continued to observe applications submitted to the FFEs and SBE–FPs that contain incorrect consumer information. We have also received consumer complaints stating the information provided on their eligibility applications submitted by agents, brokers, or web-brokers on their behalf was incorrect. These complaints can be difficult to investigate and adjudicate, because the only evidence available is often the word of one person against another and the FFEs and SBE–FPs generally do not have access to other contextual information to help resolve the matter. By requiring the creation and maintenance of documentation that the assisting agent, broker, or web-broker confirmed with the consumer or their authorized representative that the entered information was reviewed and accurate, the adjudication of such complaints could be expedited and more easily resolved. In addition, the inclusion of incorrect consumer information on eligibility applications may result in consumers receiving inaccurate eligibility determinations, and may affect consumers' tax liability, or produce other potentially negative results. If a consumer receives an incorrect APTC determination or is unaware they are enrolled in a QHP, that consumer may owe money to the IRS when they file their Federal income tax return. Ensuring a consumer's income determination has been reviewed and is accurate would help avoid these situations. Incorrect consumer information on eligibility applications may also affect Exchange operations or HHS's analysis of Exchange trends. For example, a high volume of applications all containing the erroneous information, such as U.S. citizens attesting to not having an SSN, could hinder the efficient and effective operation of the Exchanges on the Federal platform by requiring HHS to focus its time and efforts on addressing these erroneous applications. This proposal is consistent with the fact that the consumer or their authorized representative is the individual with the knowledge to confirm the accuracy of the information provided on the application and would serve as an additional safeguard and procedural step to ensure the accuracy of the application information submitted to Exchanges. Thus, we propose to revise § 155.220(j)(2)(ii) to require agents, brokers, and web-brokers to document that the eligibility application information was reviewed and confirmed to be accurate by the consumer or their authorized representative before application submission.

We also propose to establish in new proposed § 155.220(j)(2)(ii)(A) standards for what constitutes adequate documentation that eligibility application information has been reviewed and confirmed to be accurate by the consumer or their authorized representative. First, we propose to revise § 155.220(j)(2)(ii)(A) to establish that documenting that eligibility application information has been reviewed and confirmed to be accurate by the consumer or their authorized representative would require the consumer or their authorized representative to take an action that produces a record that can be maintained and produced by the agent, broker, or web-broker and produced to confirm the consumer or their authorized representative has reviewed and confirmed the accuracy of the eligibility application information.

We do not propose any specific method for documenting that eligibility application information has been reviewed and confirmed to be accurate by the consumer or their authorized representative. To provide guidance to agents, brokers, and web-brokers, we propose to include in § 155.220(j)(2)(ii)(A) a non-exhaustive list of acceptable methods to document that eligibility application information has been reviewed and confirmed to be accurate, including obtaining the signature of the consumer or their authorized representative (electronically or otherwise), verbal confirmation by the consumer or their authorized representative that is captured in an audio recording, or a written response (electronic or otherwise) from the consumer or their authorized

[146] 45 CFR 155.220(c)(1). Also see, *e.g.,* 77 FR at 18334–18336.

[147] This is evidenced by the language in § 155.220(j)(1) that refers to agents, brokers, or web-brokers that *assist* or *facilitate* enrollment (emphasis added).

representative to a communication sent by the agent, broker, or web-broker. We also invite comment on whether there may be other acceptable methods of documentation that HHS should consider specifying to be permissible for purposes of documenting that eligibility application information has been reviewed and confirmed to be accurate by the consumer or their authorized representative. For example, we are specifically interested in any current best practices or approaches that agents, brokers or web-brokers may use to create records or otherwise document that eligibility application information was reviewed by the consumer or their authorized representative prior to submission to the Exchange.

We also propose that the consumer would be able to review and confirm the accuracy of application information on behalf of other applicants (for example, dependents or other household members), and authorized representatives would be able to provide review and confirm the accuracy of application information on behalf of the people they are designated to represent, as it may be difficult or impossible to obtain confirmation from each consumer whose information is included on an application. This would allow agents, brokers, and web-brokers to continue assisting consumers as they currently do (for example, often by working with an individual representing a household when submitting an application for a family).

Next, we propose to require at new proposed § 155.220(j)(2)(ii)(A)(*1*) that the eligibility application information documentation, which would be created by the assisting agent, broker, or web-broker, must include an explanation of the attestations at the end of the eligibility application that the eligibility application information has been reviewed by and confirmed to be accurate by the consumer or their authorized representative. At the end of the Exchange eligibility application, one of the attestations the consumer must currently agree to before submitting the application is as follows: ''I'm signing this application under penalty of perjury, which means I've provided true answers to all of the questions to the best of my knowledge. I know I may be subject to penalties under Federal law if I intentionally provide false information.'' The documentation the agent, broker, or web-broker creates to satisfy this proposed requirement would be required to include this language for awareness and to remind the consumer that they are responsible for the accuracy of the application information, even if the information was entered into the application on their behalf by an agent or broker assisting them. We believe that this proposal would help ensure that the consumer or their authorized representative understands the importance of confirming the accuracy of the information contained in the eligibility application and further safeguard against the provision and submission of incorrect eligibility application information. We also believe that that proposal would help safeguard consumers from the negative consequences of failing to understand the attestations and potentially attesting to conflicting information. For example, one common error we see on applications completed by agents, brokers, or web-brokers is an attestation that a consumer does not have an SSN while also including an attestation that the consumer is a U.S. citizen. These conflicting attestations can generate DMIs, which, if not resolved during the allotted resolution window, could result in the consumer's coverage being terminated. For these reasons, we propose to add a requirement at new § 155.220(j)(2)(ii)(A)(*1*) that the documentation include the date the information was reviewed, the name of the consumer or their authorized representative, an explanation of the attestations at the end of the eligibility application, and the name of the assisting agent, broker, or web-broker.

Lastly, at new proposed § 155.220(j)(2)(ii)(A)(*2*) we propose to require agents, brokers, and web-brokers to maintain the documentation demonstrating that the eligibility application information was reviewed and confirmed as accurate by the consumer or their authorized representative for a minimum of 10 years. Section 155.220(c)(5) states HHS or our designee may periodically monitor and audit an agent, broker, or web-broker to assess their compliance with applicable requirements. However, there is not currently a maintenance of records requirement directly applicable to all agents, brokers, and web-brokers assisting consumers through the FFEs and SBE–FPs.[148] Capturing a broad-based requirement mandating that all agents, brokers, and web-brokers assisting consumers in the FFEs and SBE–FPs maintain the records and documentation demonstrating that information captured in their application has been reviewed and confirmed to be accurate by the consumer or their authorized representative they are assisting would provide a clear, uniform standard. It also would ensure this documentation is maintained for sufficient time to allow for monitoring, audit, and enforcement activities to take place.[149] Therefore, consistent with other Exchange maintenance of records requirements,[150] we propose to capture in new proposed § 155.220(j)(2)(iii)(A)(*2*) that agents, brokers, and web-brokers must maintain the documentation described in proposed § 155.220(j)(2)(ii)(A) for a minimum of 10 years, and produce the documentation upon request in response to monitoring, audit, and enforcement activities conducted consistent with § 155.220(c)(5), (g), (h), and (k).

We seek comment on these proposals.

c. Documenting Receipt of Consumer Consent (§ 155.220(j))

We propose to amend § 155.220(j)(2)(iii) to require agents, brokers, or web-brokers assisting with and facilitating enrollment through FFEs and SBE–FPs or assisting an individual with applying for APTC and CSRs for QHPs to document the receipt of consent from the consumer, or the consumer's authorized representative designated in compliance with § 155.227, qualified employers, or qualified employees they are assisting. We propose that documentation of receipt of consent would be created by the assisting agent, broker, or web-broker and would require the consumer seeking to receive assistance, or the consumer's authorized representative, to take an action, such as providing a signature or a recorded verbal authorization, that produces a record that can be maintained by the agent, broker, or web-broker and produced to confirm the consumer's or their authorized representative's consent was provided. With regard to the content of

[148] Section 155.220(c)(3)(i)(E) requires web-brokers to maintain audit trails and records in an electronic format for a minimum of 10 years and cooperate with any audit under this section. Section 156.340(a)(2) places responsibility on QHP issuers participating in Exchanges using the Federal platform to ensure their downstream and delegated entities (including agents and brokers) are complying with certain requirements, including the maintenance of records requirements in § 156.705. In addition, under § 156.340(b), agents and brokers that are downstream entities of QHP issuers in the FFEs must be bound by their agreements with the QHP issuer to comply with certain requirements, including the records maintenance standards in § 156.705. Section 156.705(c) and (d) requires QHP issuers in the FFEs to maintain certain records for 10 years and to make all such records available to HHS, the OIG, the Comptroller General, or their designees, upon request.

[149] While investigations consumer complaints are an example of a more immediate, real-time monitoring and oversight activity, market conduct examinations, audits, and other types of investigations (*e.g.,* compliance reviews) may occur several years after the applicable coverage year.

[150] See, for example, 45 CFR 155.220(c)(3)(i)(E) and 156.705(c).

the documentation of consent, in addition to the date consent was given, name of the consumer or their authorized representative, and the name of the agent, broker, web-broker, or agency being granted consent, we propose the documentation would be required to include a description of the scope, purpose, and duration of the consent provided by the consumer, or their authorized representative, as well as the process by which the consumer or their authorized representative may rescind such consent. Lastly, we propose that documentation of the consumer's or their authorized representative's, consent be maintained by the agent, broker, or web-broker for a minimum of 10 years and produced upon request in response to monitoring, audit, and enforcement activities conducted consistent with § 155.220(c)(5), (g), (h) and (k).

Currently, § 155.220(j)(2)(iii) requires agents, brokers, or web-brokers assisting with or facilitating enrollment through the FFEs or SBE–FPs or assisting an individual in applying for APTC and CSRs for QHPs to obtain the consent of the individual, employer, or employee prior to providing such assistance. However, § 155.220(j)(2)(iii) does not currently require agents, brokers, or web-brokers to document the receipt of consent. We have observed several cases in which there have been disputes between agents, brokers, or web-brokers and the individuals they are assisting, or between two or more agents, brokers, or web-brokers, about who has been authorized to act on behalf of a consumer or whether anyone has been authorized to do so. We have also received complaints alleging enrollments by agents, brokers, and web-brokers that occurred without the consumer's consent, and have encountered agents, brokers, and web-brokers who attest they have obtained consent and have acted in good faith, but who do not have reliable records of such consent to defend themselves from allegations of misconduct. Thus, we are proposing this standard because we believe that it would be beneficial to have reliable records of consent to help with the resolution of such disputes or complaints and to minimize the risk of fraudulent activities such as unauthorized enrollments. For these reasons, we propose to revise § 155.220(j)(2)(iii) to require agents, brokers, and web-brokers to document the receipt of consent from the consumer seeking to receive assistance or the consumer's authorized representative, employer, or employee prior to assisting with or facilitating enrollment through the FFEs and SBE–FPs, making updates to an existing application or enrollment, or assisting the consumer in applying for APTC and CSRs for QHPs.

We also propose to establish in proposed new § 155.220(j)(2)(iii)(A)–(C) standards for what constitutes obtaining and documenting consent to provide agents, brokers, and web-brokers with further clarity regarding this proposed requirement. First, we propose to add new proposed § 155.220(j)(2)(iii)(A) to establish that obtaining and documenting the receipt of consent would require the consumer seeking to receive assistance, or the consumer's authorized representative designated in compliance with § 155.227, to take an action that produces a record that can be maintained by the agent, broker, or web-broker and produced to confirm the consumer's or their authorized representative's consent has been provided.

We do not intend to prescribe the method to document receipt of individual consent, so long as whatever method is chosen requires the consumer or their authorized representative to take an action and results in a record that can be maintained and produced by the agent, broker, or web-broker. Therefore, we propose to include in new proposed § 155.220(j)(2)(iii)(A) a non-exhaustive list of acceptable means to document receipt of consent, including obtaining the signature of the consumer or their authorized representative (electronically or otherwise), verbal confirmation by the consumer or their authorized representative that is captured in an audio recording, a response from the consumer or their authorized representative to an electronic or other communication sent by the agent, broker, or web-broker, or other similar means or methods that HHS specifies in guidance. Other methods of documenting individual consent may be acceptable, such as requiring individuals to create user accounts on an agent's or agency's website where they designate or indicate the agents, brokers, or web-brokers to whom they have provided consent. Under this proposal, agents, brokers, and web-brokers would also be permitted to continue to utilize State Department of Insurance forms, such as agent or broker of record forms, provided these forms cover the minimum requirements set forth in this proposed rule. If agents, brokers, and web-brokers have already adopted consent documentation processes consistent with this proposed framework, no changes would be required if this proposed standard is finalized. We intend to allow for documentation methods well-suited to the full range of ways agents, brokers, and web-brokers interact with consumers they are assisting (for example: in-person, via phone, electronic communications, use of an agent's or agency's website, etc.). We also intend for the primary applicant to be able to provide consent on behalf of other applicants (for example, dependents or other household members), and authorized representatives to be able to provide consent on behalf of the people they are designated represent (for example, incapacitated persons), as it may be difficult or impossible to obtain consent from each individual whose information is included on an application. This would allow agents, brokers, and web-brokers to continue assisting individuals as they currently do (for example, often by working with an individual representing a household when submitting an application for a family).

Second, we propose to require at new proposed § 155.220(j)(2)(iii)(B) that the consent documentation must include the date consent was given, name of the consumer or their authorized representative, name of the agent, broker, web-broker, or agency being granted consent, a description of the scope, purpose, and duration of the consent obtained by the individual, as well as a process through which the consumer or their authorized representative may rescind consent. Agents, brokers, and web-brokers may work with individuals in numerous capacities. For example, they may assist individuals with applying for financial assistance and enrolling in QHPs through the FFEs and SBE–FPs, as well as shopping for other non-Exchange products. Similarly, agents, brokers, and web-brokers may have different business models such that individuals may interact with specific individuals consistently or numerous individuals representing a business entity that may vary upon each contact (for example, call center representatives), and the methods of interaction may vary as well (for example: in-person, phone calls, use of an agent's or agency's website etc.). In addition, individuals may wish to change the agents, brokers, or web-brokers they work with and provide consent to over time. For these reasons, the scope, purpose, and duration of the consent agents, brokers, and web-brokers seek to obtain from individuals can vary widely. Therefore, this proposal is intended to ensure individuals are making an informed decision when providing their consent

to the agents, brokers, or web-brokers assisting them, that individuals can make changes to their provision of consent over time, and that the documentation of consent at a minimum captures who is providing and receiving consent, for what purpose(s) the consent is being provided, when consent was provided, the intended duration of the consent, and how specifically consent may be rescinded. We expect that the information in the consent documentation would align with the information in the corresponding individuals' applications (for example: names, phone numbers, or email addresses should align as applicable depending on whether the consent is obtained via email, text message, call recording, or otherwise), except for in instances in which consent is being provided by an authorized representative.

Lastly, at new proposed § 155.220(j)(2)(iii)(C), we propose to require agents, brokers, and web-brokers to maintain the documentation described in proposed § 155.220(j)(2)(iii)(A) for a minimum of 10 years. Section 155.220(c)(5) states HHS or our designee may periodically monitor and audit an agent, broker, or web-broker to assess their compliance with applicable requirements. However, there is not currently a maintenance of records requirement directly applicable to all agents, brokers, and web-brokers assisting consumers through the FFEs and SBE–FPs.[151] Capturing a broad-based requirement mandating that all agents, brokers, and web-brokers assisting consumers in the FFEs and SBE–FPs to maintain the records and documentation demonstrating receipt of consent from consumers or their authorized representative would provide a clear, uniform standard. It would also ensure these records and documentation are maintained for sufficient time to allow for monitoring, audit, and enforcement activities to take place.[152] Therefore, consistent with other Exchange maintenance of records requirements,[153] we propose to capture in new proposed § 155.220(j)(2)(iii)(C) that agents, brokers, and web-brokers must maintain the documentation described in proposed § 155.220(j)(2)(iii)(A) for a minimum of 10 years, and produce the documentation upon request in response to monitoring, audit and enforcement activities conducted consistent with § 155.220(c)(5), (g), (h) and (k).

We seek comment on these proposals, including whether there are other means or methods of documentation that HHS should consider specifying are permissible for purposes of documenting the receipt of consent from consumer or their, qualified employers, or qualified employees.

4. Eligibility Standards (§ 155.305)

a. Failure to File and Reconcile Process (§ 155.305(f)(4))

We are proposing to amend § 155.305(f)(4) which currently prohibits an Exchange from determining a taxpayer eligible for APTC if HHS notifies the Exchange that a taxpayer (or a taxpayer's spouse, if married) has failed to file a Federal income tax return and reconcile their past APTC for a year for which tax data would be utilized for verification of household income and family size in accordance with § 155.320(c)(1)(i).

As background, Exchange enrollees whose taxpayer fails to comply with current paragraph § 155.305(f)(4) are referred to as having failed to ''file and reconcile''. Since 2015, HHS has taken regulatory and operational steps to help increase taxpayer compliance with filing and reconciliation requirements under the Code as described at 26 CFR 1.36B–4(a)(1)(i) and (a)(1)(ii)(A) by tying eligibility for future APTC to the taxpayer's reconciliation of past APTC paid. However, since the finalization of the requirement at § 155.305(f)(4), HHS has determined that the costs of the current policy outweigh the benefits for a number of reasons. For one, Exchanges have faced a longstanding operational challenge, specifically that Exchanges sometimes have to determine an enrollee ineligible for APTC without having up-to-date information on the tax filing status of households while Federal income tax returns are still being processed by the IRS. Currently, Exchanges determine an enrollee ineligible for APTC if the IRS, through data passed from the IRS to HHS, via the Federal Data Services Hub (the Hub), tells an Exchange that the taxpayer did not comply with the requirement to file a Federal income tax return and reconcile APTC for one specific tax year. To address the challenge of receiving up-to-date information, and to promote continuity of coverage in an Exchange QHP, we are proposing a new process for Exchanges to conduct FTR while also ensuring that Exchanges preserve program integrity by paying APTC only to consumers who are eligible to receive it. HHS believes that any FTR process should encourage compliance with the filing and reconciling requirement under the Code, minimize the potential for APTC recipients to incur large tax liabilities over time, and support eligible enrollees' continuous enrollment in Exchange coverage with APTC by avoiding situations where enrollees become uninsured when their APTC is terminated.

For Exchanges using the Federal eligibility and enrollment platform, which includes the FFEs and SBE–FPs, taxpayers who have not met the requirement of § 155.305(f)(4) are put into the FTR process with the Exchange. As part of the normal process used by Exchanges using the Federal eligibility and enrollment platform during Open Enrollment, enrollees for whom IRS data indicates an FTR status for their taxpayer receive notices from the Exchange alerting them that IRS data shows that their taxpayer has not filed a Federal income tax return for the applicable tax year and reconciled APTC for that year using IRS Form 8962. FTR Open Enrollment notices sent directly to the taxpayer clearly state that IRS data indicates the taxpayer failed to file and reconcile, whereas FTR Open Enrollment notices sent to the applicant's household contact, who may or may not be the taxpayer, list a few different reasons consumers may be at risk of losing APTC, including the possibility that IRS data indicates the taxpayer failed to file and reconcile. Notices to the applicant's household contact can be confusing because of the multiple reasons listed. Both of these Open Enrollment notices encourage taxpayers identified as having an FTR status to file their Federal income tax return and reconcile their APTC for that year using IRS Form 8962, or risk losing APTC eligibility for the next coverage year.

In late 2015, to allow consumers with an FTR status to be determined eligible for APTC temporarily (if otherwise eligible), HHS added a question to the single, streamlined application used by the Exchanges using the Federal eligibility and enrollment platform that allows enrollees to attest on their

[151] Section 155.220(c)(3)(i)(E) requires web-brokers to maintain audit trails and records in an electronic format for a minimum of 10 years and cooperate with any audit under this section. Section 156.340(a)(2) places responsibility on QHP issuers participating in Exchanges using the Federal platform to ensure their downstream and delegated entities (including agents and brokers) are complying with certain requirements, including the maintenance of records requirements in § 156.705. Section 156.705(c) requires QHP issuers in the FFEs to maintain certain records for 10 years.

[152] While investigations consumer complaints are an example of a more immediate, real-time monitoring and oversight activity, market conduct examinations, audits, and other types of investigations (*e.g.,* compliance reviews) may occur several years after the applicable coverage year.

[153] See, for example, 45 CFR 155.220(c)(3)(i)(E) and 156.705(c).

application, under the penalty of perjury, that they have filed and reconciled their APTC by checking a box that says, ''Yes, I reconciled premium tax credits for past years.'' [154] Enrollees who check this attestation and enroll in coverage during Open Enrollment retain their APTC, even if IRS data has not been updated to reflect their most current Federal income tax filing status or if the individual has not actually reconciled their APTC. Allowing enrollees to attest to filing and reconciling even though IRS data indicates that they did not, is a critical step to safeguard enrollees from losing APTC erroneously as the IRS typically takes several weeks to process Federal income tax returns, with additional time required for returns or amendments that are filed using a paper process.

After Open Enrollment, Exchanges using the Federal platform then conduct a second look at FTR data to follow up and verify an enrollee(s)' reconciliation attestation by conducting a verification of their taxpayer's FTR status early in the next coverage year, which includes additional notices to enrollees and taxpayers. This verification process early in the next coverage year is referred to as FTR Recheck. State Exchanges that operate their own eligibility and enrollment platform have each implemented similar processes to check the FTR status of their enrollees annually based on data provided by the IRS, to identify and notify enrollees who are at risk of losing APTC eligibility, and to allow enrollees to attest under the penalty of perjury that they have filed and reconciled their APTC.

There are many reasons we are proposing the changes to § 155.305(f)(4) described herein. First, HHS' and State Exchanges' experiences with running FTR operations have shown that Exchange enrollees often do not understand the requirement that their taxpayer must file a Federal income tax return and reconcile their APTC or that they must also submit IRS Form 8962 to properly reconcile their APTC, even though the single, streamlined application used by Exchanges on the Federal platform and QHP enrollment process require a consumer to attest to understanding the requirement to file and reconcile in two places. For example, HHS is aware anecdotally that many third-party tax preparers, such as accountants, are not aware of the requirement to file and reconcile, nor prompt consumers to also include IRS Form 8962 along with their Federal income tax return. Although enrollees who rely on third party tax preparers such as accountants or third-party tax preparation software to prepare their Federal income tax returns are still required to file and reconcile even if their tax preparer was unaware of the requirement, consumers should have the opportunity to receive additional guidance from Exchanges on the requirement to file and reconcile to promote compliance and prevent termination of APTC.

While annual FTR notices help with this issue as the notices alert consumers that they did not provide adequate documentation to fulfill the requirement to file and reconcile, the current process that requires Exchanges to determine an enrollee ineligible for APTC after 1 year of having an FTR status is overly punitive. Some consumers may have their APTC ended due to delayed data, in which case their only remedy is to appeal to get their APTC reinstated. Consumers also may be confused or may have received inadequate education on the requirement to file and reconcile, in which case they must actually file, reconcile, and appeal to get their APTC reinstated. By requiring Exchanges to determine an enrollee ineligible for APTC only after having an FTR status for two consecutive tax years (specifically, years for which tax data would be utilized for verification of household income and family size), Exchanges would have more opportunity to conduct outreach to consumers whom data indicate have failed to file and reconcile to prevent erroneous terminations of APTC and to provide access to APTC for an additional year even when APTC would have been correctly terminated under the original FTR process. Under the proposed change, Exchanges on the Federal platform would continue to send notices to consumers for the year in which they have failed to reconcile APTC as an initial warning to inform and educate consumers that they need to file and reconcile or risk being determined ineligible for APTC if they fail to file and reconcile for a second consecutive tax year. This change would also alleviate burden on HHS hearing officers by reducing the number of appeals related to denial of APTC due to FTR, and prevent consumers who did reconcile, but for whom IRS data was not updated quickly enough, from having to go through an appeal process to have their APTC rightfully reinstated.

HHS believes in ensuring consumers have access to affordable coverage and places high value on consumers maintaining continuity of coverage in the Exchange as HHS has found that FFE and SBE–FP enrollees who lose APTC tend to end their Exchange coverage and will experience coverage gaps, as they cannot afford unsubsidized coverage. In light of this, HHS believes it is imperative that any change to the current FTR operations be done carefully and that HHS thoughtfully balance how it enforces the requirement to file and reconcile, since a consequence of losing APTC effectively means many consumers may lose access to needed medical care.

Therefore, given these challenges that both Exchanges and consumers have faced with the requirement to file and reconcile, we are proposing to revise § 155.305(f)(4) under which Exchanges would not be required, or permitted, to determine consumers ineligible for APTC due to having an FTR status for only 1 year. Given that HHS's experience running FTR shows continued issues with compliance with the requirement to file and reconcile, we propose that beginning on January 1, 2024, Exchanges must find an applicant ineligible for APTC only if the applicant has an FTR delinquent status for two consecutive years (specifically, two consecutive years for which tax data would be utilized for verification of household income and family size).

Previously, CMS announced that Exchanges on the Federal platform would not act on data from the IRS for enrollees who have failed to file Federal income tax returns and reconcile a previous year's APTC with the PTC allowed for the year. The guidance also announced flexibility for State Exchanges that operate their own eligibility and enrollment platforms to take similar action.[155] Due to the ongoing COVID–19 PHE in 2020, for plan year 2021, CMS temporarily paused ending APTC for enrollees with an FTR status due to IRS processing delays of 2019 Federal income tax returns.[156] CMS then extended this pause for the 2023 plan year in July 2022.[157] As a result of these changes, 55 percent of enrollees who were automatically re-enrolled during 2021 open enrollment with an FTR status

[154] We note that this question was removed from the single streamlined application once the FTR process was paused in 2020 for the 2021 PY.

[155] See CMS. (2022, July 18). *Failure to File and Reconcile (FTR) Operations Flexibilities for Plan Year 2023. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/FTR-flexibilities-2023.pdf.*

[156] See CMS. (2021, July 23). *Failure to File and Reconcile (FTR) Operations Flexibilities for Plan Years 2021 and 2022—Frequently Asked Questions (FAQ). https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/FTR-flexibilities-2021-and-2022.pdf.*

[157] See CMS. (2022, July 18). *Failure to File and Reconcile (FTR) Operations Flexibilities for Plan Year 2023. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/FTR-flexibilities-2023.pdf.*

remained enrolled in Exchange coverage as of March 2021. In contrast, only 12 percent of those enrollees with an FTR status who were automatically re-enrolled without APTC during the 2020 open enrollment were still enrolled in coverage as of March 2020. These results show the significant impact that loss of APTC due to FTR status has on whether enrollees continue to remain in coverage offered through the Exchange as these impacted enrollees must pay the full cost of their Exchange plan, which is often unaffordable without APTC.

CMS proposes to continue to pause FTR until the point in time that HHS and the IRS will be able to implement the new FTR policy, if finalized. That is to say, until the IRS can update its systems to implement the new FTR policy, and HHS can notify the Exchange of an enrollee's consecutive 2-year FTR status, the Exchange will not determine enrollees ineligible for APTC based on either the one-year or 2-year FTR status. We believe that removing APTC after 2 consecutive years of an FTR status instead of one will help consumers avoid gaps in coverage by increasing retention in the Exchange even if they have failed to reconcile for 1 year, and will reduce the punitive nature of the current process which may erroneously terminate APTC for consumers who have filed and reconciled. We also believe that these proposed changes would help protect consumers from accruing large tax liabilities over multiple years by notifying and ending APTC for consumers with an FTR status for two consecutive years. Finally, we believe these proposed changes would allow Exchanges to maintain program integrity by denying APTC to consumers who have, over the course of two years, been given ample notification of their obligation to file and reconcile and have nevertheless failed to do so.

We seek comment on this proposal, especially from States or other interested parties regarding tax burdens on consumers which would inform our decision on this proposal.

5. Verification Process Related to Eligibility for Insurance Affordability Programs (§§ 155.315 and 155.320)

a. Income Inconsistencies

We propose to amend § 155.320 to require Exchanges to accept an applicant's or enrollee's attestation of projected annual household income when the Exchange requests tax return data from the IRS to verify attested projected annual household income, but the IRS confirms there is no such tax return data available. We further propose to amend § 155.315(f) to add that income inconsistencies must receive an automatic 60-day extension in addition to the 90 days provided by § 155.315(f)(2)(ii).

Section 155.320 sets forth the verification process for household income. The Exchange requires that an applicant or enrollee applying for financial assistance must attest to their projected annual household income. *See* § 155.320(a)(1) and (c)(3)(ii)(b). The regulation also requires that for any individual in the applicant's or enrollee's tax household (and for whom the Exchange has a SSN), the Exchange must request tax return data regarding income and family size from the IRS.[158] *See* § 155.320(c)(i)(A). When the Exchange requests tax return data from the IRS and the data indicates that attested projected annual household income represents an accurate projection of the tax filer's household income for the benefit year for which coverage is requested, the Exchange must determine eligibility for APTC and CSR based on the IRS tax data. *See* § 155.320(c)(3)(ii)(C).

When the Exchange requests tax return data from the IRS and the IRS returns data that reflects that the attested projected annual household income *is not* an accurate projection of the tax filer's household income for the benefit year for which coverage is requested, the applicant or enrollee is considered to have experienced a change in circumstances, which allows HHS to establish procedures for determining eligibility for APTC on information other than IRS tax return data, as described in § 155.320(c)(3)(iii)–(vi). *See* ACA § 1412(b)(2).

The Exchange also considers an applicant or enrollee to have experienced a change in circumstances when the Exchange requests tax return data from the IRS to verify attested projected household income, but the IRS confirms such data is unavailable. This is because tax data is usually unavailable when an applicant or enrollee has experienced a change in family size, other household circumstances (such as a birth or death), filing status changes (such as a marriage or divorce), or the applicant or enrollee was not required to file a tax return for the year involved. *See* § ACA 1412(b)(2). When an applicant or enrollee has experienced a change in circumstances as described in ACA § 1412(b)(2), the Exchange determines eligibility for APTC and CSR using alternate procedures designed to minimize burden and protect program integrity, described in § 155.320(c)(3)(iii)–(vi).

If an applicant or enrollee qualifies for an alternate verification process as described above, and the attested projected annual household income is greater than the income amount returned by the IRS, the Exchange accepts the applicant's attestation without further verification under § 155.320(c)(iii)(A). If an applicant qualifies for an alternate verification process, and the attested projected annual household income is more than a reasonable threshold less than the income amount returned by the IRS, or there is no IRS data available, the Exchange generates an income inconsistency (also referred to as a data matching issue or DMI) and proceeds with the process described in § 155.315(f)(1) through (4), unless a different electronic data source returns an amount within a reasonable threshold of the projected annual household income. *See* § 155.320(c)(3)(iv) and (c)(3)(vi)(D). This process usually requires the applicant or enrollee to present satisfactory documentary evidence of projected annual household income. If the applicant fails to provide documentation verifying their projected annual household income attestation, the Exchange determines the consumer's eligibility for APTC and CSRs based on available IRS data, as required in § 155.320(c)(3)(vi)(F). However, if there is no IRS data available, the Exchange must determine the applicant ineligible for APTC and CSRs as required in § 155.320(c)(3)(vi)(G). We propose to make clarifying revisions to the current regulations to ensure consistency between the regulations and the current operations of the Exchanges on the Federal platform, as described here.

We propose to add § 155.320(c)(5) which would require Exchanges to accept an applicant's or enrollee's attestation of projected annual household income when the Exchange requests IRS tax return data but IRS confirms such data is not available. The current process is overly punitive to consumers and burdensome to Exchanges; reasons for IRS not returning consumer data can extend beyond the consumer not filing tax returns, and can be attributed to tax household composition changes (such as birth, marriage, and divorce), name changes, or other demographic updates or mismatches—all of which are legitimate changes that currently prevent a consumer from avoiding an income

[158] The Exchange must also request data regarding Social Security Benefits from the Social Security Administration.

DMI. Additionally, the consequence of receiving an income DMI and being unable to provide sufficient documentation to verify projected household income outweighs the intended programmatic benefits: under § 155.320(c)(3)(vi)(G) consumers are determined completely ineligible for APTC and CSRs. With respect to burden on Exchanges, DMI verification by the Exchange requires an outlay of administrative hours to monitor and facilitate the resolution of income inconsistencies. Within the Federal Platform, this administrative task accounts for approximately 300,000 hours of labor annually, which we believe is proportionally mirrored by State Exchanges.

Accordingly, we propose to accept an applicant's or enrollee's attestation of projected annual household income when IRS tax return data is requested but is not available, and to determine the applicant or enrollee eligible for APTC or CSRs in accordance with the applicant's or enrollee's attested projected household income, to more fairly determine eligibility for consumers and to reduce unnecessary burden on Exchanges. This proposal is consistent with § 1412(b)(2) of the ACA, which allows the Exchange to utilize alternate verification procedures when a consumer has experienced substantial changes in income, family size or other household circumstances, or filing status, or when an applicant or enrollee was not required to file a tax return for the applicable year.[159] It is also consistent with the flexibility under ACA § 1411(c)(4)(B) to modify methods for verification of the information where we determine such modifications would reduce the administrative costs and burdens on the applicant.

We clarify that the Exchange would continue to generate income DMIs when IRS tax data is available and the attested projected household income amount is more than a reasonable threshold below the income amount returned by the IRS, and other sources cannot provide income data within the reasonable threshold. Additionally, the Exchange would continue to generate income DMIs when IRS tax data cannot be requested, because an applicant or enrollee did not provide sufficient information (namely, a social security number), and other sources cannot provide income data within the reasonable threshold of the attested projected household income. Under § 1411(c)(3) of the ACA, only data from the IRS is required to be used to determine if income is inconsistent. Currently, there are no reliable and accurate income data sources legally available to the Exchange that would provide quality data for the purpose of generating income DMIs. Income data from other electronic data sources may continue to be used by Exchanges to verify income when the attested projected household income amount is more than a reasonable threshold below the income amount returned by the IRS or IRS data cannot be requested.

Lastly, we propose to revise § 155.315(f) to add new paragraph (f)(7) to require that applicants must receive an automatic 60-day extension in addition to the 90 days currently provided by § 155.315(f)(2)(ii) to allow applicants sufficient time to provide documentation to verify household income. The extension would be automatically granted when consumers exceed the allotted 90 days without resolving any active household income DMIs. This proposal aligns with current § 155.315(f)(3), which provides extensions to applicants beyond the existing 90 days if the applicant demonstrates that a good faith effort has been made to obtain the required documentation during the period. It is also consistent with the flexibility under ACA § 1411(c)(4)(B) to modify methods for verification of the information where we determine such modifications would reduce the administrative costs and burdens on the applicant.

We have found that 90 days is often an insufficient amount of time for many applicants to provide this income documentation, since it can require multiple documents from various household members along with an explanation of seasonal employment or self-employment, including multiple jobs. As applicants are asked to provide a projection for their next year's income, they often submit documents that do not fully explain their attestation due to the complexities noted above, which requires contact from the Exchange and additional document submission, which often pushes the verification timeline past 90 days. An additional 60 days would allow consumers more time to gather multiple documents from multiple sources, and also allows time for back and forth review with the Exchange. The majority of households with income DMIs are low income and consumers often have multiple sources of employment that can change frequently. Therefore, collecting and submitting documentation to verify projected household income is extremely complicated and difficult. The proposed extension would provide consumers with necessary time to gather and submit sufficient documentation to verify projected household income. The current authority allowing for the granting of extensions is applied on a case by case basis and requires the consumers to demonstrate difficulty before the 90- day deadline, which does not address the need for additional time more broadly for households with income DMIs.

A review of income DMI data indicates that when consumers receive additional time, they are more likely to successfully provide documentation to verify their projected household income. Between 2018 and 2021, over one third of consumers who resolved their income DMIs on the Exchange did so in more than 90 days. These consumers were provided additional time under § 155.315(f)(3), but the extension under this existing provision places the burden on the consumer to obtain more time to submit documentation. The proposed extension would treat consumers more equitably and would take into consideration the complicated process of obtaining and submitting income documents for these households. We believe the proposed extension would provide more opportunity to work with consumers to submit the correct documentation to verify their projected annual household income. Extensions enabled HHS to determine eligibility for more consumers truly eligible for coverage. HHS continues to study consumer behavior in resolving consistencies to continue to support accurate eligibility determination.

HHS has found that income DMIs have a negative impact on access, health equity, and the risk pool. Per a review of PY 2022 data, the majority of income DMIs disproportionately impacted households with lower attested household income. Among households with an income DMI in PY 2022, more than 60 percent attested to a household income of less than $25,000; compared to households without an income DMI, where only about 40 percent attested to household income less than $25,000. Additionally, households with an attested household income below $25,000 successfully submitted documentation to verify their income 25 percent less often than households with higher household incomes.

Income DMIs also may pose a strain on populations of color. A review of available data indicates that income DMI expirations are higher than expected among Black or African American consumers. Further, the proposed changes would ensure that all consumers are able to continue to have access to more affordable coverage by continuing to receive their APTC, which

[159] 42 U.S.C. 18081

also supports HHS' goal of consumers maintaining continuous coverage.

Income DMIs also negatively impact the risk pool. When households are unable to submit documentation to verify their household income and lose eligibility for APTC, they are much more likely to drop coverage since they must pay the entire monthly premium, which in many cases may be significantly more than the premium minus the APTC. We found that consumers who were unable to submit sufficient documentation to verify their income and lost their eligibility for APTC were half as likely as other consumers to remain covered through the end of the plan year. Consumers aged 25–35 were the age group most likely to lose their APTC eligibility due to an income DMI, resulting in a loss of a population that, on average, has a lower health risk, thereby negatively impacting the risk pool. This finding underscores the importance of consumers being provided ample time to resolve their Income DMIs in order to support HHS' commitment to advancing health equity for consumers participating in the Exchange.

Given the information we have on the negative and disproportionate impacts of income DMIs, we are proposing to adjust the household income verification requirements in order to treat consumers more equitably, help ensure continuous coverage, and strengthen the risk pool. If the proposed changes are finalized, Exchanges would utilize only data from the IRS to determine if income is inconsistent and would accept attestation when tax return data is requested from IRS but not returned. In cases where the IRS returns tax data that reflects that the attested projected annual household income is not an accurate projection of the tax filer's household income, Exchanges would continue existing operations. Additionally, Exchanges would utilize the additional time provided to work with consumers to submit documentation to verify their projected annual household income. While the increased protection for consumers from loss of eligibility for APTC could present a program integrity risk, households are required to provide true answers to application questions under penalty of perjury. Additionally, HHS does not believe that individuals with a mismatch due to situations such as family size change have a greater incentive to misreport income than their counterparts, given that changes in family size and other changes in circumstances are unlikely to be correlated with income misreporting incentives. HHS will continue to engage with partners to evaluate the impact of this proposal on APTC accuracy.

We seek comment on these proposals.

6. Annual Eligibility Redetermination (§ 155.335)

We propose amending § 155.335(j)(1) and (2) to allow Exchanges, beginning for PY 2024, to modify their re-enrollment hierarchies such that enrollees who are eligible for CSRs in accordance with § 155.305(g) and who would otherwise be automatically re-enrolled in a bronze-level QHP without CSRs, to instead be automatically re-enrolled in a silver-level QHP (with income-based CSRs) in the same product with a lower or equivalent premium (after APTC), provided that certain conditions are met.[160] Furthermore, we propose to amend the Exchange re-enrollment hierarchy to allow all Exchanges (Exchanges on the Federal platform and SBEs) to ensure enrollees whose QHPs are no longer available to them and enrollees who would be re-enrolled into a silver-level QHP in order to receive income-based CSRs are re-enrolled into plans with the most similar network to the plan they had in the previous year, provided that certain conditions are met. To honor other criteria the enrollee may have used to make the original selection, we propose to limit re-enrollment of such enrollees into plans offered by the same issuer and of the same product if the enrollee's plan and product remains available through the Exchange for renewal consistent with § 147.106. We propose that Exchanges (including Exchanges on the Federal platform and SBEs) would implement this option beginning with the open enrollment period for plan year 2024 coverage, if operationally feasible, and if not then beginning with the open enrollment period for plan year 2025 coverage.

The re-enrollment hierarchy previously prioritized placing an enrollee in a similar metal level; however, HHS now believes other factors, such as access to income-based CSRs and net premium (that is, premium minus the APTC), should also be taken into account. As discussed later, HHS is considering whether for future years it would be appropriate to modify the re-enrollment process to incorporate both net premium and out-of-pocket costs attributable to cost sharing (referred to in this preamble as total out-of-pocket cost) when both directing re-enrollment to a plan at the same metal level as the enrollee's current QHP and directing re-enrollment to a plan at a higher metal level than the enrollee's current QHP in all Exchanges.[161] [162]

In the 2014 Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges (79 FR 52994, 52998 through 53001), we established the Exchange re-enrollment hierarchy at § 155.335(j) with the goal of ensuring continuous coverage for consumers who opt not to make an active plan selection for the upcoming year. In paragraph (j)(1), we finalized that if an enrollee remains eligible for enrollment in a QHP through the Exchange upon annual redetermination, and the product under which the QHP in which the enrollee was enrolled remains available for renewal, consistent with § 147.106, such enrollee will have his or her enrollment in a QHP through the Exchange under the product renewed unless he or she terminates coverage, including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with § 155.430. We further finalized that the QHP in which the enrollee's coverage will be renewed will be selected according to the following order of priority: (1) in the same plan as the enrollee's current QHP, unless the current QHP is not available through the Exchange; (2) if the enrollee's current QHP is not available, the enrollee's coverage will be renewed in a QHP at the same metal level as the enrollee's current QHP within the same product; (3) if the enrollee's current QHP is not available through the Exchange and the enrollee's product no longer includes a QHP at the same metal level as the enrollee's current QHP, the enrollee's coverage will be renewed in a plan that is one metal level higher or lower than the enrollee's current QHP (with the exception of when the enrollee's current QHP is a silver level

[160] Under § 144.103, a product is defined as a discrete package of health insurance coverage benefits that are offered using a particular product network type (such as health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity) within a service area.

[161] As defined at § 155.20, cost sharing means any expenditure required by or on behalf of an enrollee with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services.

[162] Total out-of-pocket costs could also include balance billing amounts, but for purposes of this preamble, we use the term total out-of-pocket costs to refer to net premium and out-of-pocket costs attributable to amounts such as coinsurance, copayments, and deductibles.

plan); or (4) if the enrollee's current QHP is not available through the Exchange and the enrollee's product no longer includes a QHP that is at the same metal level as, or one metal level higher or lower, than the enrollee's current QHP, the enrollee's coverage will be renewed in any other QHP offered under the product in which the enrollee's current QHP is offered in which the enrollee is eligible to enroll.[163]

Under paragraph (j)(2), we finalized standards to address re-enrollment in situations in which no plans under the product under which an enrollee's QHP is offered are available through the Exchange for renewal. In this situation, the enrollee may be enrolled in a QHP under a different product offered by the same issuer, to the extent permitted by applicable State law, unless the enrollee terminates coverage including termination of coverage in connection with voluntarily selecting a different QHP. In such cases, the re-enrollment will occur according to the following order of priority: (1) in a QHP through the Exchange at the same metal level as the enrollee's current QHP in the product offered by the same issuer that is the most similar to the enrollee's current product; (2) if the issuer does not offer another QHP through the Exchange at the same metal level as the enrollee's current QHP, the enrollee will be re-enrolled in a QHP through the Exchange that is one metal level higher or lower than the enrollee's current QHP in the product offered by the same issuer through the Exchange that is the most similar to the enrollee's current product; or (3) if the issuer does not offer another QHP through the Exchange at the same metal level as, or one metal level higher or lower than the enrollee's current QHP, the enrollee will be re-enrolled in any other QHP offered through the Exchange by the same issuer in which the enrollee is eligible to enroll.

In the 2017 Payment Notice (81 FR 12203), we finalized the rule to provide for automatic re-enrollment in a QHP offered by another issuer through the Exchange in order to maintain coverage with APTC and income-based CSRs for the majority of Exchange enrollees who are receiving these subsidies, as opposed to permitting a QHP issuer that no longer has a QHP available to an enrollee through an Exchange to re-enroll the enrollee outside the Exchange. Specifically, we established that, beginning in PY 2017, if no QHP from the same issuer is available to enrollees through the Exchange, the Exchange could direct alternate enrollments for such enrollees to the extent permitted by applicable State law into a QHP from a different issuer. In such cases, the re-enrollment will occur as directed by the applicable State regulatory authority, or, if the applicable State regulatory authority declines to direct this activity, such alternate enrollments would be directed by the Exchange. This rule provides considerable flexibility to Exchanges to specify the logic that will be used to assign enrollees in this situation to specific plans.

In the 2023 Payment Notice (87 FR 27208, 27273), HHS announced it would consider proposing amendments to the Exchange re-enrollment hierarchy in future rulemaking and would take into account comments received. In the preamble to the 2023 Payment Notice proposed rule (87 FR 584, 652), we solicited comments on incorporating the net premium, maximum out-of-pocket amount (MOOP), deductible, and total out-of-pocket cost of a plan into the Exchange re-enrollment hierarchy.[164] We also solicited comments on additional criteria or mechanisms HHS could consider to ensure that the Exchange hierarchy for re-enrollment aligns with plan generosity and consumer needs (87 FR at 652). Additionally, we sought comment on the following examples: (1) re-enrolling a current bronze QHP enrollee into an available silver QHP with a lower net premium and higher plan generosity (that is, a higher metal level) offered by the same QHP issuer; and (2) re-enrolling a current silver QHP enrollee into another available silver QHP, under the enrollee's current product and with a service area that is serving the enrollee that is issued by the same QHP issuer, which has lower total out-of-pocket cost (87 FR at 652). As described in further detail later, we propose to codify example (1) described above by amending § 155.335(j)(1) and (2) to allow Exchanges, beginning for PY 2024, to modify their re-enrollment hierarchies such that enrollees who are eligible for CSRs in accordance with § 155.305(g) and who would otherwise be automatically re-enrolled in a bronze-level QHP without CSRs, would instead be automatically re-enrolled in a silver-level QHP (with income-based CSRs) in the same product with a lower or equivalent premium after APTC. We believe initially limiting the scope to only income-based CSR-eligible enrollees who are currently in a bronze QHP and have a lower cost silver CSR QHP available would allow issuers and Exchanges to incrementally update their processes, as opposed to incorporating net premium and out-of-pocket cost (OOPC) throughout the hierarchy for PY 2024.

We received substantial comments from diverse interested parties and have carefully considered these comments. Several commenters encouraged HHS to take net premium or total out-of-pocket cost into account for the re-enrollment hierarchy. Many commenters supported amending § 155.335(j)(1)(i) to allow the enrollee to be re-enrolled into a different plan with a lower net premium and higher generosity if there is no change in the issuer, product, service area, and provider network. Some commenters raised concerns with § 155.335(j)(1)(ii) through (iv) and (j)(2)(iii), which outline the re-enrollment rules when an enrollee's current QHP is no longer available, since they allow consumers to be re-enrolled in a plan with far higher costs if the issuer and provider networks types are prioritized. Commenters explained that the current policy does not provide flexibility for enrollees to be re-enrolled into a different plan even if a change in market conditions has significantly raised the old plan's cost to the enrollees. Further, commenters stated that the majority of enrollees who do not shop at all during the Open Enrollment Period (OEP) care more about cost than the issuer or provider network. More specifically, commenters cited research on plans sold through Covered California that showed, on average, families in California were charged an extra $466 a year in annual premiums as a result of remaining with a plan that no longer served their interests. Commenters stated that including total out-of-pocket cost and plan generosity into re-enrollment rules would be particularly beneficial for situations when enrollees are eligible for

[163] Under § 155.335(j)(1)(iii)(A), if the enrollee's current QHP is not available through the Exchange and the enrollee's product no longer includes a QHP at the same metal level as the enrollee's current QHP and the enrollee's current QHP is a silver level plan, the enrollee will be re-enrolled in a silver level QHP under a different product offered by the same QHP issuer that is most similar to the enrollee's current product. If no such silver level QHP is available for enrollment through the Exchange, the enrollee's coverage will be renewed in a QHP that is one metal level higher or lower than the enrollee's current QHP under the same product.

[164] MOOP refers to the limit on cost sharing an enrollee has to pay for covered services in a plan year. After the enrollee spends this amount on cost sharing for in-network essential health benefits, the health plan pays 100 percent of the costs of covered essential health benefits. For purposes of this section of preamble, the term total out-of-pocket costs refers to net premium and out-of-pocket costs attributable to cost sharing and excludes any costs attributable to balance billing.

cost-sharing reductions and are not enrolled in a silver plan.

Commenters also recommended that provider network considerations be incorporated into any revised re-enrollment hierarchy. Specifically, commenters explained that a revised hierarchy that does not incorporate provider networks could result in enrollees losing access to their providers, increased out-of-network costs, and/or being placed in narrower network plan. Some commenters urged the Exchange to provide accessible notices and reasonable opportunities for the consumer to return to their former plan or drop coverage. Commenters also mentioned the importance of enhancing the consumer shopping experience and decision support tools to improve consumer understanding, particularly around cost sharing. In the 2023 Payment Notice, HHS did not finalize any changes to § 155.335(j).

HHS is aware of interested parties' concerns that enrollees in the Exchanges on the Federal platform may fail to return to the Exchange to make an active plan selection in situations in which changing plans could be beneficial to the enrollee, and that re-enrollment rules may default enrollees into less beneficial plans than other available plans. Currently, the Federal hierarchy for re-enrollment ensures an enrollee's coverage will be renewed in the same plan as the enrollee's current QHP, unless the current QHP is not available through the Exchange. If the enrollee's current QHP is no longer available through the Exchange, the Federal hierarchy prioritizes the same metal level and product network type in order to determine the most similar plans within the same service area. However, if that is not an option, an enrollee will be re-enrolled in a QHP that is one metal level lower or higher within the same service area (with the exception of silver plans). In the 2022 OEP, 28 percent of returning Exchange enrollees using the *HealthCare.gov* platform were auto re-enrolled.[165]

The current hierarchy assumes that the same metal level would be least disruptive to enrollees in terms of premium and coverage. However, in some instances it may be to the enrollee's advantage to move to a different metal level. For example, for PY 2022, approximately 110,000 consumers who were automatically re-enrolled also had available to them a plan at one metal level higher than their current plan in the same product from the same issuer with the same network that had a lower net premium [166] More specifically, approximately 38,000 consumers who were automatically re-enrolled into bronze plans also had available a silver-level plan in the same product from the same issuer with the same network that had lower total costs. Furthermore, the Federal hierarchy does not consider the availability of lower premium plans at the same metal level under the same product as the enrollee's current QHP. Directing re-enrollment into lower or same cost, higher metal level plans would place enrollees in more affordable plans with lower out-of-pocket costs, which would lower health insurance costs for those lower-income (CSR-eligible) individuals. Currently, a large majority of Hispanic, Black, and Asian enrollees using the *HealthCare.gov* platform are in the 94 or 87 percent CSR-eligible populations (68, 66, and 62 percent, respectively).[167] As such, re-enrolling enrollees who would otherwise be automatically re-enrolled in a bronze-level QHP without CSRs, into a silver-level QHP (with income-based CSRs) may also improve coverage and affordability for racial and ethnic minorities. Interested parties have emphasized the critical importance of automatic re-enrollment policies for immigrants and racial and ethnic minorities who may face greater challenges in understanding and accessing the active re-enrollment process, and who are disproportionately impacted by cost increases due often to lower wealth and discretionary income. While the vast majority of re-enrollees through *HealthCare.gov* actively select a plan for the upcoming year during the open enrollment period, some remain in their auto re-enrollment plan.

We are aware that some number of enrollees who are automatically re-enrolled are eligible for income-based CSRs (or become eligible for these CSRs through the annual redetermination process under this section), but remain enrolled in a bronze-level QHP, under which they cannot receive income-based CSRs. Further, we know that in some cases, a silver-level QHP in the same product, with the same issuer and network and lower or equivalent premiums, is available. In order to assist these enrollees in obtaining access to income-based CSRs given their eligibility, and without additional net premium, we propose revisions at § 155.335(j). All of these considerations informed our decision to propose the following revisions to the re-enrollment hierarchy at § 155.335(j), as well as our specific approach for implementing these requirements.

We propose revising § 155.335(j)(1)(i) and adding paragraphs (j)(1)(i)(A), (B), and (C) to amend the Exchange re-enrollment hierarchy for enrollment in coverage beginning in PY 2024. Specifically, we propose that, if the enrollee's current QHP is available and: (1) the enrollee is not CSR-eligible, in accordance with § 155.305(g), the Exchange will re-enroll the enrollee in the same plan as the enrollee's current QHP (paragraph (j)(1)(i)(A)); (2) the enrollee is CSR-eligible, in accordance with § 155.305(g), and the enrollee's current QHP is a bronze level plan, the Exchange will re-enroll the enrollee either in the same plan as the enrollee's current QHP, or, at the option of the Exchange, in a silver level QHP within the same product that has a lower or equivalent premium after APTC and that has the most similar network compared to the enrollee's current QHP (paragraph (j)(1)(i)(B)); and (3) the enrollee is CSR-eligible, in accordance with § 155.305(g), and the enrollee's current QHP is not a bronze level plan, the Exchange will re-enroll the enrollee in the same plan as the enrollee's current QHP (paragraph (j)(1)(i)(C)). With respect to current operations, the only effective change to the re-enrollment hierarchy would be the change proposed in paragraph (j)(1)(i)(B). HHS does not propose to shift enrollment out of the enrollee's current product or issuer if the enrollee's current product and/or issuer are available through the Exchange. We believe retaining coverage in the enrollee's current product when available is important in order to honor the various criteria the enrollee may have used to make the original selection and ensure there is no disruption to the enrollee's benefit coverage, such as the product network type (for example, HMO, PPO, etc.) and covered items and services. Furthermore, we believe it is of particular importance to ensure the enrollee's specific provider coverage is maintained beyond a product's provider network type when the enrollee is being auto re-enrolled into a different QHP than their current QHP.

We also propose amending paragraphs (j)(1)(ii) through (iv), which outline the steps for re-enrollment determinations when the enrollee's current QHP is no longer available and the enrollee's current product is still available through the Exchange for renewal. Specifically, we propose revising paragraph (j)(1)(ii) by adding

[165] CMS (2021, April 21). *2022 Marketplace Open Enrollment Public Use Files. https://www.cms.gov/research-statistics-data-systems/marketplace-products/2021-marketplace-open-enrollment-period-public-use-files.*

[166] CMS. (2022). Internal Eligibility and Enrollment Data.

[167] CMS. (2021, October). Internal Eligibility and Enrollment Data.

paragraphs (j)(1)(ii)(A), (B), and (C) to specify for enrollment in coverage beginning in PY 2024, that if the enrollee's current QHP is not available through the Exchange and: (1) the enrollee is not CSR-eligible, in accordance with § 155.305(g), the Exchange will re-enroll the enrollee in a QHP within the same product, at the same metal level and that has the most similar network compared to the enrollee's current QHP (paragraph (j)(1)(ii)(A)); (2) the enrollee is CSR-eligible, in accordance with § 155.305(g), and the enrollee's current QHP is a bronze level plan, the Exchange will re-enroll the enrollee in a bronze level QHP within the same product, or, at the option of Exchange, in a silver level QHP within the same product that has a lower or equivalent premium after APTC and that has the most similar network compared to the enrollee's current QHP (paragraph (j)(1)(ii)(B)); and (3) the enrollee is CSR-eligible, in accordance with § 155.305(g), and the enrollee's current QHP is not a bronze level plan, the Exchange will re-enroll the enrollee in a QHP within the same product at the same metal level and that has the most similar network compared to the enrollee's current QHP (paragraph (j)(1)(ii)(C)).

We also propose amending paragraphs (j)(1)(iii)(A) through (B), which outline the re-enrollment rules when the enrollee's current QHP is not available through the Exchange and the enrollee's product no longer includes a QHP at the same metal level as the enrollee's current QHP. Specifically, we propose, beginning for PY 2024, amending paragraphs (j)(1)(iii)(A) and (B) to require if: (1) the enrollee's current QHP is a silver level plan, the Exchange will re-enroll the enrollee in a silver level QHP under a different product offered by the same QHP issuer that is most similar to and that has the most similar network compared to the enrollee's current product; if no such silver level QHP is available for enrollment through the Exchange, the Exchange will re-enroll the enrollee in a QHP under the same product that is one metal level higher or lower than the enrollee's current QHP and that has the most similar network compared to the enrollee's current QHP (paragraph (j)(1)(iii)(A)); and (2) the enrollee's current QHP is not a silver level plan, the Exchange will re-enroll the enrollee in a QHP under the same product that is one metal level higher or lower than the enrollee's current QHP and that has the most similar network compared to the enrollee's current QHP (paragraph (j)(1)(iii)(A)).

We propose amending paragraph (j)(1)(iv), which outlines the re-enrollment rules when the enrollee's current QHP is not available through the Exchange and the enrollee's product no longer includes a QHP at the same metal level as, or one metal level higher or lower than, the enrollee's current QHP. We propose, adding to paragraph (j)(1)(iv) which would provide, beginning for PY 2024, if the enrollee's current QHP is not available through the Exchange and the enrollee's product no longer includes a QHP that is at the same metal level as, or one metal level higher or lower than the enrollee's current QHP, the Exchange will re-enroll the enrollee in any other QHP offered under the product in which the enrollee's current QHP is offered in which the enrollee is eligible to enroll that has the most similar network compared to the enrollee's current QHP.

We propose amending paragraphs (j)(2)(i) through (iii), which outlines the re-enrollment rules when the enrollee's current product is no longer available through the Exchange for renewal. Specifically, we propose to amend paragraph (j)(2)(i) to provide, beginning for the PY 2024, that if the enrollee is not CSR eligible, the Exchange will re-enroll the enrollee in a QHP in the product offered by the same issuer that is the most similar to the enrollee's current product at the same metal level as and with the most similar network compared to the enrollee's current QHP. We propose revising and redesignating paragraph (j)(2)(ii) as paragraph (j)(2)(iv), which would require, if the issuer does not offer another QHP at the same metal level as the enrollee's current QHP, the Exchange will re-enroll the enrollee in a QHP that is one metal level higher or lower than the enrollee's current QHP and that has the most similar network compared to the enrollee's current QHP in the product offered by the same issuer through the Exchange that is the most similar to the enrollee's current product. We propose to add a new paragraph (j)(2)(ii) to establish that if the enrollee is CSR-eligible, in accordance with § 155.305(g), and the enrollee's current QHP is a bronze level plan, the Exchange will re-enroll the enrollee in a bronze level QHP, or, at the option of the Exchange, in a silver level QHP that has a lower or equivalent premium after APTC and that has the most similar network compared to the enrollee's current QHP in the product offered by the same issuer through the Exchange that is most similar to the enrollee's current product.

We also propose, beginning for PY 2024, revising and redesignating paragraph (j)(2)(iii) as paragraph (j)(2)(v), which would state that if the issuer does not offer another QHP through the Exchange at the same metal level as, or one metal level higher or lower than the enrollee's current QHP, the Exchange will re-enroll the enrollee in any other QHP offered by the same issuer in which the enrollee is eligible to enroll in the product that is most similar to the enrollee's current product and in a QHP within that product that has the most similar network to the enrollee's current QHP. Lastly, we propose to add a new paragraph (j)(2)(iii) to establish that if the enrollee is CSR-eligible, in accordance with § 155.305(g), and the enrollee's current QHP is not a bronze level plan, the Exchange will re-enroll the enrollee in a QHP at the same metal level that has the most similar network compared to the enrollee's current QHP in the product offered by the same issuer that is the most similar to the enrollee's current product.

We believe that enrollees are best able to make plan selections themselves, and outreach from the Exchanges on the Federal platform always encourages enrollees to actively return, provide their latest eligibility information, and shop and compare Exchange plans to make the selection that best meets their needs. Income-based CSR-eligible enrollees in Exchanges on the Federal platform who are subject to the proposed policy would receive a notice from the Exchange advising them that they will be re-enrolled into a silver plan if they do not make an active selection on or before December 15th, and would also see the silver plan highlighted in the online shopping experience if they return on or before December 15th to review their options. The notice would also inform the enrollee that if they prefer to keep their bronze plan, they can actively select it through December 15th, for an effective date of January 1st. Enrollees in Exchanges on the Federal platform who do not make an active selection on or before December 15th would receive an additional communication from the Exchange after December 15th reminding them of their new plan enrollment for January 1st, as well as their ability to make a different plan selection by January 15th that would be effective starting February 1st.

This proposal is consistent with the 2014 Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health

Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges (79 FR 52994, 53001) explanation of the guaranteed renewability provisions at § 147.106. If a product remains available for renewal, including outside the Exchange, the issuer must renew the coverage within the product in which the enrollee is currently enrolled at the option of the enrollee, unless an exception to the guaranteed renewability requirements applies. However, to the extent that the issuer is subject to § 155.335(j) with regard to an enrollee's coverage through the Exchange, the issuer must, subject to applicable State law regarding automatic re-enrollments, automatically enroll the enrollee in accordance with the re-enrollment hierarchy, even where that results in re-enrollment in a plan under a different product offered by the same QHP issuer through the Exchange. Enrollments completed pursuant to § 155.335(j) will be considered to be a renewal of the enrollee's coverage, provided the enrollee also is given the option to renew coverage within his or her current product outside the Exchange. This proposal is intended to provide greater financial security to bronze plan enrollees who do not actively re-enroll and may not be aware that a more generous silver plan at the same or lesser cost may be available with dramatically more costs covered by the plan. Additionally, some of these consumers may have been initially enrolled before more generous APTC became available with the passage of the ARP,[168] and may not have been initially income-based CSR-eligible when they first enrolled, or may have been helped by an agent, broker or assister who did not adequately explain the benefits of silver enrollment for CSR-eligible enrollees. This proposal would assist bronze enrollees who may be less engaged and are not aware that a more generous version of their plan was available at the same or lesser cost.

Additionally, we note that HHS is not proposing any changes to SEP eligibility or duration in connection with the proposed changes at § 155.335(j). Currently, under § 155.420(d)(1)(i), a qualified individual is eligible for a SEP to enroll in or change from one QHP to another if the qualified individual loses MEC, which includes when an enrollee's current product is no longer available for renewal. As such, it is not considered a loss of MEC when an enrollee is re-enrolled from a bronze QHP to a silver QHP within the same product and their current plan is still available. We also note that consistent with longtime binder payment policy for Exchange enrollees, auto re-enrollment into a different plan or product with the same issuer that offers their current plan would not require enrollees with already effectuated coverage to make a new binder payment. This means, for example, that a CSR-eligible bronze plan enrollee receiving APTC who is auto re-enrolled in a silver plan offered by the same issuer as their current bronze plan would enter the 3-month APTC grace period if they were late on paying for January coverage in the future year.[169]

We acknowledge the operational complexities issuers and States may face as a result of these proposed changes. Issuers would continue to identify the re-enrollment plan for all enrollees still served by the issuer in the new plan year, except that the Exchange would identify the silver re-enrollment plan for bronze enrollees if those enrollees were redetermined CSR eligible in accordance with § 155.305(g). In order to ensure enrollees are auto re-enrolled in a plan with the most similar network to their current QHP, in the situations where the enrollee would not be auto re-enrolled into their current QHP, HHS would place enrollees into a plan with the same network ID as their current QHP, if possible. Similar to the current Plan ID Crosswalk process, issuers would be able to submit justifications for HHS review if they believed a different network ID in the following plan year had the most similar network to the enrollee's current QHP.[170] Exchanges and State regulators would have a more complicated analysis in assuring that the issuer-identified re-enrollment plan was consistent with the proposed premium and network requirements at § 155.335(j). However, we believe incorporating net premium and provider networks into re-enrollment determinations would help ensure the hierarchy for re-enrollment in all Exchanges takes into account plan generosity and consumer needs beyond merely the retention of the most similar plan available. The Exchanges would need to develop new Exchange notices to provide the enrollees advance and sufficient notice that their plan will change unless they return during open enrollment, and would seek to improve other existing notices, as applicable, to improve transparency and enrollees' understanding of their re-enrollment options. We believe it is important to ensure re-enrollment rules default consumers into lower-cost or more generous plans; promote consumer access to affordable, high-quality coverage; and increase consumer understanding of their re-enrollment options by developing additional consumer notices and guidance.

We seek comment on this proposal. We also seek comments on using network IDs to determine the most similar network. Consistent with the definition of a product at § 144.103, the product ID accounts for different product network types (for example, HMO, PPO, etc.) whereas network IDs account for specific provider differences. As discussed earlier, in situations where the enrollee would not be auto re-enrolled into their current QHP, HHS intends to place enrollees into a plan with the same network ID as their current QHP to ensure enrollee are being auto re-enrolled into plans with the most similar network. We particularly solicit comments on how States review network IDs and the criteria or thresholds States use to determine whether a new network ID is warranted, for example, whether States require that an issuer create a new network ID if there is a five percent difference in the providers covered under a network.

Additionally, HHS is considering whether for future years it would be appropriate to incorporate net premium and total out-of-pocket cost throughout the Exchange re-enrollment hierarchy. We solicit comments on amending the hierarchy at § 155.335(j), for future plan years, to also allow the Exchange take the following actions in the following circumstances: (1) if the enrollee's current plan is not available, regardless of income-based CSR eligibility, direct re-enrollment to a plan at a higher metal level than their current QHP, with a lower or equivalent net premium and total out-of-pocket cost, within the same product, network, and QHP issuer; (2) if the enrollee's current plan is not available and the enrollee does not have a plan at a higher metal level than their current QHP with a lower or equivalent net premium and total out-of-pocket cost, regardless of income-based CSR eligibility, direct re-enrollment to a plan at the same metal level as their current QHP, with a lower or equivalent net premium and total out-of-pocket cost, within the same product, network, and

[168] With the passage of the IRA, these enhanced subsidies have been extended for an additional three years (through 2025).

[169] Please refer to the following for further explanation on binder payments and re-enrollment: CMS. (2022, July 28). 2022 Federally-facilitated Exchange (FFE) and Federally-facilitated Small Business Health Options Program (FF–SHOP) Enrollment Manual. (Exhibit 12, pp. 33–37, and p. 87). *https://www.hhs.gov/guidance/document/2022-enrollment-manual.*

[170] CMS (2022). *Qualified Health Plan Certification Website. https://www.qhpcertification.cms.gov/s/Plan%20Crosswalk.*

QHP issuer; and (3) if a plan at the same metal level as their current QHP is not available and the enrollee is not income-based CSR eligible, direct re-enrollment to a QHP that is one metal level higher or lower than the enrollee's current QHP, with a lower or equivalent net premium and total out-of-pocket cost, under the same product, network, and issuer. For example, an Exchange could consider re-enrolling a current gold QHP enrollee into another available gold QHP, within the enrollee's service area and current product that is issued by the same QHP issuer that has a lower or equivalent net premium and out-of-pocket cost. We also solicit comments on re-enrolling consumers into the lowest cost silver plan in the following year if the consumer chose the lowest cost silver plan in the current plan year. Due to operational complexities, we seek comment on whether the actuarial value (AV) of a plan should be used as a proxy for estimating the total costs that an enrollee may be subject to under a given plan.[171] Specifically, we solicit comments on whether the Exchange should ensure that the net premium of the higher AV plan is less than or equal to the net premium of the default plan or use net premium and total out-of-pocket cost calculations to determine if enrollees should be upgraded to a higher metal level in future plan years.

We also seek comments on whether 73 percent CSR plan variation-eligible enrollees should be re-enrolled into silver plan variations or gold level plans since in some cases gold plans may be more affordable than silver plan variations for 73 percent CSR-eligible enrollees. Additionally, we solicit comments on the States' process for calculating total out-of-pocket cost to understand if, and to what extent, the States' methodology for calculating total out-of-pocket costs vary. Furthermore, we solicit comment on whether the re-enrollment hierarchy should also factor in potential out-of-pocket costs, not attributable to cost sharing, such as balance billing, and if so, how.

HHS also seeks broad comment on alternative auto-enrollment policies that we should consider in future years.[172] For example, we are curious about interested parties' thoughts on an auto-enrollment policy under which consumers who have entered delinquency on their QHP premiums would be auto-enrolled into QHPs with no net premium after application of APTC (referred to as zero-dollar plans). In accordance with §§ 155.430(b)(2)(ii) and 156.270, a QHP/SADP may terminate an enrollee's coverage for non-payment of premiums, subject to certain conditions. Specifically, § 156.270(d) requires issuers to observe a three-consecutive-month grace period before terminating coverage for those enrollees who are eligible for, and have elected to receive, APTC and who, upon failing to timely pay their premiums, are receiving APTC. Research suggests that even small net premiums can significantly decrease enrollment and that this could be because paying even a small premium requires enrollees to take additional action.[173] [174] Enrollees may experience life changes that make it challenging to pay their monthly premiums on an ongoing basis. Currently, the Exchanges on the Federal platform only track nonpayment once the three-month APTC grace period has expired, and do not know when the enrollee first becomes delinquent on payment of premiums. Since providers are notified when an individual is in the second and third month of the grace period, they know that claims may not be paid and may require that the enrollee pay in full at the point of service. A potential challenge with auto enrolling enrollees into zero-dollar premium plans, with retroactive coverage, if they go into delinquency is that re-processing any claims for those enrollees able to self-pay during the pended months would be difficult if the zero-dollar premium auto-assignment was to the original issuer and would be especially burdensome if the new plan was issued by another issuer. We solicit comments on if auto enrolling enrollees into zero-dollar premium plans if they go into delinquency should be prospective or retroactive. In order to mitigate the barriers enrollees face to enroll, effectuate, and maintain coverage, HHS is considering enrolling consumers who enter delinquency into zero-dollar plans.

We also solicit comments on enrolling consumers into zero dollar plans if they fail to make a binder payment. Sometimes QHP applicants select plans, but fail to make a binder payment to effectuate coverage, and thus have their coverage canceled by the issuer. As mentioned previously in this proposed rule, enrollees face non-financial burdens that cause them to miss these payments or in some cases fail to complete the enrollment process. As such, it is likely that by alleviating or eliminating these non-financial burdens, some enrollees would choose to enroll in coverage. We request comments on these proposals.

7. Special Enrollment Periods (§ 155.420)

a. Use of Special Enrollment Periods by Enrollees

We propose two technical corrections to § 155.420(a)(4)(ii)(A) and (B) to align the text with § 155.420(d)(6)(i) and (ii). The proposed revisions would clarify that only one person in a tax household applying for coverage or financial assistance through the Exchange must qualify for a special enrollment period under paragraphs (d)(6)(i) and (ii) in order for the entire household to qualify for the special enrollment period.

As discussed in previous rulemaking, certain SEPs under § 155.420(d) are available to an entire tax household applying for coverage or financial assistance through the Exchange when a qualified individual *or* the qualified individual's dependent satisfies specified requirements (rather than when the qualified individual *and* the qualified individual's dependent satisfy such requirements).[175] In the 2022 Payment Notice (86 FR 24140), we finalized revisions to § 155.420(a)(4)(ii)(C) to update the language from ''if an enrollee *and* his or her dependents'' to ''if an enrollee *or* his or her dependents'' to align with the regulatory text for triggering events under § 155.420(d)(6)(i) and (ii), but we neglected to propose and finalize similar but necessary changes to the text of § 155.420(a)(4)(ii)(A) and (B) and noted that we intended to propose these changes in future rulemaking. Therefore, to align the text of § 155.420(a)(4)(ii)(A) and (B) with the triggering event provisions under § 155.420(d)(6)(i) and (ii), we are

[171] Actuarial value refers to the percentage of total average costs for covered benefits that a plan will cover. However, the enrollee could be responsible for a higher or lower percentage of the total costs of covered services for the year, depending on their actual health care needs and the terms of the insurance policy.

[172] HHS seeks comment on all auto-enrollment policies that could better ensure consumer's continuous access to health coverage, including policies that may require additional grants of authority from Congress to HHS.

[173] Fiedler, M., & McIntyre, A. (2022, September 13). *Tweaking the marketplace enrollment process could magnify effects of larger premium tax credits.* Brookings. *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2022/09/13/tweaking-the-marketplace-enrollment-process-could-magnify-effects-of-larger-premium-tax-credits/.*

[174] Drake, C., Cai, S., Anderson, D., and Sacks, D. (2021, October 22). Financial Transaction Costs Reduce Benefit Take-Up: Evidence from Zero-Premium Health Plans in Colorado. SSRN. *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3743009.*

[175] *See* 78 FR 42262. Also, the 2017 Market Stabilization Rule used the phrase ''if an enrollee *or* his or her dependent'' when describing the rule that would be finalized at what is now paragraph § 155.420(a)(4)(ii)(A), *See* 82 FR 18359.

proposing two technical corrections to § 155.420(a)(4)(ii)(A) and (B) by updating the sentence at paragraph (a)(4)(ii)(A) from ''if an enrollee *and* his or her dependents'' to ''if an enrollee *or* his or her dependents'' and by updating the sentence at paragraph (a)(4)(ii)(B) from ''if an enrollee *and* his or her dependents'' to ''if an enrollee *or* his or her dependents.'' Because these are two technical changes, we do not anticipate that it will impact Exchanges' operations or messaging.

We seek comment on this proposal.

b. Effective Dates for Qualified Individuals Losing Other Minimum Essential Coverage (§ 155.420(b))

We are proposing amendments to the coverage effective date rules at § 155.420(b)(2)(iv) to permit Exchanges the option to offer earlier coverage effective start dates for consumers attesting to a future loss of MEC. Doing so could mitigate coverage gaps when consumers lose forms of MEC (other than Exchange coverage) mid-month and allow for more seamless transitions from other coverage to Exchange coverage. We are aware that consumers may face gaps in coverage because current coverage effective date rules do not allow for retroactive or mid-month coverage effective dates for consumers whose other coverage ends mid-month. Under current rules, the earliest start date for Exchange coverage is the first day of the month following the date of loss of MEC. We are aware that in some States, Medicaid or CHIP is regularly terminated mid-month, so we are soliciting input on whether the proposed change would help consumers, especially those impacted by Medicaid/CHIP unwinding, to seamlessly transition from another form of MEC to Exchange coverage.

Consumers losing MEC, such as coverage through an employer, Medicaid, or CHIP, already qualify for a special enrollment period under § 155.420(d)(1) and may report a loss of MEC to Exchanges and select a QHP up to 60 days before or 60 days after their loss of MEC. Exchanges must generally provide a regular coverage effective date as described in § 155.420(b)(1): for a QHP selection received by the Exchange between the 1st and the 15th day of any month, the Exchange must ensure a coverage effective date of the 1st day of the following month; and for a QHP selection received by the Exchange between the 16th and the last day of any month, the Exchange must ensure a coverage effective date of the 1st day of the second following month. However, Exchanges must provide special coverage effective dates for certain special enrollment period types including loss of MEC, as described in § 155.420(b)(2), and may elect to provide coverage effective dates earlier than those specified in § 155.420(b)(1) and (2)(i), as described in § 155.420(b)(3). The loss of MEC coverage effective dates are generally governed by § 155.420(b)(2)(iv). Currently, for all Exchanges, consumers who report a future loss of MEC and select a plan on or before the loss of MEC are provided an Exchange coverage effective date of the 1st of the month after the date of loss of MEC, pursuant to § 155.420(b)(2)(iv). For example, if a consumer reports on June 1st that they will lose MEC on July 15th and they make a plan selection on or before July 15th, Exchange coverage will be effective August 1st. The consumer in this case cannot avoid a gap in coverage of more than two weeks.

For consumers reporting a loss of MEC that occurred up to 60 days in the past, Exchanges must ensure that coverage is effective in accordance with § 155.420(b)(1) (the regular coverage effective dates described above) [176] through a cross reference from § 155.420(b)(2)(iv). Alternatively, Exchanges can offer prospective coverage effective dates so that coverage is effective the first of the month following plan selection, at the option of the Exchange. *See* § 155.420(b)(2)(i). For example, if a consumer reports on July 1st a past loss of MEC that occurred on June 30th and selects a plan on July 15th, Exchange coverage is effective August 1st.

Because current regulation at § 155.420(b)(2)(iv) does not allow for retroactive or mid-month coverage effective dates, consumers may experience gaps in coverage, especially those consumers who live in States that allow mid-month terminations of Medicaid or CHIP coverage. Further, after the COVID–19 PHE comes to an end, HHS expects to see a higher than usual volume of individuals transitioning from Medicaid and CHIP coverage to the Exchange. This is because States will be required to return to normal eligibility and enrollment operations after the expiration of the continuous enrollment condition that provided a temporary increase in Federal Medicaid matching funds authorized by the Families First Coronavirus Response Act (FFCRA),[177] and we expect that many individuals experienced changes in income or household size since the continuous enrollment condition took effect. Consumers who become ineligible for Medicaid are at risk of being uninsured for a period of time and postponing use of health care services, which can lead to poorer health outcomes, if they are not able to successfully transition between coverage programs without coverage gaps.

Therefore, to ensure that qualifying individuals whose prior MEC ends mid-month are able to seamlessly transition from non-Exchange MEC to Exchange coverage as quickly as possible with no coverage gaps, we are proposing to revisions to paragraph (b)(2)(iv). Specifically, we propose to add additional language to paragraph (b)(2)(iv) that if a qualified individual, enrollee, or dependent, as applicable, loses coverage as described in paragraph (d)(1), experiences a change in eligibility for APTC per paragraph (d)(6)(iii), or experiences a loss of government contribution or subsidy per paragraph (d)(15), and if the plan selection is made on or before the day of the triggering event, the Exchange must ensure that the coverage effective date is the 1st day of the month following the date of the triggering event (as currently required under paragraph (b)(2)(iv)) and, at the option of the Exchange, if the plan selection is made on or before the last day of the month preceding the triggering event, the Exchange must ensure that coverage is effective on the first of the month in which the triggering event occurs. For example, if a consumer attests between May 16th and June 30th that they will lose MEC on July 15th and selects a plan on or before June 30th, coverage would be effective on August 1st (first of the month after the last day of prior MEC), or at the option of the Exchange, on July 1st (the first of the month in which the triggering event occurs).

We acknowledge that this proposed change may have a limited impact because many types of coverage do not typically have end dates in the middle of the month. However, for those that it does impact, the proposed change would provide earlier access to coverage and APTC and CSR. Under the current rule at paragraph (b)(2)(iv), consumers reporting a future loss of MEC may have to wait weeks for their coverage to start, even if they were proactive and attested to a coverage loss as soon as they became aware. We do not believe that this proposed change introduces

[176] For example, if a consumer selects a plan on May 2nd, coverage will be effective June 1st, if a consumer selects a plan on May 16th, coverage will be effective July 1st.

[177] FFCRA. Public Law 116–127 (2020). These provisions enabled States to receive the temporary Federal Medical Assistance Percentage increase under that section.

program integrity concerns because it only applies to those consumers who report a future loss of MEC and have been determined eligible for an SEP and found eligible for an Exchange QHP, fall within their 60-day reporting window for reporting a future loss of MEC, and select a plan on or before the last day of the month preceding the loss of MEC.

We believe this proposed change would provide additional flexibilities for Exchanges as the proposed changes to paragraph (b)(2)(iv) would provide Exchanges with the option to use the current coverage effective dates available under current paragraph (b)(2)(iv) as well as the option to provide earlier coverage effective dates for some consumers who attest to a future loss of MEC. We also acknowledge that if Exchanges do elect an earlier coverage effective date as we propose, this would result in some consumers paying for both an Exchange QHP and their other MEC for a short period of dual enrollment. However, we do not believe the partial-month period of dual enrollment should bar an enrollee from APTC or CSR benefits for the Exchange coverage if otherwise eligible. Given that consumers impacted by the proposed change to § 155.420(b)(2) will have other MEC for only part of the first month of their QHP coverage, Exchanges could look to the definition of coverage month in 26 CFR 1.36B–3, which states that a consumer may qualify when not eligible for the full calendar month for minimum essential coverage, to find a consumer who receives an earlier effective date under this rule as eligible for APTC and CSRs for the first month of their QHP coverage, despite the brief period of overlapping coverage. In order to clarify our interpretation that consumers may be eligible for APTC and CSRs as of the earlier SEP effective date proposed in this rulemaking, we are considering whether any corresponding amendments to APTC eligibility rules may be necessary and plan to codify such changes in the final rule as needed. For example, since Exchange regulations regarding APTC eligibility do not reference the statutory definition of a coverage month, we seek comment on whether Exchange regulations at § 155.305(f) should be revised to correspond with the statutory definition of a coverage month.

We believe the largest beneficiaries of these proposed changes would be consumers whose States permit mid-month terminations of Medicaid or CHIP coverage. We seek comment from interested parties on the frequency of mid-month coverage end dates, potential program integrity issues associated with earlier effective dates, and on instances when the expedited effective date would or would not mitigate coverage gaps or introduce coordination of benefits issues.

Under § 147.104(b)(5), applicable to health insurance issuers that offer health insurance coverage in the individual, small group, or large group market in a State, coverage elected during limited open and special enrollment periods described in § 147.104(b)(2) and (3) must become effective consistent with the dates described in § 155.420(b) (this excludes the special enrollment period under § 155.420(d)(6) which is explicitly excepted from § 147.104(b)(2)). Therefore, with the exception of the triggering event in § 155.420(d)(6), which is limited to coverage purchased through an Exchange, these proposed changes to the effective date for future loss of MEC would be effective for individual market coverage purchased off an Exchange, as well as for coverage purchased through an Exchange, and the proposed option of the Exchange to specify the effective date would refer to an option of the applicable State authority with respect to individual market coverage purchased off an Exchange.

While we also considered proposing retroactive coverage effective dates for consumers reporting past loss of MEC, we decided to limit these proposed changes to future loss of MEC to avoid adverse selection and reduce burden on Exchanges, States, and issuers, as allowing for retroactive coverage start dates can be operationally complex for Exchanges to implement and for issuers to process. Also, we believe the proposed changes would limit the financial burden on consumers, as consumers who report a loss of MEC in the past 60 days may not want or be able to afford to pay past premiums to effectuate coverage retroactively. While we also considered providing mid-month coverage effective dates for consumers who lose MEC mid-month, this would have been disadvantageous to affording coverage given that IRS regulations at 26 CFR 1.36B–3 generally provide that PTC is only available for a month when, as of the first day of the month, the individual is enrolled in a plan through the Exchange. We seek comment on additional regulatory changes that would improve transitions to Exchange coverage and minimize periods of uninsurance for consumers who report a loss of MEC to the Exchange.

We seek comment on these proposals.

c. Special Rule for Loss of Medicaid or CHIP Coverage (§ 155.420(c))

In order to mitigate coverage gaps when consumers lose Medicaid or CHIP coverage and to allow for a more seamless transition into Exchange coverage, we are proposing a new special rule under § 155.420(c)(6) to provide more time for consumers who lose Medicaid or CHIP coverage that is considered MEC as described in § 155.420(d)(1)(i) to report their loss of coverage and enroll in Exchange coverage. The proposed regulation would align the special enrollment period window following loss of Medicaid or CHIP with the reconsideration period available under 42 CFR 435.916(a).

Currently, qualified individuals or their dependents who lose MEC, such as coverage through an employer or most kinds of Medicaid or CHIP, qualify for a special enrollment period under § 155.420(d)(1)(i) and may report a loss of MEC to Exchanges up to 60 days before and up to 60 days after their loss of MEC. 45 CFR 155.420(c)(2). When these qualified individuals or their dependents are disenrolled from Medicaid or CHIP based on modified adjusted gross income (MAGI) following an eligibility redetermination, 42 CFR 435.916 requires that the State Medicaid agency provide a 90-day reconsideration window, which allows former beneficiaries to provide the necessary information to their State Medicaid agency to re-establish their eligibility for Medicaid or CHIP without having to complete a new application. During the 90 days following a Medicaid or CHIP denial or disenrollment, it would be reasonable for a consumer who becomes uninsured to proceed first by attempting to regain coverage through Medicaid or CHIP. However, because the special enrollment period for loss of MEC at § 155.420(d)(1)(i) currently lasts only 60 days after the loss of Medicaid or CHIP coverage, by the time that a consumer exhausts their attempt to regain coverage through Medicaid or CHIP (which they must do within 90 days of loss of Medicaid or CHIP), they may have missed their window to enroll in Exchange coverage through a special enrollment period based on loss of MEC (60 days after loss of Medicaid or CHIP).

In further support of this proposal, we are aware that most consumers losing Medicaid or CHIP may not transition to Exchange coverage in a timely manner. A recent report published by the Medicaid and CHIP Payment and Access Commission (MACPAC) [178]

[178] Medicaid and CHIP Payment Access Commission. (2022, July). *Transitions Between*

found that only about three percent of beneficiaries who were disenrolled from Medicaid or CHIP in 2018 enrolled in Exchange coverage within 12 months. The 2018 data also showed that more than 70 percent of adults and children moving from Medicaid to Exchange coverage had gaps in coverage for an average of about three months.[179] While there are likely several reasons that consumers did not transition directly from Medicaid or CHIP coverage to Exchange coverage in 2018, the proposed special rule at § 155.420(c)(6) has the potential to mitigate an administrative hurdle that may pose a barrier to enrolling in Exchange coverage in a timely manner and with little to no coverage gaps.

Therefore, to ensure that qualifying individuals are able to seamlessly transition from Medicaid or CHIP coverage to Exchange coverage as quickly as possible to and mitigate the risk of coverage gaps, we propose to create new paragraph (c)(6) which would add language stating that effective January 1, 2024, Exchanges will have the option to implement a new special rule that consumers eligible for an SEP under § 155.420(d)(1)(i) due to loss of Medicaid or CHIP coverage that is considered MEC will have up to 90 days after their loss of Medicaid or CHIP coverage to enroll in an Exchange QHP. This proposal would align the special enrollment period window following loss of Medicaid or CHIP with the reconsideration period available under 42 CFR 435.916(a). We also propose adding language to paragraph (c)(2) to clarify that a qualified individual or his or her dependent who is described in paragraph (d)(1)(i) continues to have 60 days after the triggering event to select a QHP unless an Exchange exercises the option proposed in new paragraph (c)(6). We believe these proposed changes would have a positive impact on consumers while providing additional flexibilities for Exchanges as they can choose whether to offer this special rule or not, depending on enrollment trends for their respective populations.

We seek comment on this proposal.

d. Plan Display Error Special Enrollment Periods (§ 155.420(d))

We propose amending § 155.420(d)(12) to align the policy of the Exchanges for granting SEPs to persons who are adversely affected by a plan display error with current plan display error SEP operations. We propose amending paragraph (d)(12) by changing the subject of the regulation to focus on the affected enrollment, not the affected qualified individual or enrollees.[180]

In accordance with § 155.420, SEPs allow a qualified individual or enrollee who experiences certain qualifying events to enroll in, or change enrollment in, a QHP through the Exchange outside of the annual OEP. In 2016, CMS added warnings on *HealthCare.gov* about inappropriate use of SEPs, and tightened certain eligibility rules.[181] We sought comment on these issues in the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018 proposed rule (81 FR 61456), especially on data that could help distinguish misuse of SEPs from low take-up of SEPs among healthier eligible individuals; evidence on the impact of eligibility verification approaches, including pre-enrollment verification, on health insurance enrollment, continuity of coverage, and risk pools (whether in the Exchange or other contexts); and input on what SEP-related policy or outreach changes could help strengthen risk pools. We examined attrition rates in our enrollment data and have found that the attrition rate for any particular cohort is no different at the end of the year than at points earlier in the year, suggesting that any such gaming, if it is occurring, does not appear to be occurring at sufficient scale to produce statistically measurable effects.

In the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018; Amendments to Special Enrollment Periods and the Consumer Operated and Oriented Plan Program (81 FR 94058, 94127 through 94129), CMS codified the plan display error SEP in § 155.420(d)(12) to reflect that plan display error SEP may be triggered when a qualified individual or enrollee, or their dependent, adequately demonstrates to the Exchange that a material error related to plan benefits, service area, or premium (hereinafter ''plan display error'') influenced the qualified individual's, enrollee's, or their dependents' decision to purchase a QHP through the Exchange. This generally allowed consumers who enrolled in a plan for which *HealthCare.gov* displayed incorrect plan benefits, service area, cost-sharing, or premium, and who could demonstrate that such incorrect information influenced their decision to purchase a QHP through the Exchange, to select a new plan that better suited their needs.

In the same final rule, CMS also finalized the policies at § 147.104(b)(2) to make clear that the plan display error SEP only creates an opportunity to enroll in coverage through the Exchange, and clarified that the special enrollment period is limited to plan display errors presented to the consumer by the Exchange at the point at which the consumer enrolls in a QHP (81 FR at 94128 through 94129). By this we meant that the consumer must have already completed their Exchange application, the Exchange must have determined that the consumer is eligible for QHP coverage and any applicable APTC or CSRs, and the consumer must have viewed the material error while making a final selection to enroll in the QHP.

Currently, § 155.420(d)(12) requires the qualified individual, enrollee, or their dependent, to adequately demonstrate to the Exchange that a material error related to plan benefits, service area, or premium influenced the qualified individual's or enrollee's decision to purchase a QHP through the Exchange. However, we have found that consumers may benefit when other interested parties, besides a qualified individual, enrollee, or their dependents, can demonstrate to the Exchange that a material plan error influenced the qualified individual's, enrollee's, or their dependents' enrollment decision to purchase a QHP through the Exchange. In our experience, plan display errors may not be obvious or detectable to the consumer and the Exchange until after the enrollment has been impacted by the error related to plan benefits, service area, premiums, or even cost-sharing. In majority of the plan display errors, the issuer or State regulator has identified the display error. For example, a plan display error can influence a consumer's enrollment without the consumer's knowledge when a consumer enrolls in a QHP, pays an incorrect premium amount that was submitted to and displayed on *HealthCare.gov,* and the plan display error regarding the premium amount is not known until the enrollment is cancelled by the issuer for non-payment of premiums. In this case, the plan display error would not be discovered until the issuer investigates the reason for cancellation. The issuer is the only party that can identify that the plan display error was caused by

Medicaid, CHIP, and Exchange Coverage. https://www.macpac.gov/wp-content/uploads/2022/07/Coverage-transitions-issue-brief.pdf.

[179] Ibid.

[180] In this section, ''consumer'' may be used as shorthand for ''qualified individual, enrollee, or their dependents.''

[181] February 25, 2016. Fact Sheet: Special Enrollment Confirmation Process. Available online at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-02-24.html.*

incorrect premium amounts between the issuer's records and data submitted to *HealthCare.gov,* and that can notify CMS of the plan display error. CMS can then work with the issuer to implement its established data correction processes to make the necessary corrections to the *Healthcare.gov.* This process includes CMS investigating the plan display error to determine if it is reasonable to expect that the material error has influenced the enrollment or the consumer's purchasing decision. In this example, CMS is likely to determine that the plan display error impacted the consumer's purchasing decision because the consumer was presented erroneous information when purchasing the plan and likely made an enrollment decision based on the premium and cost-sharing amount. Issuers that submit a data change request that adversely impacts the consumers' enrollment on *HealthCare.gov* are required to notify consumers of the plan display error and the remediation.

Since qualified individuals, enrollees, and their dependents are not always the parties best suited to demonstrate to the Exchange that a material plan display has influenced their enrollment, we propose revising paragraph (d)(12) to remove the burden solely from the qualified individual, enrollee, and their dependents. We propose adding cost-sharing to the list of plan display errors which is displayed on *HealthCare.gov* alongside plan benefits, service area, and premiums, and equally influence the consumer's purchasing decision or enrollment. Specifically, we propose revising § 155.420(d)(12) to reflect that an SEP is available when the enrollment in a QHP through the Exchange was influenced by a material error related to plan benefits, cost-sharing, service area, or premium. We propose to consider a material error to be one that is likely to have influenced a qualified individual's, enrollee's, or their dependent's enrollment in a QHP.

It should be noted that an error related to plan benefits, service area, cost-sharing or premium does not trigger an SEP when the error is not material, such as when the error is honored as it was displayed. Errors related to plan benefits, service area, cost-sharing or premium include situations where coding on *HealthCare.gov* causes benefits to display incorrectly, or where CMS identifies incorrect QHP data submission or discrepancy between an issuer's QHP data and its State-approved form filings.[182] If the error involves information that displays on *HealthCare.gov,* CMS works with the issuer and applicable State's regulatory authority to arrive at a solution that has minimal impact on consumers and affirms, to the extent possible, that they are not negatively affected by the error. Generally, the most straightforward and consumer-friendly resolution is for issuers to honor the benefit as it was displayed incorrectly for affected enrollees, if permitted by the applicable State regulatory authority. If the issuer chooses to honor the error and administers the plan as it was incorrectly displayed for the affected consumers, CMS will not provide the consumers with an SEP. The proposed revision to the regulation would be consistent with this approach, as the issuer's honoring of the error would effectively eliminate the materiality of the error.

Our proposal would have minimal operational impact, as interested parties currently have the infrastructure to demonstrate to the Exchange that a plan display error influenced a qualified individual's, enrollee's, or their dependents' decision to purchase a QHP through the Exchange. CMS currently engages with partners and interested parties throughout the plan display error SEP process, ensuring that issuers and States are notified of CMS decisions as appropriate. States have access to the status of all applicable plan display error SEPs and can track the progress of the plan display error SEPs until remediation. In addition, under § 156.1256, issuers ''must notify their enrollees of material plan or benefit display errors and the enrollees' eligibility for an [SEP] . . . within 30 calendar days after being notified by the [FFE] that the error has been fixed, if directed to do so by the [FFE].'' Thus, impacted consumers are also currently being notified and made aware of plan display error SEPs policies if their plan data had a significant, material error. We expect that this experience is similar on all Exchanges, and therefore are proposing that this amendment to the description of the SEP trigger would apply for all Exchanges.

We request comment on this proposal.

Additionally, HHS is considering for future years, whether consumers whose providers leave their network mid-year should be eligible for an SEP. Significant network changes, whether it is initiated by the QHP issuer or the provider, can occur at any point during the year. Under Medicare Advantage regulation 42 CFR 422.62(b)(23), individuals affected by a significant change in their plan's provider network are eligible for an SEP that permits re-enrollment into another Medicare Advantage plan or to original Medicare. CMS is seeking comments on whether QHP consumers similarly affected by a significant change in their plan's provider network should be eligible for an SEP. We also solicit comment on whether we should consider an enrollee who is impacted by a provider contract termination to be someone who is experiencing an exceptional circumstance, as specified in § 155.420(d)(9), or should be eligible for a new SEP for provider contract terminations, and what standards for when termination of a provider from the network should serve as a basis for SEP eligibility.

8. Termination of Exchange Enrollment or Coverage (§ 155.430)

a. Prohibition of Mid-Plan Year Coverage Termination for Dependent Children Who Reach the Maximum Age

We propose to add § 155.430(b)(3) to explicitly prohibit QHP issuers participating in Exchanges on the Federal platform from terminating coverage of dependent children before the end of the coverage year because the child has reached the maximum age at which issuers are required to make coverage available under Federal or State law. The ACA amended the PHS Act to require at section 2714 (implemented at § 147.120) that group health plans and health insurance issuers offering group or individual health insurance coverage that offer dependent child coverage must make such coverage available for an adult child until age 26. The ACA also adds section 9815(a)(1) to the Code and section 715(a)(1) to the Employee Retirement Income Security Act to incorporate the provisions of part A of title XXVII of the PHS Act (including section 2714) and make them applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans. This proposal to amend § 155.430 would not change the requirements under § 147.120 nor would it affect parallel provisions in 26 CFR 54.9815–2714 and 29 CFR 2590.715–2714. Some States have established higher age limits, and some issuers adopt higher than legally required age limits as a business decision.

In operationalizing this regulation on the Federal eligibility and enrollment platform, HHS has required issuers that

[182] See the following: CMS. (2022, July 28). *2022 Federally-facilitated Exchange (FFE) and Federally-facilitated Small Business Health Options Program (FF–SHOP) Enrollment Manual.* (Section 6.8.1, p. 82). *https://www.cms.gov/files/document/ffeffshop-enrollment-manual-2022.pdf.*

cover dependent children to provide coverage to dependent children until the end of the plan year in which they turn 26 (or the maximum age under State law), although this is not specifically required under § 147.120. Nevertheless, interested parties have requested that HHS' policy be codified in regulation for clarity. Doing so would reduce uncertainty for Federally-facilitated Exchange issuers regarding their obligation under § 155.430 to maintain coverage for a dependent child who has turned 26 (or the maximum age under State law) until the end of the plan year (unless coverage is otherwise permitted to be terminated). Likewise, it would provide clarity for enrollees themselves who may be uncertain about the rules governing their ability to remain enrolled as a dependent child until the end of the plan year in which they reach the maximum age (that is, age 26 or the maximum age under State law). This proposal would codify the current implementation of the Federal platform.

Payment of APTC on the Exchange, in addition to the way the Federal eligibility and enrollment platform has operationalized Exchange eligibility determinations, warrants a different policy for issuers of individual market QHPs on the Exchanges with regard to child dependents turning age 26 (or the maximum age under State law). This is especially true when comparing individual market Exchange coverage to the employer market, where the employer is typically contributing toward the cost of child dependent coverage, but only until the child dependent attains the maximum dependent age under the group health plan; in the Exchange, the dependent child can receive a portion of the family's APTC for the entire plan year. Exchange eligibility determinations for enrollment through the Exchange and for APTC are based on the tax household, and the determination is made for the entire plan year unless it is replaced by a new determination of eligibility, such as when a change is reported by the enrollee or identified by the Exchange in accordance with § 155.330. The annual basis of Exchange eligibility determinations, absent a new determination, is made clear by the annual eligibility redetermination requirements in § 155.335. Eligibility standards for enrollment through the Exchange and for APTC make no mention of an issuer's business rules regarding dependent relationships, or otherwise regarding the specific relationships between applicants. Additionally, Exchange eligibility criteria do not prohibit allocation of APTC to dependent children enrollees over the age of 26. Every family member who is part of the tax household must be listed on the Exchange application for coverage, and the IRS has no maximum age cap for tax dependents. Because eligibility determinations are made for the entire plan year, the Exchange will generally continue to pay the issuer APTC, including the portion attributable to the dependent child, through the end of the plan year in which the dependent child turns 26, or through the end of the plan year in which the dependent reaches the maximum age required under State law.

In developing the Federal eligibility and enrollment platform, HHS directed QHP issuers on Exchanges that use the Federal platform to honor the eligibility determination made by the Exchange. This requirement applies whether or not the enrollees are determined eligible for APTC. The situation for issuers on these Exchanges thus differs from those in the off-Exchange insurance market, where enrollees do not receive APTC, and in the group insurance market, where contributions by employers may end on the day in which the dependent child turns 26 (or the maximum age under State law).

To clarify, in Exchanges on the Federal platform, during the annual re-enrollment process, enrollees who, during the plan year, have reached age 26 (or the maximum age under State law) are, if otherwise eligible, re-enrolled into a separate policy (following the re-enrollment hierarchy at § 155.335(j)) beginning January 1st of the following plan year, with APTC, if applicable.

Additionally, consistent with existing policy, in circumstances in which a household with an dependent child who has reached age 26 (or the maximum age under State law) reports a change in circumstance to the Exchanges on the Federal platform during the plan year after having reached that age and becomes eligible for an SEP, the dependent child who has exceeded age 26 (or the maximum age under State law) will have their eligibility redetermined in accordance with § 155.330, the dependent child's coverage under that policy will be terminated, and they will be enrolled into their own policy, subject to payment of a binder payment. If, however, the household is not eligible for an SEP as a result of the change, the original eligibility determination from the initial enrollment will remain in place and the dependent child will remain as a covered dependent on the original policy.

Therefore, we propose to add new paragraph (b)(3) to § 155.430 to expressly prohibit QHP issuers participating in Exchanges on the Federal platform from terminating coverage until the end of the plan year for dependent children because the dependent child has reached age 26 (or the maximum age under State law). This change would provide clarity to issuers participating in Exchanges on the Federal platform regarding their obligation to maintain coverage for dependent children, as well as to enrollees themselves regarding their ability to maintain coverage. In addition, we propose to make implementation optional for State Exchanges that wish to establish a similar prohibition.

We request comments on this proposal.

9. General Eligibility Appeals Requirements (§ 155.505)

We propose revising § 155.505(g) to acknowledge the ability of the CMS Administrator to review Exchange eligibility appeals decisions prior to judicial review. Section 155.505 describes the general Exchange eligibility appeals process, including applicants' and enrollees' right to appeal certain Exchange eligibility determinations specified in § 155.505(b), and the obligation of the HHS appeals entity and State Exchange appeals entities to conduct certain Exchange eligibility appeals as described in § 155.505(c). In accordance with § 155.505(g), appellants may seek judicial review of an Exchange eligibility appeal decision made by the HHS appeals entity and State Exchange appeals entities to the extent it is available by law. Currently, the regulation specifies no other administrative opportunities for appellants to appeal Exchange eligibility appeal decisions made by the HHS appeals entity. We propose revising this regulation to acknowledge the ability of the CMS Administrator to review Exchange eligibility appeals decisions prior to judicial review.

This proposed change would ensure that accountability for the decisions of the HHS appeals entity is vested in a principal officer, as well as to bring § 155.505(g) of the appeals process to a more similar posture as other CMS appeals entities that provide Administrator review.[183] Revising the

[183] Examples include: 42 CFR 405 subpart R (Provider Reimbursement Review Board); 42 CFR 412 subpart L (Medicare Geographic Classification Review Board); 42 CFR 430.60–430.104 (Medicaid State Plan Materials/Compliance Determinations);

Continued

regulation would also provide appellants and other parties with accurate information about the availability of administrative review by the CMS Administrator if they are dissatisfied with their Exchange eligibility appeal decision.

We seek comment on this proposal.

10. Improper Payment Pre-Testing and Assessment (IPPTA) for State Exchanges (§§ 155.1500 Through 155.1515)

We propose the establishment of the IPPTA, an improper payment measurement program of APTC, that will include State Exchanges. The proposed IPPTA would prepare State Exchanges for the planned measurement of improper payments of APTC, would test processes and procedures that support HHS' review of determinations of APTC made by State Exchanges, and would provide a mechanism for HHS and State Exchanges to share information that would aid in developing an efficient measurement process. To codify the IPPTA requirements, we propose to establish new subpart P under 45 CFR part 155.

The Payment Integrity Information Act of 2019 (PIIA) [184] requires Federal agencies to annually identify, review, measure, and report on the programs they administer that are considered susceptible to significant improper payments. HHS determined that APTC are susceptible to significant improper payments and are subject to additional oversight. In accordance with 45 CFR part 155, FFEs, SBE–FPs, and State Exchanges that operate their own eligibility and enrollment systems determine the amount of APTC to be paid to qualified applicants. Only improper payments of APTC made by FFEs and SBE–FPs will be measured and reported in the Annual Financial Report beginning in 2022 as part of the Exchange Improper Payment Measurement (EIPM) program. We stated in the 2023 Payment Notice proposed rule (87 FR 654 through 655) that HHS was in the planning phase of establishing an improper payment measurement program that would include State Exchanges—the SEIPM program. We also stated in the 2023 Payment Notice proposed rule that HHS had intended to implement the proposed SEIPM program beginning with the 2023 benefit year. In response to that proposed rule, HHS received several comments from State Exchanges that indicated concerns with the proposed requirements, particularly with respect to the SEIPM program's implementation timeline and proposed data collection processes. For example, some State Exchanges commented that they would need more time and information from HHS to prepare for the implementation of the SEIPM program. We decided not to finalize the proposed rule due to commenters' concerns surrounding the proposed implementation timeline and other burdens that would be imposed by the proposed SEIPM program (87 FR 27281). HHS is now proposing the IPPTA to provide State Exchanges with more time to prepare for the planned measurement of improper payments of APTC, to test processes and procedures that support HHS' review of determinations of APTC made by State Exchanges, and to provide a mechanism for HHS and State Exchanges to share information that would aid in developing an efficient measurement process.

In 2019, HHS developed an initiative to provide the State Exchanges with an opportunity to voluntarily engage with HHS to prepare for future measurement of improper payments of APTC. HHS provided three options to State Exchanges—program analysis, program design, and piloting—designed to accommodate the State Exchanges' schedules and availability to participate in the initiative. Currently, of the 18 State Exchanges, 10 have participated in various levels of engagement.

HHS proposes that the proposed IPPTA would replace the current, voluntary State engagement initiative. HHS additionally proposes that activities already completed by State Exchanges as part of the current voluntary engagement may be used to satisfy elements of the proposed IPPTA. HHS has determined that participation from all State Exchanges is required in order to test processes and procedures that would prepare the State Exchanges for the planned measurement of improper payments of APTC.

Therefore, we propose to establish a new subpart P under 45 CFR part 155 (containing §§ 155.1500 through 155.1515) to codify the proposed IPPTA requirements. The proposed regulations at subpart P would be applicable beginning in 2024 with each State Exchange being selected to participate for a period of one calendar year which would occur either in 2024 or 2025.

a. Purpose and Scope (§ 155.1500)

We are proposing to add new subpart P to part 155, which would address various State Exchange and HHS responsibilities. HHS may use Federal contractors as needed to support the performance of IPPTA.

We are proposing to add new § 155.1500 to convey the purpose and scope of the IPPTA.

At paragraph (a), we are proposing the purpose and scope of subpart P as setting forth the requirements of the IPPTA for State Exchanges. The proposed IPPTA is an initiative between HHS and State Exchanges. The proposed requirements are intended to prepare State Exchanges for the planned measurement of improper payments, test processes and procedures that support HHS' review of determinations of APTC made by State Exchanges, and provide a mechanism for HHS and State Exchanges to share information that would aid in developing an efficient measurement process.

b. Definitions (§ 155.1505)

We are proposing to codify the definitions that are specific to IPPTA and key to understanding the processes and procedures of IPPTA.

- We are proposing the definition of ''business rules'' to mean the State Exchange's internal directives defining, guiding, or constraining the State Exchange's actions when making eligibility determinations and related APTC calculations. For example, the internal directives, methodologies, algorithms, or policies that a State Exchange applies or executes on its own data to determine whether an applicant meets the eligibility requirements for a QHP and any associated APTC would be considered to be a business rule.
- We are proposing the definition of ''entity relationship diagram'' to mean a graphical representation illustrating the organization and relationship of the data elements that are pertinent to applications for QHP and associated APTC payments.
- We are proposing the definition of ''Pre-testing and assessment'' to mean the process that uses the procedures specified in § 155.1515 to prepare State Exchanges for the planned measurement of improper payments of APTC.
- We are proposing the definition of ''Pre-testing and assessment checklist'' to mean the document that contains criteria that HHS will use to review a State Exchange's completion of the requirements of the IPPTA.
- We are proposing the definition of ''Pre-testing and assessment data request form'' to mean the document that

42 CFR 423.890 (Retiree Drug Subsidy (RDS) Appeals); 42 CFR 411.120–124 (Group Health Plan Non-conformance Appeals); 42 CFR 417.640, 417.492. 417.500, 417.494 (Health Maintenance Organization Competitive Medical Plan (HMO/CMP) Contract Related Appeals); 42 CFR 423.2345 (Termination of Discount Program Agreement Appeals).

[184] PIIA, 31 U.S.C. 3352 (2020).

specifies the structure for the data elements that HHS would require each State Exchange to submit.

• We are proposing the definition of ''Pre-testing and assessment period'' to mean the timespan during which HHS will engage in the pre-testing and assessment procedures with a State Exchange. The pre-testing and assessment period will cover one calendar year.

• We are proposing the definition of ''Pre-testing and assessment plan'' to mean the template developed by HHS in collaboration with each State Exchange enumerating the procedures, sequence, and schedule to accomplish the pre-testing and assessment.

• We are proposing the definition of ''Pre-testing and assessment report'' to mean the summary report provided by HHS to each State Exchange at the end of the State Exchange's pre-testing and assessment period that will include, but not be limited to, the State Exchange's status regarding completion of each of the pre-testing and assessment procedures specified in proposed § 155.1515, as well as observations and recommendations that result from processing and testing the data submitted by the State Exchange to HHS. At § 155.1515(g), we are proposing that the pre-testing and assessment report is intended to be used internally by HHS and each State Exchange as a reference document for performance improvement. The pre-testing and assessment report will not be released to the public by HHS unless otherwise required by law.

c. Data Submission (§ 155.1510)

We are proposing to add new § 155.1510 which would address the data submission requirements to support the IPPTA. Consistent with this, we are proposing to establish a pre-testing and assessment data request form to collect and compile information from each State Exchange. As explained below in section IV., Collection of Information Requirements, the pre-testing and assessment data request form has been submitted to OMB for review and approval. As described below, HHS proposes that each State Exchange submit to HHS a sample of no fewer than 10 tax household identification numbers (that is, the record of a tax household that applied for and was determined eligible to enroll in a QHP and was determined eligible to receive APTC in an amount greater than $0).

• At paragraph (a)(1), we are proposing that a State Exchange would be required to submit to HHS by the deadline in the pre-testing and assessment plan the following documentation for their data: (i) the State Exchange's data dictionary including attribute name, data type, allowable values, and description; (ii) an entity relationship diagram, which shall include the structure of the data tables and the residing data elements that identify the relationships between the data tables; and (iii) business rules and related calculations.

• At paragraph (a)(2), we are proposing that the State Exchange must use the pre-testing and assessment data request form, or other method as specified by HHS, to submit to HHS the application data associated with no fewer than 10 tax household identification numbers and the associated policy identification numbers that address scenarios specified by HHS to allow HHS to test all of the pre-testing and assessment processes and procedures. The proposed scenarios would include various application characteristics such as household composition, data matching inconsistencies (for example, SSN, citizenship, lawful presence, annual income) identified for the applications, special enrollment period application types (for example, relocation, marriage), periodic data matching (for example, Medicaid/CHIP, Medicare, death), application status (for example, policy terminated, policy canceled), and application types (for example, initial application). HHS understands that it is unlikely that the application data associated with a singular tax household could address all of the characteristics contained in all of the scenarios specified. Therefore, HHS proposes that while the application data for each tax household does not need to address all of the scenarios specified, the application data submitted for no fewer than 10 tax households should, when taken together as a whole, address all of the characteristics in all of the scenarios specified. For example, the application data for one tax household may address lawful presence inconsistency adjudication but not special enrollment eligibility verification. Accordingly, the application data for another tax household should address special enrollment eligibility verification. After receiving the application data associated with no fewer than 10 tax households from the State Exchange, HHS would test the data from each of the tax households against its review procedures to determine if the respective policy applications fulfill the scenarios. If the submitted application data does not collectively fulfill the scenarios, HHS would coordinate with the State Exchange to select additional tax households. For the data submitted, HHS would also require the State Exchange to provide digital copies such as PDFs of supporting consumer-submitted documentation (for example, proof of residency, proof of citizenship).

• In proposed § 155.1515(e)(2), HHS proposes that for each of the tax households, the State Exchange would align and populate the data in the pre-testing and assessment data request form with the assistance of HHS. HHS would require that the State Exchange electronically transmit the completed pre-testing and assessment data request form to HHS within the deadline specified in the pre-testing and assessment plan. Once HHS receives the transmission from the State Exchange, HHS then would execute the pre-testing and assessment processes and procedures on the application data.

• At paragraph (b), we are proposing the requirement that a State Exchange must submit the data documentation as specified in § 155.1510(a)(1) and the application data associated with no fewer than 10 tax households as specified in § 155.1510(a)(2) within the timelines in the pre-testing and assessment plan specified in § 155.1515.

d. Pre-Testing and Assessment Procedures (§ 155.1515)

We are proposing to add new § 155.1515 which would address the requirements associated with the pre-testing and assessment procedures that underlie and support the IPPTA. The pre-testing and assessment procedures are the activities of the IPPTA that are, in part, designed to test HHS' review processes and procedures that support HHS' review of determinations of the APTC made by State Exchanges, to improve the State Exchange's understanding of the IPPTA, to prepare State Exchanges for the planned measurement of improper payments, and to provide HHS and the State Exchanges with a mechanism to share information that would aid in developing an efficient measurement process.

• At paragraph (a), we are proposing the general requirement that the State Exchange must participate in the IPPTA for a period of one calendar year that would occur in either 2024 or 2025, and that the State Exchange and HHS would work together to execute the IPPTA procedures in accordance with timelines in the pre-testing and assessment plan.

• At paragraph (b), we are proposing the requirements for the orientation and planning processes.

• At paragraph (b)(1), we are proposing HHS would provide State Exchanges with an overview of the pre-testing and assessment procedures as part of the orientation process. We are also proposing that, during the orientation process, HHS would identify the documentation that a State Exchange must provide to HHS for pre-testing and assessment. For example, if data use agreements or information exchange agreements need to be executed, HHS would inform State Exchanges about that documentation requirement.

• At paragraph (b)(2), we are proposing that HHS, in collaboration with each State Exchange, would develop a pre-testing and assessment plan as part of the orientation process. The pre-testing and assessment plan would be based on a template that enumerates the procedures, sequence, and schedule to accomplish pre-testing and assessment. While HHS would need to meet milestones specified in the schedule and applicable deadlines due to the time span allotted for this proposed program, HHS would take into account feedback from the State Exchanges in an effort to minimize burden. The pre-testing and assessment plan would take into consideration relevant activities, if any, that were completed during a prior, voluntary, State engagement. The pre-testing and assessment plan would include the pre-testing and assessment checklist.

• At paragraph (b)(3), we are proposing that HHS will issue a pre-testing and assessment plan specific to a State Exchange at the conclusion of the pre-testing and assessment planning process. The pre-testing and assessment plan would be for HHS and State Exchange internal use only and would not be made available to the public by HHS unless otherwise required by law.

• At paragraph (c), we are proposing the requirements associated with notifications and updates.

• At paragraph (c)(1), we are proposing the requirements associated with HHS' responsibility to notify State Exchanges, as needed throughout the pre-testing and assessment period, concerning information related to the pre-testing and assessment processes and procedures.

• At paragraph (c)(2), we are proposing the requirements associated with information State Exchanges must provide to HHS throughout the pre-testing and assessment period regarding any operational, policy, business rules (for example, data elements and table relationships), information technology, or other changes that may impact the ability of the State Exchange to satisfy the requirements of the IPPTA during the pre-testing and assessment period. For example, HHS would need to be made aware of changes to the State Exchange's technical platform or modifications to its policies or procedures as these changes may impact specific pre-testing and assessment processes or procedures, the data to be reviewed, and ultimately a State Exchange's determinations of an applicant's eligibility for APTC. We are proposing that other decisions or changes made by a State Exchange, which could affect the pre-testing and assessment including any changes regarding items such as naming conventions or definitions of specific data elements used in the pre-testing and assessment, must be submitted to HHS. We propose this requirement because any lack of clarity in how State Exchanges make eligibility determinations and payment calculations could impact HHS' ability to assist the State Exchange in understanding the pre-testing and assessment processes and procedures and could affect HHS' recommendations in the pre-testing and assessment report.

• At paragraph (d), we are proposing the requirements regarding the submission of required data and data documentation by State Exchanges, and we state that, as specified in § 155.1510(a) of this subpart, HHS will inform State Exchanges about the form and manner for State Exchanges to submit required data and data documentation to HHS in accordance with the pre-testing and assessment plan.

• At paragraph (e), we are proposing the general requirements regarding coordination between HHS and the State Exchanges to facilitate HHS' processing of data and data documentation submitted by State Exchanges.

• At paragraph (e)(1), we are proposing the requirements associated with HHS' responsibility to coordinate with each State Exchange to track and manage the data and data documentation submitted by a State Exchange as specified in § 155.1510(a)(1) and (a)(2).

• At paragraph (e)(2), we are proposing the requirements associated with HHS' responsibility to coordinate with each State Exchange to provide assistance in aligning the data specified in § 155.1510(a)(2) from the State Exchange's existing data structure to HHS' standardized set of data elements.

• At paragraph (e)(3), we are proposing the requirement that HHS will coordinate with each State Exchange to interpret and validate the data specified in § 155.1510(a)(2).

• At paragraph (e)(4), we are proposing the requirement that HHS would use the data and data documentation submitted by the State Exchange to execute the pre-testing and assessment procedures.

• At paragraph (f), we are proposing the requirements that HHS would issue the pre-testing and assessment checklist in conjunction with and as part of the pre-testing and assessment plan. The pre-testing and assessment checklist criteria we are proposing would include but would not be limited to:

++ At paragraph (f)(1), the State Exchange's submission of the data documentation as specified in § 155.1510(a)(1);

++ At paragraph (f)(2), the State Exchange's submission of the data for processing and testing as specified in § 155.1510(a)(2); and

++ At paragraph (f)(3), the State Exchange's completion of the pre-testing and assessment processes and procedures related to the IPPTA program.

• At paragraph (g), we are proposing that, subsequent to the completion of a State Exchange's pre-testing and assessment period, HHS will prepare and issue a pre-testing and assessment report specific to that State Exchange. The report would be for HHS and State Exchange internal use only and would not be made available to the public by HHS unless otherwise required by law.

We seek comments on these proposals.

C. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. FFE and SBE–FP User Fee Rates for the 2024 Benefit Year (§ 156.50)

For the 2024 benefit year, we propose an FFE user fee rate of 2.5 percent of total monthly premiums and an SBE–FP user fee rate of 2.0 percent of the total monthly premiums. Section 1311(d)(5)(A) of the ACA permits an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. If a State does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the ACA directs HHS to operate an Exchange within the State. Accordingly, in § 156.50(c), we state that a participating issuer offering a plan through an FFE or SBE–FP must remit a user fee to HHS each month that is equal to the product of the annual user fee rate specified in the annual HHS

notice of benefit and payment parameters for FFEs and SBE–FPs for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE or SBE–FP. OMB Circular A–25 established Federal policy regarding user fees and what the fees can be used for. In particular, it specifies that a user fee charge will be assessed against each identifiable recipient of special benefits derived from Federal activities beyond those received by the general public.

a. FFE User Fee Rates for the 2024 Benefit Year

Based on estimated costs, enrollment (including anticipated establishment of State Exchanges in certain States in which FFEs currently are operating), and premiums for the 2023 plan year, we propose a 2024 user fee rate for all participating FFE issuers of 2.5 percent of total monthly premiums.

In § 156.50(c)(1), to support the functions of FFEs, an issuer offering a plan through an FFE must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE. As in benefit years 2014 through 2023, issuers seeking to participate in an FFE in the 2024 benefit year will receive two special benefits not available to the general public: (1) the certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP. For the 2024 benefit year, issuers participating in an FFE will receive special benefits from the following Federal activities:

- Provision of consumer assistance tools;
- Consumer outreach and education;
- Management of a Navigator program;
- Regulation of agents and brokers;
- Eligibility determinations;
- Enrollment processes; and
- Certification processes for QHPs (including ongoing compliance verification, recertification, and decertification).

Activities performed by the Federal Government that do not provide issuers participating in an FFE with a special benefit are not covered by the FFE user fee.

The proposed user fee rate reflects our estimates for the 2024 benefit year of costs for operating the Federal Exchanges, premiums, enrollment, and transitions in Exchange models (from the FFE and SBE–FP models to either the SBE–FP or State Exchange models). To develop the proposed 2024 benefit year FFE user fee rates, we considered a range of costs, premium and enrollment projections.[185] We estimated stable contract costs on FFE user fee eligible costs from the 2023 benefit year. We took a number of factors into consideration in choosing which premium and enrollment projections should inform the proposed 2024 FFE user fee rates. The enhanced PTC subsidies in section 9661 of the ARP were extended in section 12001 of the IRA through the 2025 benefit year. The extension of enhanced PTC subsidies significantly influenced our development of the 2024 enrollment and premium projections. We expect this provision of the IRA to sustain the higher enrollment levels observed in the 2021 benefit year after the ARP was established and as a result, we expect the projected total premiums where the user fee applies to increase, thereby increasing the amount of user fee that will be collected. Our 2024 enrollment estimates also account for the 2022 benefit year transition (and projected transitions through the 2024 benefit year) of States from FFEs or SBE–FPs to State Exchanges, as well as the enrollment impacts of section 1332 State innovation waivers. We project that 2024 benefit year premiums will generally increase at the rate of medical inflation. After considering the range of costs, premium and enrollment projections, we propose a 2024 user fee rate that will exert downward pressure on consumer premiums when compared to the user fee rate from prior years, and that also ensures adequate funding for Federal Exchange operations. The proposed FFE user fee rates for 2024 are slightly lower than the 2.75 percent FFE user fee rate that we established for the 2023 benefit year. After accounting for the impact of the lower user fee rate, we estimate that we would have sufficient funding available to fully fund user-fee eligible Exchange activities.

We seek comment on the proposed 2024 FFE user fee rate.

b. SBE–FP User Fee Rates for the 2024 Benefit Year

We propose to charge issuers offering QHPs through an SBE–FP a user fee rate of 2.0 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE–FP for the 2024 benefit year.

In § 156.50(c)(2), we specify that an issuer offering a plan through an SBE–FP must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an SBE–FP, unless the SBE–FP and HHS agree on an alternative mechanism to collect the funds from the SBE–FP or State instead of direct collection from SBE–FP issuers. SBE–FPs enter into a Federal platform agreement with HHS to leverage the systems established for the FFEs to perform certain Exchange functions, and to enhance efficiency and coordination between State and Federal programs. The benefits provided to issuers in SBE–FPs by the Federal Government include use of the Federal Exchange information technology and call center infrastructure used in connection with eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs, as defined at section 1413(e) of the ACA, and QHP enrollment functions under 45 CFR part 155, subpart E. The user fee rate for SBE–FPs is calculated based on the proportion of user fee eligible FFE costs that are associated with the FFE information technology infrastructure, the consumer call center infrastructure, and eligibility and enrollment services, and allocating a share of those costs to issuers in the relevant SBE–FPs.

To calculate the proposed SBE–FP rates for the 2024 benefit year, we used the same assumptions on contract costs, enrollment, and premiums as the proposed FFE user fee rates. The user fee rate for SBE–FPs is calculated based on the proportion of the total FFE costs utilized by SBE–FPs, such as the costs associated with the FFE information technology infrastructure, the consumer call center infrastructure, and eligibility and enrollment services and other applicable State health subsidy programs, which we estimate to be approximately 80 percent. Based on this methodology, the proposed 2024 SBE–FP user fee rate is lower than the user fee rate of 2.25 percent of premiums that we established for the 2023 benefit year. The lower proposed user fee rate for SBE–FP issuers for the 2024 benefit year reflects our estimates of costs for operating the Federal Exchanges, premiums, enrollment, as well as State Exchange transitions for the 2024 benefit year, and the costs associated

[185] We used the most recent projections from the Congressional Budget Office (*https://www.cbo.gov/publication/57962*) and our own internal data.

with performing these services that benefit SBE–FP issuers.

We seek comment on the proposed 2024 SBE–FP user fee rate.

2. Publication of the 2024 Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage in Guidance (§ 156.130)

As established in part 2 of the 2022 Payment Notice, HHS will publish the premium adjustment percentage, the required contribution percentage, maximum annual limitations on cost-sharing, and reduced maximum annual limitation on cost-sharing, in guidance annually starting with the 2023 benefit year. We note that these parameters are not included in this rulemaking, as HHS does not propose to change the methodology for these parameters for the 2024 benefit year, and therefore, HHS is required to publish these parameters in guidance no later than January 2023.

3. Standardized Plan Options (§ 156.201)

HHS proposes to exercise its authority under sections 1311(c)(1) and 1321(a)(1)(B) of the ACA to make minor updates to its approach with respect to standardized plan options for PY 2024 and subsequent PYs. Section 1311(c)(1) of the ACA directs the Secretary to establish criteria for the certification of health plans as QHPs. Section 1321(a)(1)(B) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA with respect to, among other things, the offering of QHPs through such Exchanges.

Standardized plan options were first introduced in the 2017 Payment Notice, and defined at § 155.20. In the first iteration of standardized plan options, HHS finalized one set of standardized plan options designed to be similar to the most popular QHPs in the 2015 individual market FFEs at the bronze, silver, and gold metal levels. Issuers were not required to offer these standardized plan options. To facilitate plan shopping and to educate consumers about the distinctive cost-sharing features of standardized plan options, these plans were differentially displayed on *HealthCare.gov* under the authority at § 155.205(b)(1). Specifically, consumers had the ability to filter plan options to view only standardized plan options and received an accompanying message explaining how standardized plan options differed from non-standardized plan options.

In the 2018 Payment Notice, HHS finalized three new sets of standardized plan options. The original standardized plan options from the 2017 Payment Notice were updated to reflect changes in QHP enrollment data in 2016, to include SBE–FP data, and to account for State cost-sharing laws. Standardized plan options were once more differentially displayed, but this time, they were also labeled ''Simple Choice'' plans to make them more easily distinguishable from non-standardized plan options. HHS also established display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively (81 FR 94117 through 94118, 94148; 45 CFR 155.220(l) and 155.221(i)). Under these requirements, these entities must differentially display standardized plan options in accordance with the requirements under § 155.205(b)(1) in a manner consistent with how standardized plan options are displayed on *HealthCare.gov,* unless HHS approved a deviation.

Standardized plan options were then discontinued in the 2019 Payment Notice, but the discontinuance was challenged in the United States District Court for the District of Maryland. On March 4, 2021, the court decided City of Columbus, *et al.* v. Cochran.[186] The court reviewed nine separate policies HHS had promulgated in the 2019 Payment Notice, vacating four of them. The court specifically vacated the portion of the 2019 Payment Notice that ceased HHS' practice of designating some plans in the FFEs as ''standardized options,'' a policy that the 2019 Payment Notice stated was seeking to maximize innovation by issuers in designing and offering a wide range of plans to consumers (83 FR 16974 and 16975). Subsequently, HHS announced its intent to engage in rulemaking under which it would propose to resume standardized plan options in time for PY 2023.[187] Relatedly, President Biden's Executive Order on Promoting Competition in the American Economy directed HHS to implement standardized plan options in order to facilitate the plan selection process for consumers on the Exchanges.[188]

More recently, in the 2023 Payment Notice, HHS finalized the requirement for PY 2023 and beyond that issuers offering QHPs through FFEs and SBE–FPs must offer through the Exchange standardized QHP options designed by HHS at every product network type (as described in the definition of ''product'' at § 144.103), at every metal level, and throughout every service area that they offer non-standardized QHP options in the individual market. HHS did not require issuers in the small group market to offer these standardized plan options. Furthermore, HHS did not subject issuers in State Exchanges to these requirements. HHS also exempted issuers in FFEs and SBE–FPs that are already required to offer standardized plan options under State action taking place on or before January 1, 2020, such as issuers in the State of Oregon,[189] from the requirement to offer the standardized plan options finalized in the 2023 Payment Notice.

In the 2023 Payment Notice, HHS finalized two sets of standardized plan options for two different sets of States at the following metal levels: one bronze plan, one bronze plan that meets the requirement to have an AV up to 5 points above the 60 percent standard, as specified in § 156.140(c) (known as an expanded bronze plan), one standard silver plan, one version of each of the three income-based silver CSR plan variations, one gold plan, and one platinum plan. HHS did not finalize standardized plan option designs for the Indian CSR plan variations as provided for at § 156.420(b) given that the cost-sharing parameters for these plan variations are already largely specified, but HHS still required issuers to offer these plan variations for standardized plan options.[190]

In the 2023 Payment Notice, HHS also elaborated upon the methodology it utilized in creating the standardized plan options designs. Specifically, HHS explained that it designed these plans to be similar to the most popular QHPs in FFEs and SBE–FPs in PY 2021. This was done based on an examination of the proportion of consumers enrolled in plans with different cost sharing types (including copayment exempt from the deductible, copayment subject to the deductible, coinsurance exempt from

[186] 523 F. Supp. 3d 731 (D. Md. 2021).

[187] In part 3 of the 2022 Payment Notice, we explained that we would not be able to fully implement those aspects of the court's decision regarding standardized plan options in time for issuers to design plans and for Exchanges to be prepared to certify such plans as QHPs for PY 2022, and therefore, intended to address these issues in time for plan design and certification for PY 2023. See 86 FR 24140, 24264.

[188] Executive Order 14036 on Promoting Competition in the American Economy, July 9, 2021. See 86 FR 36987.

[189] See Or. Admin. R. 836–053–0009.

[190] See QHP Certification Standardized Plan Options FAQs, *https://www.qhpcertification.cms.gov/s/Standardized%20Plan%20Options%20FAQs.*

the deductible, and coinsurance subject to the deductible) for every benefit category in the actuarial value (AV) calculator at each metal level.

HHS chose the cost-sharing type with the majority or plurality of enrollees. HHS then chose the enrollee-weighted median values for this cost-sharing type as the copayment amount or coinsurance rate for each benefit category before modifying these plans to have an AV near the lower end of the de minimis range for each metal level to ensure the competitiveness of these plans. HHS applied this methodology in selecting the deductibles and MOOPs for these plans, as well.

HHS also explained that it designed two separate sets of standardized plan options in order to accommodate applicable cost-sharing laws in different sets of FFE and SBE–FP States, similar to the approach previously taken for standardized plan options. Specifically, in the 2018 Payment Notice, HHS designed three sets of standardized plan options tailored to unique cost-sharing laws in different States. The second and third sets of these standardized plan options differed from the first set only to the extent necessary to comply with State cost sharing laws.

The second set of standardized plan options in the 2018 Payment Notice was designed to work in States that: (1) require that cost sharing for physical therapy, occupational therapy, and speech therapy be no greater than the cost sharing for primary care visits; (2) limit the cost-sharing amount that can be charged for a 30-day supply of prescription drugs by tier; or (3) require that all drug tiers carry a copayment rather than coinsurance. The second set of standardized plan options applied to Arkansas, Delaware, Iowa, Kentucky, Louisiana, Missouri, Montana, and New Hampshire. The third set was designed to work in a State with maximum deductible requirements and other cost sharing standards. The third set of standardized plan options was designed to work in the Exchange in New Jersey, which has since transitioned to become a State Exchange and was thus outside the scope of this particular rulemaking.

HHS explained that it included several of the defining features of the second set of standardized plan options from the 2018 Payment Notice in the first set of standardized plan options in the 2023 Payment Notice. As a result, in the first set of standardized plan options, there was cost sharing parity between the primary care visit, the speech therapy, and the occupational and physical therapy benefit categories. There were also copayments for all prescription drug tiers, including the non-preferred brand and specialty tiers, instead of coinsurance rates. Finally, the copayment for the mental health/substance use disorder in-network outpatient office visit sub-classification was equal to the least restrictive level for copayments for medical/surgical benefits in the in-network, outpatient office visit sub-classification (and copayments applied to substantially all medical/surgical benefits in this sub-classification), to ensure issuers were able to design plans that comply with the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) and its implementing regulations.[191] This first set of standardized plan options applied to all FFE and SBE–FP issuers, excluding those in Delaware and Louisiana.

HHS further explained that it included all of the defining features of the second set of standardized plan options from the 2018 Payment Notice in the second set of standardized plan options in the 2023 Payment Notice. As a result, in this set of standardized plan options, similar to the first set of standardized plan options, there was cost-sharing parity between the primary care visit, the speech therapy, and the occupational and physical therapy benefit categories, and there were copayments for all prescription drug tiers, including the non-preferred brand and specialty tiers, instead of coinsurance rates. Additionally, the copayment for the mental health/substance use disorder in-network outpatient office visit sub-classification was equal to the least restrictive level for copayments for medical/surgical benefits in the in-network, outpatient office visit sub-classification (and copayments applied to substantially all medical/surgical benefits in this sub-classification), to ensure issuers were able to design plans that comply with MHPAEA and its implementing regulations.

The feature that distinguished the first set of standardized plan options from the second is that the second set of standardized plan options had copayments of $150 or less for the specialty drug tiers of standardized plan options at all metal levels. This feature was included in the second set of standardized plan options in order to accommodate relevant specialty tier prescription drug cost sharing laws in Delaware and Louisiana (87 FR 674 through 676; 87 FR 27311 through 27313).[192]

In the 2023 Payment Notice, HHS also exercised the authority under § 155.205(b)(1) to resume the differential display of standardized plan options, including those standardized plan options required under State action taking place on or before January 1, 2020, on *HealthCare.gov* beginning with the PY 2023 open enrollment period. Similarly, also beginning with the PY 2023 open enrollment period, HHS resumed enforcement of the existing standardized plan options display requirements under §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv) for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including those using the Classic DE and EDE Pathways—meaning these entities were required to differentially display standardized plan options in a manner consistent with how standardized plan options were displayed on *HealthCare.gov,* unless HHS approved a deviation, beginning with the PY 2023 open enrollment period.

Most recently, after publishing the 2023 Payment Notice, HHS conducted extensive interested party engagement with a range of participants, including issuers, agents, brokers, web-brokers, States, State Exchanges, researchers, disease advocacy groups, and consumer support groups (87 FR 27318). HHS discussed a range of topics related to standardized plan options in these engagement sessions, including plan designs, cost sharing, pre-deductible coverage of particular benefits, formulary tiering, enhancing choice architecture, plan display on *HealthCare.gov,* reducing the risk of plan choice overload (either through direct limits on the number of non-standardized plan options or a revised version of the meaningful difference standard), and advancing health equity.

For PY 2024 and subsequent PYs, we would maintain a large degree of continuity with our approach to standardized plan options in the 2023 Payment Notice, except for minor updates as proposed in this section. First, in contrast to the policy finalized in the 2023 Payment Notice, we propose, for PY 2024 and subsequent PYs, to no longer include a standardized

[191] In general, MHPAEA requires that the financial requirements (such as coinsurance and copays) and treatment limitations (such as visit limits) imposed on mental health or substance use disorder benefits cannot be more restrictive than the predominant financial requirements and treatment limitations that apply to substantially all medical/surgical benefits in a classification.

[192] See 87 FR 674 through 676 and 87 FR 27311 through 27313 for a more detailed discussion on the methodology HHS used to create the standardized plan options in the 2023 Payment Notice.

plan option for the non-expanded bronze metal level. Accordingly, we propose at new § 156.201(b) that for PY 2024 and subsequent PYs, FFE and SBE–FP issuers offering QHPs through the Exchanges must offer standardized QHP options designed by HHS at every product network type (as described in the definition of ''product'' at § 144.103), at every metal level except the non-expanded bronze level, and throughout every service area that they offer non-standardized QHP options. We propose to re-designate the current regulation text at § 156.201 as paragraph (a) and revise it to apply only to PY 2023.

Thus, for PY 2024 and subsequent PYs, we propose standardized plan options for the following metal levels: one bronze plan that meets the requirement to have an AV up to 5 points above the 60 percent standard, as specified in § 156.140(c) (known as an expanded bronze plan), one standard silver plan, one version of each of the three income-based silver CSR plan variations, one gold plan, and one platinum plan. Consistent with our approach in the 2023 Payment Notice, we are not proposing standardized plan options for the Indian CSR plan variations as provided for at § 156.420(b) given that the cost-sharing parameters for these plan variations are already largely specified. We would continue to require issuers to offer these plan variations for all standardized plan options offered, and we propose to remove the regulation text language stating that standardized plan options for these plan variations are not required to clarify that while issuers must, under § 156.420(b), continue to offer such plan variations based on standardized plan options, those plan variations will themselves not be standardized plan options based on designs we will specify in this rulemaking.[193]

We propose to discontinue standardized plan options for the non-expanded bronze metal level mainly due to AV constraints. Specifically, it is not feasible to design a non-expanded bronze plan that includes any pre-deductible coverage while maintaining an AV within the permissible AV de minimis range for the non-expanded bronze metal level. Furthermore, few issuers chose to offer non-expanded bronze standardized plan options in PY 2023, with the majority of issuers offering bronze plans instead choosing to offer only expanded bronze standardized plan options. Thus, we believe discontinuing non-expanded bronze standardized plan options would minimize burden without any deleterious consequences. We also clarify that issuers would still be permitted to offer non-standardized plan options at the non-expanded bronze metal level, meaning consumers would still have the ability to choose these plan options if they so choose. We also clarify that if an issuer offers a non-standardized plan option at the bronze metal level, whether expanded or non-expanded, it would need to also offer an expanded bronze standardized plan option.

Similar to the approach taken in the 2023 Payment Notice, we propose to create standardized plan options that resemble the most popular QHP offerings that millions are already enrolled in by selecting the most popular cost-sharing type for each benefit category; selecting enrollee-weighted median values for each of these benefit categories based on refreshed PY 2022 cost-sharing and enrollment data; modifying these plans to be able accommodate State cost-sharing laws; and decreasing the AVs for these plan designs to be at the floor of each AV de minimis range primarily by increasing deductibles.

Furthermore, consistent with the approach taken in the 2023 Payment Notice, we propose to create two sets of standardized plan options at the previously proposed metal levels, with the same sets of designs applying to the same sets of States as in the 2023 Payment Notice. Specifically, the first set of standardized plan options would continue to apply to FFE and SBE–FP issuers in all FFE and SBE–FP States, excluding those in Delaware, Louisiana, and Oregon, and the second set of standardized plan options would continue to apply to Exchange issuers specifically in Delaware and Louisiana. See Table 10 and Table 11 for the two sets of standardized plan options we propose for PY 2024.

In addition, since SBE–FPs use the same platform as the FFEs, we would continue to apply the standardized plan option requirements equally on FFEs and SBE–FPs. We continue to believe that proposing a distinction between FFEs and SBE–FPs for purposes of these requirements would create a substantial financial and operational burden that we believe outweighs the benefit of permitting such a distinction.

Also, consistent with our policy in PY 2023, we would continue to apply these requirements to applicable issuers in the individual market but not in the small group market. We also would continue to exempt issuers offering QHPs through FFEs and SBE–FPs that are already required to offer standardized plan options under State action taking place on or before January 1, 2020, such as issuers in the State of Oregon,[194] from the requirement to offer the standardized plan options included in this rule. In addition, we would continue to exempt issuers in State Exchanges from these requirements for several reasons. First, we do not wish to impose duplicative standardized plan option requirements on issuers in the eight State Exchanges that already have standardized plan option requirements. Additionally, we continue to believe that State Exchanges are best positioned to understand both the nuances of their respective markets and consumer needs within those markets. Finally, we continue to believe that States that have invested the necessary time and resources to become State Exchanges have done so in order to implement innovative policies that differ from those on the FFEs, and we do not wish to impede these innovative policies so long as they comply with existing legal requirements.

Furthermore, consistent with the policy finalized in the 2023 Payment Notice, we would continue to differentially display standardized plan options, including those standardized plan options required under State action taking place on or before January 1, 2020, on *HealthCare.gov* under the authority at § 155.205(b)(1). We would also continue enforcement of the standardized plan options display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively. This means that these entities would be required to differentially display the 2024 benefit year standardized plan options in accordance with the requirements under § 155.205(b)(1) in a manner consistent with how standardized plan options are displayed on *HealthCare.gov,* unless HHS approves a deviation, beginning with the 2024 benefit year open enrollment period. Consistent with our PY 2023 policy, any requests from web-brokers and QHP issuers seeking approval for an alternate differentiation format would continue to be reviewed based on whether the same or similar level of differentiation and clarity is being

[193] See QHP Certification Standardized Plan Options FAQs, *https://www.qhpcertification.cms.gov/s/Standardized%20Plan%20Options%20FAQs.*

[194] See Or. Admin. R. 836–053–0009.

provided under the requested deviation as is provided on *HealthCare.gov.*

Consistent with the approach to plan designs in the 2023 Payment Notice, we would also continue to use the following four tiers of prescription drug cost sharing in the proposed standardized plan options: generic drugs, preferred brand drugs, non-preferred brand drugs, and specialty drugs. We believe the use of four tiers of prescription drug cost-sharing in the standardized plan options will continue to allow for predictable and understandable drug coverage. We believe the use of four tiers of prescription drug cost-sharing will also play an important role in facilitating the consumer decision-making process by allowing consumers to more easily compare formularies between plans, and allow for easier year-to-year comparisons with their current plan. The continued use of four tiers will also minimize issuer burden since, for PY 2023, issuers have already created standardized plan options with formularies that include only four tiers of prescription drug cost-sharing. We will consider including additional drug tiers for future years, and invite comment on the appropriate number of drug tiers to use in standardized plan options in the future. However, we would continue to use four tiers of prescription drug cost-sharing in standardized plan options for PY 2024 and subsequent PYs to maintain continuity with our approach to standardized plan options in PY 2023.

We are aware of concerns that issuers may not be including specific drugs at appropriate cost-sharing tiers for the standardized plan options; for example, some issuers may be including brand name drugs in the generic drug cost-sharing tier, while others include generic drugs in the preferred or non-preferred brand drug cost-sharing tiers. We believe that consumers understand the difference between generic and brand name drugs, and that it is reasonable to assume that consumers expect that only generic drugs are covered at the cost-sharing amount in the generic drug cost-sharing tier, and that only brand name drugs are covered at the cost-sharing amount in the preferred or non-preferred brand drug cost-sharing tiers.

Accordingly, we propose to revise § 156.201 to add a new paragraph (c) specifying that issuers of standardized plan options must (1) place all covered generic drugs in the standardized plan options' generic drug cost-sharing tier, or the specialty drug tier if there is an appropriate and non-discriminatory basis in accordance with § 156.125 for doing so, and (2) place brand name drugs in either the standardized plan options' preferred brand or non-preferred brand tiers, or specialty drug tier if there is an appropriate and non-discriminatory basis in accordance with § 156.125 for doing so. For purposes of this proposal, ''non-discriminatory basis'' means there must be a clinical basis for placing a particular prescription drug in the specialty drug tier in accordance with § 156.125.

We also specify that within the Prescription Drug Template, for standardized plan options, issuers should enter zero cost preventive drugs for tier one, generic drugs for tier two, preferred brand drugs for tier three, non-preferred drugs for tier four, specialty drugs for tier five, and medical services drugs for tier six, if applicable.

We propose the approach described in this section for PY 2024 and subsequent PYs for several reasons. To begin, we are continuing to require FFE and SBE–FP issuers to offer standardized plan options in large part due to continued plan proliferation, which has only increased since the standardized plan option requirements were finalized in the 2023 Payment Notice. With this continued plan proliferation, it is increasingly important to continue to attempt to streamline and simplify the plan selection process for consumers on the Exchanges. We believe these standardized plan options can continue to play a meaningful role in that simplification by reducing the number of variables that consumers have to consider when selecting a plan option, thus allowing consumers to more easily compare available plan options. More specifically, with these standardized plan options, consumers will continue to be able to take other meaningful factors into account, such as networks, formularies, and premiums, when selecting a plan option. We further believe these standardized plan options include several distinctive features, such as enhanced pre-deductible coverage for several benefit categories, that will continue to play an important role in reducing barriers to access, combatting discriminatory benefit designs, and advancing health equity. Including enhanced pre-deductible coverage for these benefit categories will ensure consumers are more easily able to access these services without first meeting their deductibles. Furthermore, including copayments instead of coinsurance rates for a greater number of benefit categories will enhance consumer certainty and reduce the risk of unexpected financial harm sometimes associated with high coinsurance rates.

Additionally, given that insufficient time has passed to assess all the impacts of the standardized plan option requirements finalized in the 2023 Payment Notice, we propose to maintain a high degree of continuity with respect to many of the standardized plan option policies previously finalized to reduce the risk of disruption for all involved interested parties, including issuers, agents, brokers, States, and enrollees. We believe making major departures from the methodology used to create the standardized plan options as finalized in the 2023 Payment Notice could result in drastic changes in these plan designs that could potentially create undue burden for these interested parties. Furthermore, if the standardized plan options that HHS creates vary significantly from year to year, those enrolled in these plans could experience unexpected financial harm if the cost-sharing for services they rely upon differs substantially from the previous year. Ultimately, we believe consistency in standardized plan options is important to allow both issuers and enrollees to become accustomed to these plan designs.

We seek comment on our proposed approach to standardized plan options for PY 2024 and subsequent PYs. We also seek comment on the specific approach to tiering for these standardized plan options within the Prescription Drug Template.

TABLE 10: 2024 Proposed Standardized Plan Options Set One (For All FFE and SBE-FP Issuers, Excluding Issuers in Delaware, Louisiana, and Oregon)

	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Actuarial Value	64.39%	70.00%	73.00%	87.03%	94.06%	78.02%	88.10%
Deductible	$7,500	$6,000	$5,700	$700	$0	$1,500	$0
Annual Limitation on Cost Sharing	$9,400	$9,100	$7,200	$3,000	$1,800	$8,700	$3,200
Emergency Room Services	50%	40%	40%	30%	25%*	25%	$100*
Inpatient Hospital Services (Including Mental Health & Substance Use Disorder)	50%	40%	40%	30%	25%*	25%	$350*
Primary Care Visit	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Urgent Care	$75*	$60*	$60*	$30*	$5*	$45*	$15*
Specialist Visit	$100*	$80*	$80*	$40*	$10*	$60*	$20*
Mental Health & Substance Use Disorder **Outpatient** ***Office Visit***	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Imaging (CT/PET Scans, MRIs)	50%	40%	40%	30%	25%*	25%	$100*
Speech Therapy	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Occupational, Physical Therapy	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Laboratory Services	50%	40%	40%	30%	25%*	25%	$30*
X-rays/Diagnostic Imaging	50%	40%	40%	30%	25%*	25%	$30*
Skilled Nursing Facility	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Facility Fee (Ambulatory Surgery Center)	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Surgery Physician & Services	50%	40%	40%	30%	25%*	25%	$150*
Generic Drugs	$25*	$20*	$20*	$10*	$0*	$15*	$5*
Preferred Brand Drugs	$50	$40*	$40*	$20*	$15*	$30*	$10*
Non-Preferred Brand Drugs	$100	$80	$80	$60	$50*	$60*	$50*
Specialty Drugs	$500	$350	$350	$250	$150*	$250*	$150*

*Benefit category not subject to the deductible.

TABLE 11: 2024 Proposed Standardized Plan Options Set Two (For Exchange Issuers in Delaware and Louisiana)

	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Actuarial Value	64.39%	70.00%	73.00%	87.04%	94.08%	78.04%	88.11%
Deductible	$7,500	$6,000	$5,700	$700	$0	$1,500	$0
Annual Limitation on Cost Sharing	$9,400	$9,100	$7,200	$3,000	$1,900	$8,700	$3,200
Emergency Room Services	50%	40%	40%	30%	25%*	25%	$100*
Inpatient Hospital Services (Including Mental Health & Substance Use Disorder)	50%	40%	40%	30%	25%*	25%	$350*
Primary Care Visit	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Urgent Care	$75*	$60*	$60*	$30*	$5*	$45*	$15*
Specialist Visit	$100*	$80*	$80*	$40*	$10*	$60*	$20*
Mental Health & Substance Use Disorder **Outpatient** ***Office Visit***	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Imaging (CT/PET Scans, MRIs)	50%	40%	40%	30%	25%*	25%	$100*
Speech Therapy	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Occupational, Physical Therapy	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Laboratory Services	50%	40%	40%	30%	25%*	25%	$30*
X-rays/Diagnostic Imaging	50%	40%	40%	30%	25%*	25%	$30*
Skilled Nursing Facility	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Facility Fee (Ambulatory Surgery Center)	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Surgery Physician & Services	50%	40%	40%	30%	25%*	25%	$150*
Generic Drugs	$25*	$20*	$20*	$10*	$0*	$15*	$5*
Preferred Brand Drugs	$50	$40*	$40*	$20*	$5*	$30*	$10*
Non-Preferred Brand Drugs	$100	$80	$80	$60	$10*	$60*	$50*
Specialty Drugs	$150	$125	$125	$100	$20*	$100*	$75*

*Benefit category not subject to the deductible.

4. Non-Standardized Plan Option Limits (§ 156.202)

At § 156.202, HHS proposes to exercise the authority under sections 1311(c)(1) and 1321(a)(1)(B) of the ACA to limit the number of non-standardized plan options that issuers of QHPs can offer through Exchanges on the Federal platform (including State-based Exchanges on the Federal Platform) to two non-standardized plan options per product network type (as described in the definition of ''product'' at § 144.103) and metal level (excluding catastrophic plans), in any service area, for PY 2024 and beyond, as a condition of QHP certification. Section 1311(c)(1) of the ACA directs the Secretary to establish criteria for the certification of health plans as QHPs. Section 1321(a)(1)(B) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA with respect to, among other things, the offering of QHPs through such Exchanges.

Under this proposed requirement, an issuer would, for example, be limited to offering through an Exchange two gold HMO and two gold PPO non-standardized plan options in any service area in PY 2024 or any subsequent PY. As an additional clarifying example, if an issuer wanted to offer two Statewide bronze HMO non-standardized plan options as well as two additional bronze HMO non-standardized plan options in one particular service area that covers less than the entire State, in the service areas that all four plans would cover, the issuer could choose to offer through the Exchange either the two bronze HMO non-standardized plan options offered Statewide or the two bronze HMO non-standardized plan options offered in that particular service area (or any combination thereof, so long as the total number of non-standardized plan options does not exceed the limit of two per issuer, product network type, and metal level in the service area).

Similar to the approach taken with respect to standardized plan options in the 2023 Payment Notice and in this proposed rule, HHS proposes to not apply this requirement to issuers in State Exchanges for several reasons. First, HHS does not wish to impose duplicative requirements on issuers in the State Exchanges that already limit the number of non-standardized plan options. Additionally, HHS believes that State Exchanges are best positioned to understand both the nuances of their respective markets and consumer needs within those markets. Finally, HHS

believes that States that have invested the necessary time and resources to become State Exchanges have done so in order to implement innovative policies that differ from those on the FFEs, and HHS does not wish to impede these innovative policies, so long as they comply with existing legal requirements.

However, consistent with the approach taken with respect to standardized plan options in the 2023 Payment Notice and in this this proposed rule, since SBE–FPs use the same platform as the FFEs, HHS proposes to apply this requirement equally on FFEs and SBE–FPs. HHS believes that proposing a distinction between FFEs and SBE–FPs for purposes of this requirement would create a substantial financial and operational burden that HHS believes outweighs the benefit of permitting such a distinction.

Finally, also in alignment with the approach taken with standardized plan options in the 2023 Payment Notice as well as the approach taken in this proposed rule, HHS proposes that this proposed requirement would not apply to plans offered through the SHOPs or to SADPs, given that the nature of these markets differ substantially from the individual medical QHP market, in terms of issuer participation, plan offerings, plan enrollment, and services covered. For example, the degree of plan proliferation observed in individual market medical QHPs over the last several plan years is not evident to the same degree for QHPs offered through the SHOPs or for SADPs offered in the individual market. For these reasons, HHS does not believe the same requirements should be applied to these other markets.

HHS believes that given the large number of plan offerings that would continue to exist on the Exchanges, a sufficiently diverse range of plan offerings would still exist for consumers to continue to select innovative plans that meet their unique health needs, even if HHS did ultimately choose to limit the number of non-standardized plan options that issuers can offer. Thus, even if consumers believe that their health needs may not be best met with the standardized plan options included in this current rulemaking, they would still have the option to select from a sufficient number of other non-standardized plan options.

Under this proposed limit, we estimate that the weighted average number of non-standardized plan options (which does not take into consideration standardized plan options) available to each consumer would be reduced from approximately 107.8 in PY 2022 to 37.2 in PY 2024, which we believe still provides consumers with a sufficient number of plan offerings.[195] Additionally, we estimate that of a total of 106,037 non-standardized plan option plan-county combinations offered in PY 2022, approximately 60,949 (57.5 percent) of these plan-county combinations would no longer be permitted to be offered, a number we believe would still provide consumers with a sufficient degree of choice during the plan selection process.[196]

Finally, if this limit were adopted, we estimate that of the approximately 10.21 million enrollees in the FFEs and SBE–FPs in PY 2022, approximately 2.72 million (26.6 percent) of these enrollees would have their current plan offerings affected, and issuers would therefore be required to select another QHP to crosswalk these enrollees into for PY 2024.[197] CMS would utilize the existing discontinuation notices and process as well as the current re-enrollment hierarchy at § 155.335(j) to ensure a seamless transition and continuity of coverage for affected enrollees. In addition, CMS would ensure that the necessary consumer assistance would be made available to affected enrollees as part of the expanded funding for Navigator programs.

In the 2023 Payment Notice, HHS solicited comment on enhancing choice architecture and on preventing plan choice overload for consumers on *HealthCare.gov* (87 FR 689 through 691 and 87 FR 27345 through 27347). In this comment solicitation, HHS noted that although it continues to prioritize competition and choice on the Exchanges, it was concerned about plan choice overload, which can result when consumers have too many choices in plan options on an Exchange. HHS referred to a 2016 report by the RAND Corporation reviewing over 100 studies which concluded that having too many health plan choices can lead to poor enrollment decisions due to the difficulty consumers face in processing complex health insurance information.[198] HHS also referred to a study of consumer behavior in Medicare Part D, Medicare Advantage, and Medigap that demonstrated that a choice of 15 or fewer plans was associated with higher enrollment rates, while a choice of 30 or more plans led to a decline in enrollment rates.[199]

With this concern in mind, HHS explained in the 2023 Payment Notice that it was interested in exploring possible methods of improving choice architecture and preventing plan choice overload. HHS expressed interest in exploring the feasibility and utility of limiting the number of non-standardized plan options that FFE and SBE–FP issuers can offer through the Exchanges in future plan years as one option to reduce the risk of plan choice overload and to further streamline and optimize the plan selection process for consumers on the Exchanges. Accordingly, HHS sought comment on the impact of limiting the number of non-standardized plan options that issuers can offer through the Exchanges, on effective methods to achieve this goal, the advantages and disadvantages of these methods, and if there were alternative methods not considered.

In response to this comment solicitation, many commenters agreed that the number of plan options that consumers can choose from on the Exchanges has increased beyond a point that is productive for consumers. Many of these commenters further explained that consumers do not have the time, resources, our health literacy to be able to meaningfully compare all available plan options. These commenters also agreed that when consumers are faced with an overwhelming number of plan options, many of which are similar with only minor differences between them, the risk of plan choice overload is significantly exacerbated.

Similarly, during the standardized plan option interested party engagement

[195] Utilizing weighted as opposed to unweighted averages takes into consideration the number of enrollees in a particular service area when calculating the average number of plans available to enrollees. As a result of weighting by enrollment, service areas with a higher number of enrollees have a greater impact on the overall average than service areas with a lower number of enrollees. Weighting averages allows a more representative metric to be calculated that more closely resembles the actual experience of enrollees.

[196] Plan-county combinations are the count of unique plan ID and FIPS code combinations. This measure is used because a single plan may be available in multiple counties, and specific limits on non-standardized plan options may have different impacts on one county where there are four plans of the same product network type and metal level versus another county where there are only two plans of the same product network type and service area, for example.

[197] These calculations assume that the non-standardized plan options removed due to the proposed limit would be those with the fewest enrollees based on PY 2022 data, which includes individual market medical QHPs for Exchanges using the *HealthCare.gov* eligibility and enrollment platform, including SBE–FPs.

[198] Taylor EA, Carman KG, Lopez A, Muchow AN, Roshan P, and Eibner C. Consumer Decisionmaking in the Health Care Marketplace. RAND Corporation. 2016.

[199] Chao Zhou and Yuting Zhang, ''The Vast Majority of Medicare Part D Beneficiaries Still Don't Choose the Cheapest Plans That Meet Their Medication Needs.'' Health Affairs, 31, no.10 (2012): 2259–2265.

sessions HHS conducted after publishing the 2023 Payment Notice, many participants agreed that the number of plan options was far too high and supported taking additional action to prevent plan choice overload. In short, many 2023 Payment Notice commenters and interested party engagement participants supported limiting the number of non-standardized plan options that issuers can offer to streamline the plan selection process for consumers on the Exchanges.

In addition, current QHP submission data provide support for the argument that enacting such a limit would be beneficial for consumers. For example, it is estimated that there will be a weighted average of 113.6 plans available per enrollee on *HealthCare.gov* in PY 2023 compared to a weighted average of 107.8 plans available per enrollee in PY 2022 and a weighted average of 25.9 plans available per enrollee in PY 2019.[200] Similarly, it is expected that there will be a weighted average of 18.3 plan offerings per issuer in PY 2023 compared to 17.1 plan offerings per issuer in PY 2022 and 9.7 plan offerings per issuer in PY 2019.[201] With this continued plan proliferation for both enrollees and issuers, HHS believes that limiting the number of non-standardized plan options that FFE and SBE–FP issuers of QHPs can offer through the Exchanges beginning in PY 2024 could greatly enhance the consumer experience on *HealthCare.gov.*

To reduce the risk of plan choice overload, HHS also considered solely focusing on enhancing choice architecture on *HealthCare.gov,* instead of enhancing choice architecture in conjunction with limiting the number of non-standardized plan options that issuers can offer, an approach recommended by several commenters in the 2023 Payment Notice. HHS agrees that enhancements to the consumer experience on *HealthCare.gov* are critical in ensuring that consumers are able to more meaningfully compare plan choices and more easily select a health plan that meets their unique health needs. As such, HHS made several enhancements to *HealthCare.gov* for the open enrollment period for PY 2023. HHS also intends to continue conducting research to inform further enhancements to the consumer experience on *HealthCare.gov* for PY 2024 and subsequent plan years.

That said, HHS believes that enhancing choice architecture on *HealthCare.gov* is necessary but, alone, insufficient to reduce the risk of plan choice overload for several reasons. First, *HealthCare.gov* is not the only pathway for consumers to search for, compare, select, and enroll in a QHP, and it is not the only information resource consumers seek when considering Exchange coverage. Instead, consumers shop through a multitude of channels, sometimes utilizing a mix of customer service channels including the Marketplace Call Center; online on *HealthCare.gov;* through assisters, agents, and brokers; and through certified enrollment partners (such as Classic DE and EDE web brokers and issuers). Thus, HHS believes that consumers enrolling in QHPs through these alternative pathways would not benefit to the same degree as those enrolling through *HealthCare.gov* if HHS focused on reducing plan choice overload solely by making enhancements to *HealthCare.gov.* Moreover, considering that an increasingly greater portion of QHP enrollment is occurring through these alternative enrollment pathways, HHS believes that a more comprehensive approach to reducing plan choice overload that would also benefit those utilizing these alternative enrollment pathways is required.

Furthermore, while enhancements to choice architecture and the plan comparison experience can play a critical role in streamlining the plan selection process and reducing the risk of plan choice overload, the number of plans available per enrollee has increased beyond a number that is beneficial for consumers, and this high number of plan choices makes it increasingly difficult to meaningfully manage choice architecture on *HealthCare.gov* and through other Exchange customer service channels.

Relatedly, HHS believes that low-income consumers would particularly benefit from a policy that limits the number of plans. This is because silver plans deliver the most value to low-income consumers, but it is exactly these consumers—who often have the lowest health insurance literacy—who now face choosing among the highest number of near-duplicate silver plans, which will continue unless limits on the number of these plans are set. Near-duplicate plans are the most difficult to filter and sort out by interface improvements.

As such, HHS believes that having an excessive number of plans (particularly those at the silver metal level) places an inequitable burden on those who need insurance the most, those who face the greatest challenges in selecting the most suitable health plan, and those who can least withstand the consequences of choosing a plan that costs too much and delivers too little. For this reason, HHS believes that reducing the number of available plans (particularly silver plans) by limiting the number of non-standardized plan options that issuers can offer, can play an important role in advancing the agency's commitments to health equity.

In short, HHS believes that limiting the number of non-standardized plan options that issuers can offer in conjunction with enhancing the plan comparison experience on *HealthCare.gov* is the most effective method to streamline the plan selection process and to reduce the risk of plan choice overload for consumers on the *HealthCare.gov* Exchanges.

As an alternative to limiting the number of non-standardized plan options that issuers in FFEs and SBE–FPs can offer through the Exchanges to reduce the risk of plan choice overload, HHS could also apply a meaningful difference standard. Such a standard was previously codified at § 156.298.

The original meaningful difference standard was introduced in the 2015 Payment Notice, revised in the 2017 Payment Notice, and discontinued and removed from regulation in the 2019 Payment Notice. The meaningful difference standard was originally intended to enhance the consumer experience on the Exchanges by preventing duplicative plan offerings. The decision to discontinue the meaningful difference standard in the 2019 Payment Notice was made largely due to the decreased number of plan offerings on the Exchanges (that is, there was a weighted average of 25.9 plans available per enrollee in PY 2019), as well as the low number of plans flagged under the prior review.

Under the original meaningful difference standard introduced in the 2015 Payment Notice, a plan was considered to be ''meaningfully different'' from another plan in the same service area and metal tier (including catastrophic plans) if a reasonable consumer would be able to identify one or more material differences among the following characteristics between the plan and other plan offerings: (1) cost sharing; (2) provider networks; (3) covered benefits; (4) plan type; (5) Health Savings Account eligibility; or (6) self-only, non-self-only, or child only plan offerings (79 FR 13813, 13840). Additionally, CMS believed that a

[200] Weighted averages were calculated by accounting for the number of enrollees in particular service areas, with service areas with a higher number of enrollees having a more significant impact on the overall average than service areas with a lower number of enrollees.

[201] Ibid.

reasonable consumer would be likely to identify a difference in MOOP of $100 or more or a difference in deductible of $50 for purposes of the meaningful difference standard.[202] The 2017 Payment Notice eliminated the Health Savings Account eligibility element, and revised the self-only, non-self-only, or child-only plan offerings element (87 FR 27208, 27345). In the 2017 Letter to Issuers, the MOOP and deductible dollar difference thresholds were increased to $500 and $250, respectively.[203]

In the 2023 Payment Notice comment solicitation on enhancing choice architecture and preventing plan choice overload (87 FR 27208, 27345), in addition to soliciting comment on limiting the number of non-standardized plan options that issuers can offer, HHS also solicited comment on resuming the meaningful difference standard as one potential method it could use to reduce the risk of plan choice overload. In response to this comment solicitation, many commenters and standardized plan option interested party engagement participants supported resuming the meaningful difference standard, with the caveat that the standard should be strengthened since the original version of the standard from the 2015 Payment Notice as well as the updated version of the standard from the 2017 Payment Notice both failed to meaningfully reduce duplicative plan offerings.

These commenters and workgroup participants further explained that earlier versions of the meaningful difference standard relied on several criteria and difference thresholds (that is, only having one difference among the following attributes: cost sharing, provider networks, covered benefits, plan type, Health Savings Account eligibility, or self-only, non-self-only, or child only plan offerings) which allowed issuers to more easily meet the standard. Several of these commenters and workgroup participants noted that no State Exchange currently utilizes the meaningful difference standard to reduce the risk of plan choice overload.

As such, HHS proposes, as an alternative to our proposal to limit the number of non-standardized plan options that an FFE or SBE–FP issuer may offer on the Exchange, to impose a new meaningful difference standard, which would be more stringent than the previous standard, for PY 2024 and subsequent PYs. Specifically, instead of including all of the criteria from the original standard from the 2015 Payment Notice (that is, cost sharing, provider networks, covered benefits, plan type, Health Savings Account eligibility, or self-only, non-self-only, or child only plan offerings), HHS proposes grouping plans by issuer ID, county, metal level, product network type, and deductible integration type, and then evaluating whether plans within each group are ''meaningfully different'' based on differences in deductible amounts.

With this proposed approach, two plans would need to have deductibles that differ by more than $1,000 to satisfy the new proposed meaningful difference standard. We believe that adopting this approach for a new meaningful difference standard would more effectively reduce the risk of plan choice overload and streamline the plan selection process for consumers on the Exchanges. With a dollar deductible difference threshold of $1,000, we estimate that the weighted average number of non-standardized plan options (which does not take into consideration standardized plan options) available to each consumer would be reduced from approximately 107.8 in PY 2022 to 53.2 in PY 2024, which we believe still provides consumers with a sufficient number of plan offerings. In addition, we estimate that of a total of 106,037 non-standardized plan option plan-county combinations offered in PY 2022, approximately 49,629 (46.8 percent) of these plan-county combinations would no longer be permitted to be offered, a number we believe would still provide consumers with a sufficient degree of choice during the plan selection process.[204] If this dollar deductible difference threshold were adopted, we estimate that of the approximately 10.21 million enrollees in the FFEs and SBE–FPs in PY 2022, approximately 2.64 million (25.9 percent) of these enrollees would have their current plan offerings affected.[205]

We seek comment on the feasibility and utility of limiting the number of non-standardized plan options that FFE and SBE–FP issuers can offer through the Exchanges beginning in PY 2024. We also seek comment on whether the limit of two non-standardized plan options per issuer, product network type, and metal level in any service area is the most appropriate approach, or if a stricter or more relaxed limit should be adopted instead. In addition, we seek comment on the advantages and disadvantages of utilizing a phased approached of limiting the number of non-standardized plan options (for example, if there were a limit of three non-standardized plan options per issuer, product network type, metal level, and service area for PY 2024, two for PY 2025, and one for PY 2026). We also seek comment on the effect that adopting such a limit would have on particular product network types, and whether this limit would cause a proliferation of product network types that are not actually differentiated for consumers.

Furthermore, we seek comment on whether we should consider additional factors, such as variations of products or networks, when limiting the number of non-standardized plan options—which would mean that issuers would be limited to offering two non-standardized plan options per product network type, metal level, product, and network variation (for example, by network ID) in any service area (or some combination thereof). If we were to adopt such an approach, issuers would be permitted to offer two non-standardized gold HMOs within one product as well as an additional two non-standardized gold HMOs within a second product in a particular service area, for example. This would also mean that issuers would be permitted to offer two non-standardized gold HMOs with one particular network ID as well as two additional non-standardized gold HMOs with a different network ID in a particular service area, for example.

We also seek comment on whether permitting additional variation only for specific benefits, such as adult dental and adult vision benefits, instead of permitting any variation in a product (for example, by product ID) would be more appropriate—which would mean,

[202] 2015 Letter to Issuers in the Federally-facilitated Marketplaces, chapter 3, section 3. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf*.

[203] 2017 Letter to Issuers in the Federally-facilitated Marketplaces, chapter 2, section 12. Available at *https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/final-2017-letter-to-issuers-2-29-16.pdf*.

[204] Plan-county combinations are the count of unique plan ID and FIPS code combinations. This measure is used because a single plan may be available in multiple counties, and specific limits on non-standardized plan options or specific dollar deductible difference thresholds may have different impacts on one county where there are four plans of the same product network type and metal level versus another county where there are only two plans of the same product network type and metal level, for example.

[205] These calculations assume that the non-standardized plan options removed due to the proposed limit would be those with the fewest enrollees based on PY 2022 data, which includes individual market medical QHPs for Exchanges using the *HealthCare.gov* eligibility and enrollment platform, including SBE–FPs.

for example, that issuers could offer two gold HMO non-standardized plan options without adult vision and dental benefits and two gold HMO non-standardized plan options with adult vision and dental benefits in the same service area.

In addition, we seek comment on imposing a new meaningful difference standard in place of limiting the number of non-standardized plan options that issuers can offer. We also seek comment on additional or alternative specific criteria that would be appropriate to include in the meaningful difference standard to determine whether plans are ''meaningfully different'' from one another, including whether the same criteria and difference thresholds from the original standard from the 2015 Payment Notice or the updated difference thresholds from the 2017 Payment Notice should be instituted, or some combination thereof. Finally, we seek comment on the specific deductible dollar difference thresholds that would be appropriate to determine whether plans are considered to be ''meaningfully different'' from other plans in the same grouping, and whether a deductible threshold of $1,000 would be most appropriate and effective, or if a stricter or more relaxed threshold should be adopted instead.

5. QHP Rate and Benefit Information (§ 156.210)

a. Age on Effective Date for SADPs

We propose at new § 156.210(d)(1) to require issuers of stand-alone dental plans (SADPs), as a condition of Exchange certification, to use an enrollee's age at the time of policy issuance or renewal (referred to as age on effective date) as the sole method to calculate an enrollee's age for rating and eligibility purposes, beginning with Exchange certification for PY 2024. We propose that this requirement apply to Exchange-certified SADPs, whether sold on- or off-Exchange.

Since PY 2014, the process the FFEs use in QHP certification allows SADP issuers seeking certification of their SADPs to enter multiple options to explain how age is determined for rating and eligibility purposes. Because the Federal eligibility and enrollment platform operationalizes the rating and eligibility standards when an applicant seeks SADP coverage through an SBE–FP, issuers in SBE–FPs have also been required to comply with this part of the process. While market rules at § 147.102(a)(1)(iii) require medical QHP issuers to enter age on effective date as the method to calculate an enrollee's age for rating and eligibility purposes, SADP issuers have been able to enter any of the following four options in the Business Rules Template: (1) Age on effective date; (2) Age on January 1st of the effective date year; (3) Age on insurance date (age on birthday nearest the effective date); or (4) Age on January 1st or July 1st.[206]

Despite the availability of these other options for SADPs, age on effective date is the most commonly used age rating methodology; the vast majority of individual market SADP issuers have used the age on effective date method since PY 2014. Not only is it the most commonly used method, but it is also the most straightforward methodology for consumers to understand. For example, under the age on effective date method, if an enrollee is age 30 at the time of a plan's effective date, the enrollee is rated at age 30 for the rest of the plan year. The less commonly used options are likely more confusing for consumers, who may experience a mismatch between their age on the date on which they enrolled into an SADP versus the age on which the rate charged to them is based, due to the alternate age calculation methodologies. Thus, consumers can more easily understand the premium rate they are charged when the age on effective date method is used instead of the other methods, reducing consumers confusion.

Allowing Exchange-certified SADPs to rate by other methods imposes unnecessary complexity, not only to CMS as operator of the FFEs and the Federal eligibility and enrollment platform, but also to enrollment partners and consumers in the Exchanges on the Federal platform. For example, the added complexity results in occasional inability to effectuate enrollment due to the unclear logic used to support the uncommon and alternative Exchange-certified SADP rating methods, which require expensive manual workarounds for the Exchanges on the Federal platform and Exchange-certified SADP issuers. Using the other methods also affects the efficiency of Classic DE and EDE partners, who rely more on Application Programming Interfaces (APIs) and must account for these alternate Exchange-certified SADP age calculation methods. It is more challenging for the Classic DE and EDE partners to replicate the logic needed for enrolling consumers into Exchange-certified SADPs using methods other than the conventional age on effective date method. Additionally, the more complicated alternative age calculation methods currently in use make it more difficult for consumers to understand the premium rate they are charged. Thus, requiring Exchange-certified SADPs to use the age on effective date methodology to calculate an enrollee's age as a condition of QHP certification, and consequently removing the less commonly used and more complex age calculation methods, will reduce consumer confusion and promote operational efficiency.

By helping to reduce consumer confusion and promote operational efficiency during the QHP certification process, this proposed policy would help facilitate more informed enrollment decisions and enrollment satisfaction. Accordingly, we believe it is appropriate to extend this proposed certification requirement to SADPs seeking certification on the FFEs as well as the SBE–FPs and SBEs. We seek comment on any anticipated challenges that this proposal could present for SBEs using their own platform, and whether and to what extent we should, if this proposal is finalized, limit or delay this proposed certification requirement for those SBEs.

We acknowledge the potential that Exchange-certified SADPs whose issuers use the alternative age calculation methods could withdraw from the Exchanges rather than comply with this new requirement. However, we do not anticipate that any such issuers would choose to withdraw from the Exchanges because of this proposal; and even if an issuer were to withdraw, we would expect that any such withdrawal would cause minimal disruption to consumers and other Exchange-certified plans. Given that a large majority of Exchange-certified SADP issuers are already using the age on effective date method, and based on the current availability of such plans in all service areas, we do not anticipate that consumers or other Exchange-certified plans would be materially affected.[207]

We seek comment on this proposal to require Exchange-certified SADPs, whether sold on- or off-Exchange, to use age on effective date as the sole method

[206] See, for example, Qualified Health Plan Issuer Application Instructions, Plan Year 2023, Extracted section: Section 3B: Business Rules. *https://www.qhpcertification.cms.gov/s/Business%20Rules.*

[207] In the EHB Rule (78 FR at 12853), we operationalized section 1302(b)(4)(F) of the ACA to permit QHP issuers to omit coverage of the pediatric dental EHB if an Exchange-certified SADP exists in the same service area in which they intend to offer coverage. As a corollary, if no such SADP is offered through an Exchange in that service area, then all health plans offered through the Exchange in that service area would be required to provide coverage of the pediatric dental EHB, as section 2707(a) of the PHS Act requires all non-grandfathered plans in the individual and small group markets to provide coverage of the EHB package described at section 1302(a) of the ACA.

to calculate an enrollee's age for rating and eligibility purposes, beginning with PY 2024.

b. Guaranteed Rates for SADPs

We propose at new § 156.210(d)(2) to require issuers of SADPs, as a condition of Exchange certification, to submit guaranteed rates beginning with Exchange certification for PY 2024. We propose that this requirement apply to Exchange-certified SADPs, whether they are sold on- or off-Exchange.

SADPs are excepted benefits, as defined by section 2791(c)(2)(A) of the PHS Act and HHS implementing regulations at §§ 146.145(b)(3)(iii)(A) and 148.220(b)(1), and are not subject to the PHS Act insurance market reform provisions that generally apply to non-grandfathered health plans in the individual and group markets inside and outside the Exchange.[208] In particular, because SADP issuers are not required to comply with the premium rating requirement under section 2701 of the PHS Act applicable to non-grandfathered individual and small group health insurance coverage, we have permitted SADP issuers in the FFEs and SBE–FPs to comply with the rate information submission requirements at § 156.210 under a modified standard.[209] Specifically, CMS has historically granted SADP issuers the flexibility to offer guaranteed or estimated rates. By indicating the rate is a guaranteed rate, the SADP issuer commits to charging the consumer the approved premium rate, which has been calculated using consumers' geographic location, age, and other permissible rating factors. Estimated rates require enrollees to contact the issuer to determine a final rate.

This flexibility for SADPs to offer estimated rates was effective for SADP issuers beginning with PY 2014. It was necessary because the relevant certification template was originally designed to support medical QHPs, which forced operational limits that prevented the accurate collection of rating rules for SADPs. Since PY 2014, we have improved the certification templates to allow SADPs to set the maximum age for dependents to 18, and to rate all such dependents. Thus, the FFEs and SBE–FPs can now accommodate dental rating rules properly in most reasonable circumstances.

We believe this proposal would significantly benefit enrollees. Consistent with §§ 156.440(b) and 156.470, APTC may be applied to the pediatric dental EHB portion of SADP premiums. If SADP issuers submit estimated rates and subsequently modify their actual rates, the Exchanges, including State Exchanges (including State Exchanges on the Federal platform) and FFEs, could incorrectly calculate APTC for the pediatric dental EHB portion of a consumer's premium, which could potentially cause consumer harm. Thus, since low-income individuals may qualify for APTC[210] and are disproportionately impacted by limited access to affordable health care,[211] we believe this proposed policy change would help advance health equity by helping ensure that low-income individuals who qualify for APTC are charged the correct premium amount when enrolling in SADPs on the Exchange.

We acknowledge that requiring guaranteed rates presents a small risk that SADP issuers that offer estimated rates could cease offering SADPs on the Exchanges. While we recognize this risk, we strongly believe that the benefits of this proposal far exceed the disadvantages. Specifically, as discussed previously, we believe this proposed policy change would significantly reduce the risk of consumer harm by reducing the risk of incorrect APTC calculation for the pediatric dental EHB portion of premiums. Thus, we believe this proposed policy would have a positive financial impact by ensuring that SADP enrollees receive the correct APTC calculation for the pediatric dental EHB portion of premiums, and therefore, are charged the correct premium rate.

We also note that although the FFEs and SBE–FP issuers currently allow SADP issuers to submit estimated rates, the vast majority elect to submit guaranteed rates. The vast majority of SADP issuers offering on-Exchange and off-Exchange Exchange-certified SADPs also elect to submit guaranteed rates. Given that most SADP issuers already submit guaranteed rates, the majority of SADP issuers are unlikely to be impacted by this proposal.

Because we believe this proposed policy would significantly benefit enrollees by ensuring that SADP enrollees receive the correct APTC calculation for the pediatric dental EHB portion of premiums, and therefore, are charged the correct premium rate, we believe it is appropriate to apply this proposed certification requirement to SADPs seeking certification on the FFEs as well as the SBE–FPs and SBEs. We seek comment on any anticipated challenges that this proposal could present for SBEs using their own platform, and whether and to what extent we should, if this proposal is finalized, limit or delay this proposed certification requirement for those SBEs.

We seek comment on this proposal to require Exchange-certified SADP issuers to submit guaranteed rates as a condition of Exchange certification beginning with Exchange certification for PY 2024.

6. Plan and Plan Variation Marketing Name Requirements for QHPs (§ 156.225)

We propose to add a new paragraph (c) to § 156.225 to require that QHP plan and plan variation[212] marketing names include correct information, without omission of material fact, and do not include content that is misleading. If finalized as proposed, CMS would review plan and plan variation marketing names during the annual

[208] See 42 U.S.C. 300gg–21(b) and (c) and 42 U.S.C. 300gg–63(b). Examples of PHS Act insurance market reforms added by the ACA that do not apply to stand-alone dental plans include but are not limited to section 2702 guaranteed availability standards, section 2703 guaranteed renewability standards, and section 2718 medical loss ratio standards.

[209] See, for example, the 2014 Final Letter to Issuers on Federally-facilitated and State Partnership Exchanges for more information on how SADPs in the FFEs and SBE–FPs have flexibility to comply with the rate information submission requirements at § 156.210.

[210] The PTC is generally available to people who buy Marketplace coverage and who have a household income that equals or exceeds the Federal poverty level, and who meet other eligibility criteria.

[211] Research and policy analysis has shown that low-income individuals are disproportionately impacted by lack of access to affordable health care. According to a 2018 Health Affairs Health Policy Brief, compared to higher-income Americans, low-income individuals face greater barriers to accessing medical care. More specifically, low-income individuals are less likely to have health insurance, receive new drugs and technologies, and have ready access to primary and specialty care. *See* Khullar, D., & Chokshi, D. A. (2018). Health, Income, And Poverty: Where We Are And What Could Help. *Health Affairs. https://doi.org/10.1377/hpb20180817.901935*. Additionally, a 2007 study found that barriers to health care can be insurmountable for low-income families, even those with insurance coverage. In particular, this study found that families reported three major barriers to health care: lack of insurance coverage, poor access to services, and unaffordable costs. *See* DeVoe, J. E., Baez, A., Angier, H., Krois, L., Edlund, C., Carney, P. A. (2007). Insurance + Access ≠ Health Care: Typology of Barriers to Health Care Access for Low-Income Families. *Annals of Family Medicine, 5*(6), 511–518. *https://doi.org/10.1370/afm.748.*

[212] In practice, CMS and interested parties often use the term ''plan variants'' to refer to ''plan variations.'' Per § 156.400, plan variation means a zero-cost sharing plan variation, a limited cost sharing plan variation, or a silver plan variation. Issuers may choose to vary plan marketing name by the plan variant—for example, use one plan marketing name for a silver plan that meets the actuarial value (AV) requirements at § 156.140(b)(2), and a different name for that plan's equivalent that meets the AV requirements at § 156.420(a)(1), (2), or (3).

QHP certification process in close collaboration with State regulators in States with Exchanges on the Federal platform.

Section 1311(c)(1)(A) of the ACA states that the Secretary shall establish QHP certification criteria, which must include, at a minimum, that a QHP meet marketing requirements and not employ marketing practices or benefit designs that have the effect of discouraging enrollment by individuals with significant health needs. CMS, States, and QHP issuers work together to ensure that consumers can make informed decisions when selecting a health insurance plan based on factors such as QHP benefit design, cost-sharing requirements, and available financial assistance. In PY 2022, Exchanges on the Federal platform saw a significant increase in the number of plan and plan variation marketing names that included cost-sharing information and other benefit details. Following Open Enrollment for PY 2022, CMS received complaints from consumers in multiple States who misunderstood cost-sharing information in their QHP's marketing name.

Upon further investigation, CMS and State regulators determined that this language was often incorrect or could be reasonably interpreted by consumers as misleading based on information in corresponding plan benefit documentation submitted as part of the QHP certification process.[213] CMS's review of QHP data for PY 2023 indicates continued use of cost-sharing information in plan and plan variation marketing names.

This proposed policy would require all information included in plan and plan variation marketing names that relates to plan attributes to correspond to and match information that issuers submit for the plan in the Plans & Benefits Template, and in other materials submitted as part of the QHP certification process, such as any content that is part of the Summary of Benefits and Coverage. If necessary, this information can be included in the ''Benefit Explanation'' field of the Plans & Benefits Template. Consumers applying for coverage should be able to understand references to benefit information in plan and plan variation marketing names, and they should be able to confirm any information from a plan or plan variation marketing name in the plan's publicly available benefit descriptions. Also, plan benefit or cost sharing information in a plan or plan variation marketing name should not conflict with plan or plan variation information displayed on *HealthCare.gov* during the plan selection process in terms of dollar amount and, where applicable, terminology.

Under this proposal, as an example, CMS would flag plan and plan variation marketing names for revision to help consumers understand the cost-sharing and coverage implications. The following are examples of information that should be validated to ensure accuracy and consistency across the plan or plan variation marketing name, Plans & Benefits Template, *HealthCare.gov* plan selection information, and other applicable QHP certification materials. These examples are not all-inclusive, but they illustrate the kinds of information in plan and plan variation marketing names that could mislead consumers through inaccurate information or omission of material facts.

- Cost-sharing amounts that do not specify limitations the plan or plan variation includes, such as whether the cost-sharing amount is only available for drugs in a certain prescription drug category/tier, providers in a specific network or tier, or for a certain number of provider visits following which a higher cost-sharing amount will apply;
- Dollar amounts that do not specify what they refer to (for example, deductible, maximum out-of-pocket, or something else), whether they apply only to medical, drug, or another type of benefit, or whether, in cases of deductible or maximum out-of-pocket amounts, they apply to an individual or a family;
- Benefits, such as adult dental care, that are listed in a plan or plan variation marketing name to indicate that they are covered, but that plan documents indicate are not covered; and
- Reference(s) to health savings accounts (HSAs) in marketing names of plans or plan variations that do not permit enrollees to set up an HSA.[214]

We seek comment on this proposal and whether there are additional methods of preventing consumer confusion and market disruption related to this issue. In particular, we seek comment on the potential to identify components of plan and plan variation marketing names that could be uniformly structured and defined across QHPs, so as to consistently communicate information and ensure that plan and plan variation marketing names complement and do not contradict other sources of plan detail, such as cost-sharing and benefit information, displayed during the plan selection process on *HealthCare.gov* and other enrollment platforms. For example, we seek comment on whether, to address this, CMS should establish a required format for plan and plan variation marketing names that specifies elements such as name of issuer, metal level, and limited cost-sharing information.

7. Plans That Do Not Use a Provider Network: Network Adequacy (§ 156.230) and Essential Community Providers (§ 156.235)

We propose to revise the network adequacy and ECP standards at §§ 156.230 and 156.235 to state that all individual market QHPs and SADPs and all SHOP QHPs across all Exchanges must use a network of providers that complies with the standards described in those sections, and to remove the exception that these sections do not apply to plans that do not use a provider network.

In the Exchange Establishment Rule, we established the minimum network adequacy criteria that health and dental plans must meet to be certified as QHPs at § 156.230. In the 2016 Payment Notice, we modified § 156.230(a), in part, to specify that network adequacy requirements apply only to QHPs that use a provider network to deliver services to enrollees and that a provider network includes only providers that are contracted as in-network. We also revised § 156.235(a) to state that the ECP criteria apply only to QHPs that use a provider network. In Part 1 of the 2022

[213] For example, in some cases a plan marketing name described a limited benefit in a way that could be understood as being unlimited, such as a ''$5 co-pay'' when the $5 co-pay was only available for an initial visit. Consumers were concerned upon learning the full extent of the cost-sharing for which they would be responsible during the plan year.

[214] An HSA is a tax-exempt trust or custodial account that a taxpayer may set up with a qualified HSA trustee to pay or reimburse certain medical expenses they incur. (*See* IRS Publication 969 (2021), Health Savings Accounts and Other Tax-Favored Health Plans: *https://www.irs.gov/publications/p969#en_US_2021_publink1000204030.*) Taxpayers must meet certain requirements to qualify for an HSA, including being enrolled in a High Deductible Health Plan (HDHP) as defined in Section 223(c)(2) of the U.S. Tax Code. HDHP requirements include minimum levels for family and individual deductible amounts—for example, for calendar year 2022, an HDHP was defined as a health plan with an annual deductible not less than $1,400 for self-only coverage or $2,800 for family coverage, with annual out-of-pocket expenses not more than $7,050 for self-only coverage or $14,100 for family coverage. (*See* IRS Rev. Proc. 2021–25: *https://www.irs.gov/pub/irs-drop/rp-21-25.pdf.*) Plan variants with limited or no cost sharing, such as those described at § 156.420(a)(1) and (b)(1), by definition do not meet the requirements to be HDHPs, and enrollees in these plans therefore cannot set up an HSA. CMS will consider references to HSAs in the names of plans that do not qualify as HDHPs to be incorrect and misleading.

Payment Notice (86 FR 6138), we added section (f) to § 156.230 to state that a plan for which an issuer seeks QHP certification or any certified QHP that does not use a provider network (meaning that the plan or QHP does not condition or differentiate benefits based on whether the issuer has a network participation agreement with a provider that furnishes covered services) is not required to comply with the network adequacy standards at paragraphs (a) through (e) of § 156.230 to qualify for certification as a QHP. In that rule, we also stated that plans that do not utilize a provider network must still comply with all applicable QHP certification requirements to obtain QHP certification, which ensures that any plan that does not comply with applicable QHP certification requirements will be denied QHP certification (86 FR 6138).

Since 2016, only a single issuer has sought a certification on an FFE for a plan that does not use a network. Despite lengthy negotiations with this issuer, our experience with this plan convinced us that commenters to Part 1 of the 2022 Payment Notice who raised concerns about the burden plans without networks place on enrollees appear to have been correct, and so, for that reason and the other reasons explained below, we are proposing to revisit this policy.

Section 1311(c)(1)(B) and (C) of the ACA directs HHS to establish by regulation certification criteria for QHPs, including criteria that require QHPs to ensure a sufficient choice of providers (in a manner consistent with applicable provisions under section 2702(c) of the PHS Act, which governs insured health plans that include a provider network), provide information to enrollees and prospective enrollees on the availability of in-network and out-of-network providers, and to include within health insurance plan provider networks those ECPs that serve predominantly low income, medically underserved individuals. HHS carries out this directive through establishing network adequacy and ECP requirements and reviewing QHP compliance with such requirements.

When we added section (f) to § 156.230 in Part 1 of the 2022 Payment Notice to except plans that do not use a provider network from meeting the network adequacy standards described at § 156.230(a) through (e), we did not intend to allow a plan to ignore the minimum statutory criteria for QHP certification. Plans without provider networks still are required by section 1311(c)(1)(B) of the ACA to ensure sufficient choice of providers and provide information to enrollees and prospective enrollees on the availability of in-network and out-of-network providers to obtain certification, even though they are not currently subject to §§ 156.230 and 156.235. Whether a plan that does not use a network provides sufficient a choice of providers is a more nuanced inquiry than a simple assertion that an enrollee can receive benefits for any provider. For a prospective enrollee, a ''sufficient choice of providers'' likely involves factors like the burden of accessing those providers, including whether there are providers nearby that they can see without unreasonable delay that would accept such a plan's benefit amount as payment in full, or whether they are able to receive all of the care for a specific health condition from a single provider without incurring additional out-of-pocket costs. These are among the factors involved in determining whether a network plan is in compliance with the network adequacy and ECP standards at §§ 156.230 and 156.235; a plan's compliance with these regulatory standards is one way that HHS can verify that plans meet the statutory criteria that QHPs ensure a sufficient choice of providers, including ECPs.

To more effectively ensure that all plans provide sufficient choice of providers and to provide for consistent standards across all QHPs, we believe it would be appropriate to revise the network adequacy and ECP standards at §§ 156.230 and 156.235 to state that all QHPs, including SADPs, must use a network of providers that complies with the standards described in those sections and to remove the exception at § 156.230(f). Consistent standards also would allow for easier comparability across all QHPs in a more comprehensible manner for prospective enrollees. The benefits of easier comparability between plans and other challenges posed by plan choice overload are discussed in more detail in the preamble sections about Standardized Plan Options and Non-Standardized Plan Option Limits.

We have previously stated that ''nothing in [the ACA] requires a QHP issuer to use a provider network,'' (84 FR at 6154) and it is true that the ACA includes no standalone network requirement. However, after revisiting the statute, we now doubt that a plan without a network can comply with the statutory requirement at section 1311(c)(1)(C) of the ACA that ''a plan shall, at a minimum . . . include within health insurance plan networks those essential community providers, where available, that serve predominately low-income, medically-underserved individuals.'' We have always understood Section 1311(c)(1)(C) of the ACA to require all plans to provide sufficient access to ECPs, where available, whether or not the plan included a provider network. But we have not previously considered whether this specific statutory text is consistent with a policy exempting plans without a network from network adequacy regulations. We now understand the statute's text to best support a reading that access to ECPs will be provided ''within health insurance networks.''

Additionally, under section 1311(e)(1)(B) of the ACA and § 155.1000(c)(2), an Exchange may certify plans only if it determines that making the plans available through the Exchange is in the interests of qualified individuals. Section 155.1000 provides Exchanges with broad discretion to certify health plans that may otherwise meet the QHP certification standards specified in part 156. When we implemented section 1311(e)(1)(B) of the ACA at § 155.1000(c)(2) in the Exchange Establishment Rule, we noted that ''an Exchange could adopt an 'any qualified plan' certification, engage in selective certification, or negotiate with plans on a case-by-case basis'' (77 FR 18405). Under this authority, we believe that requiring QHPs to use a provider network would be in the interests of qualified individuals and would better protect consumers from potential harms that could arise in cases where QHPs do not use provider networks. For example, the implementation of a provider network can help mitigate against risks of substantial out-of-pocket costs, ensure access without out-of-pocket costs to preventive services that must be covered without cost sharing, and, in the individual market, facilitate comparability of standardized plan options. Furthermore, studies have found that provider networks allow for insurer-negotiated prices and controlled (that is, reduced) costs in the form of reduced patient cost sharing, premiums, and service price, as compared with such services obtained out of network.[215] [216]

This proposed revision would assure HHS that all plans certified as QHPs

[215] Benson NM, Song Z. Prices And Cost Sharing For Psychotherapy In Network Versus Out Of Network In The United States. Health Aff (Millwood). 2020 Jul;39(7):1210–1218. *https://www.healthaffairs.org/doi/10.1377/hlthaff.2019.01468.*

[216] Song, Z., Johnson, W., Kennedy, K., Biniek, J. F., & Wallace, J. Out-of-network spending mostly declined in privately insured populations with a few notable exceptions from 2008 to 2016. Health Aff. 2020;39(6), 1032–1041. *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2019.01776.*

offer sufficient choice of providers in compliance with a consistent set of criteria for easier comparability across all QHPs and better ensure substantive consumer protections afforded by the ACA without undue barriers to access those protections. This consistency would be valuable to consumers as it ensures all consumers will have access to a set of providers with whom their plan has contracted in accordance with our established network adequacy and ECP requirements and allows for easier comparison between plans for prospective enrollees. This will also allow consumers to seek care from providers with whom their plan has negotiated a rate, limiting their potential exposure to out-of-pocket costs under the plan.

Accordingly, pursuant to the authority delegated to HHS to establish criteria for the certification of health plans as QHPs, we propose to remove the exception at § 156.230(f) and to revise §§ 156.230 and 156.235 to state that all individual market QHPs and SADPs and all SHOP plan QHPs across all Exchanges-types must use a network of providers that complies with the standards described in those sections, beginning with PY 2024. Under this proposal, an Exchange could not certify as a QHP a health plan that does not use a network of providers. However, we solicit comment on whether it is possible to design a plan that does not use a network in a way that would address our concerns about the plan's ability to offer a sufficient choice of providers without excessive burden on consumers, or what regulatory standards such a plan could meet to ensure a sufficient choice of providers without excessive burden on consumers.

This proposal would also generally apply to SADPs. Since 2014, the FFEs have received, and approved, QHP certification applications for SADPs that do not use a provider network in every plan year. However, the number of SADPs that do not use a provider network has never accounted for a significant number of SADPs approved as QHPs on the FFEs. At their most prevalent in PY 2014, only 50 of the 1,521 SADPs certified as QHPs on the FFEs were plans that do not use a provider network. In PY 2022, only 8 of the 672 SADPs certified as QHPs on the FFEs were plans that do not use a provider network.

Further, the number of SADPs on the FFEs that do not use a provider network appears to be limited since 2017 to fewer and fewer States; while 9 FFE States had SADPs that do not use a provider network certified as QHPs in PY 2014, only 2 FFE States still had SADPs that do not use a provider network certified in PY 2022. Since PY 2021, only 85 counties in Alaska and Montana still have SADPs that do not use a provider network certified as QHPs. We assume that the few SADP issuers that still offer SADPs that do not use a provider network on the FFEs in Alaska and Montana only do so because of difficulty in maintaining a sufficient provider network in those States. We believe it is reasonable to assume that consumers increasingly gravitate towards SADPs that use a network, given this overall decrease in the availability of SADPs that do not use a provider network. We invite comment to confirm these understandings, as well as comment on the prevalence of SADPs that do not use a provider network offered outside of the FFEs in the non-grandfathered individual and small group markets.

TABLE 12: Prevalence of SADPs that Do Not Use a Provider Network on the FFEs, Plan Years 2014-2023 *

Plan Year	SADPs Without Provider Networks	SADPs With Provider Networks	FFE States with SADPs Without Provider Networks	Counties (#) with SADPs Without Provider Networks	% Counties in Affected FFE States with Only SADPs Without Provider Networks
2023	15	684	2; Alaska and Montana	85	AK: 90%, MT: 0% (every county had plans with provider network options)
2022	8	672	2; Alaska and Montana	85	AK: 90%, MT: 0% (every county had plans with provider network options)
2021	17	688	4; Alaska, Montana, North Dakota, Wyoming	85	0% in all affected FFE States
2020	17	736	4; Alaska, Montana, North Dakota, Wyoming	161	100% in all affected FFE States (the only SADP options in affected counties were plans without provider networks)
2019	38	893	5; Alaska, Montana, Nebraska, North Dakota, Wyoming	162	100% in all affected FFE States (the only SADP options in affected counties were plans without provider networks)
2018	40	932	6; Alaska, Montana, Nebraska, North Dakota, Utah, Wyoming	163	100% in all affected FFE States (the only SADP options in affected counties were plans without provider networks)
2017	41	1,053	5; Alaska, Montana, Nebraska, North Dakota, Oregon, Wyoming	197	0% in all affected FFE States (every county had plans with provider network options)
2016	15	1,045	5; Alaska, Montana, Oregon, South Dakota, Wyoming	210	0% in all affected FFE States (every county had plans with provider network options)
2015	17	1,128	4; Montana, Ohio, South Dakota, Wyoming	233	0% in all affected FFE States (every county had plans with provider network options)
2014	50	1,521	9; Alaska, Iowa, Idaho, Missouri, Montana, Nebraska, South Carolina, South Dakota, Wyoming	571	0% in all affected FFE States (every county had plans with provider network options)

* Data for the number of SADPs sourced from Health Insurance Exchange Public Use Files (Exchange PUFs), available at: https://www.cms.gov/CCIIO/Resources/Data-Resources/marketplace-puf.

Given the overall lack of popularity of SADPs that do not use a provider network, we believe that consumers find that such plans do not offer the same levels of protections against out-of-pocket costs as network plans. Thus, we believe it would be appropriate to revise §§ 156.230 and 156.235 so that all SADPs must use a network of providers that complies with the standards described in those sections as a condition of QHP certification, beginning with PY 2024.

However, we are cognizant that it can be more challenging for SADPs to establish a network of dental providers based on the availability of nearby dental providers, and we are aware this proposal could result in no SADPs offered through Exchanges in States like Alaska and Montana, which have historically offered SADPs without

provider networks (see Table 12). Further, we are aware that having no Exchange-certified SADPs offered through an Exchange in an area would impact all non-grandfathered individual and small group plans in such areas. Without an SADP available on the respective Exchange, all non-grandfathered individual and small group health plans in impacted areas would be required to cover the pediatric dental EHB. We note that section 1302(b)(4)(F) of the ACA states that if such an SADP is offered through an Exchange, another health plan offered through such Exchange shall not fail to be treated as a QHP solely because the plan does not offer coverage of pediatric dental benefits offered through the SADP.

In the EHB Rule (78 FR at 12853), we operationalized this provision at section 1302(b)(4)(F) of the ACA to permit QHP issuers to omit coverage of the pediatric dental EHB if an Exchange-certified SADP exists in the same service area in which they intend to offer coverage. As a corollary, if no such SADP is offered through an Exchange in that service area, then all health plans offered through the Exchange in that service area would be required to provide coverage of the pediatric dental EHB, as section 2707(a) of the ACA requires all non-grandfathered plans in the individual and small group markets to provide coverage of the EHB package described at section 1302(a) of the ACA. However, to our knowledge, at least one Exchange-certified SADP has been offered in all service areas nationwide since implementation of this requirement in 2014, and no Exchange has required a medical QHP to provide coverage of the pediatric dental EHB in this manner. We solicit comment to confirm this understanding.

To prevent a situation where this proposal would require health plans in those areas to cover the pediatric dental EHB, we solicit comment on the extent to which we should finalize a limited exception to this proposal only for SADPs that sell plans in areas where it is prohibitively difficult for the issuer to establish a network of dental providers; this exception would not be applicable to health plans. Under such an exception, we could consider an area to be ''prohibitively difficult'' for the SADP issuer to establish a network of dental providers on a case-by-case basis, taking into account a number of non-exhaustive factors, such as the availability of other SADPs that use a provider network in the service area, and prior years' network adequacy data to identify counties in which SADP issuers have struggled to meet standards due to a shortage of dental providers. Other factors could include an attestation from the issuer about extreme difficulties in developing a dental provider network, or data provided in the ECP/NA template or justification forms during the QHP application submission process that reflect such extreme difficulties. We seek comment on whether it would be appropriate to finalize such an exception in this rule, other factors that we might consider in evaluating whether an exception is appropriate, as well as alternative approaches to such an exception.

We seek comment on this proposal, as well as on other topics included in this section.

Compliance With Appointment Wait Time Standards

In the 2023 Payment Notice, HHS finalized the requirement that issuers demonstrate compliance with appointment wait time standards via attestation, beginning in PY 2024. Issuers must work with their network providers to collect the necessary data to assess appointment wait times and determine if their provider network meets the wait time standards detailed in the 2023 Letter to Issuers, as CMS will begin conducting such reviews of issuer attestations for PY 2024.

8. Essential Community Providers (§ 156.235)

We propose to expand access to care for low-income and medically underserved consumers by strengthening ECP standards for QHP certification, as discussed in this section. First, HHS proposes to establish two additional stand-alone ECP categories at § 156.235(a)(2)(ii)(B) for PY 2024 and beyond: Mental Health Facilities and Substance Use Disorder (SUD) Treatment Centers. In doing so, two provider types currently categorized as ''Other ECP Providers'' (Community Mental Health Centers and Substance Use Disorder (SUD) Treatment Centers) would be recategorized within these new proposed stand-alone ECP categories. We propose to crosswalk the Community Mental Health Centers provider type into the newly created stand-alone Mental Health Facilities category and the SUD Treatment Centers provider type into the newly created stand-alone SUD Treatment Centers category. Additionally, we propose to add Rural Emergency Hospitals (REHs) as a provider type in the Other ECP Providers ECP category. This addition reflects the fact that on or after January 1, 2023, REHs may begin participating in the Medicare program. As CMS noted in July of this year, ''[t]he REH designation provides an opportunity for Critical Access Hospitals (CAHs) and certain rural hospitals to avert potential closure and continue to provide essential services for the communities they serve.'' [217] HHS believes that the inclusion of REHs on the ECP List may increase access to needed care for low-income and medically underserved consumers in rural communities.

ECPs include providers that serve predominantly low-income and medically underserved individuals, and specifically include providers described in section 340B(a)(4) of the PHS Act and section 1927(c)(1)(D)(i)(IV) of the Social Security Act (the Act). Section 156.235 establishes the requirements for the inclusion of ECPs in QHP provider networks. Section 156.235(a) requires QHP issuers to include a sufficient number and geographic distribution of ECPs in their networks, where available. Each plan year, HHS releases a final list of ECPs to assist issuers with identifying providers that qualify for inclusion in a QHP issuer's plan network toward satisfaction of the ECP standard under § 156.235. The list is not exhaustive and does not include every provider that participates or is eligible to participate in the 340B drug program, every provider that is described under section 1927(c)(1)(D)(i)(IV) of the Act, or every provider that may otherwise qualify under § 156.235. CMS endeavors to continue improving the ECP list for future years. These efforts include direct provider outreach to ECPs themselves, as well as reviewing the provider data with Federal partners.

Section 156.235(b) establishes an Alternate ECP Standard for QHP issuers that provide a majority of their covered professional services through physicians employed directly by the issuer or a single contracted medical group. We note that the above proposal establishing two additional ECP categories and the proposed threshold requirements discussed later in this section would affect all QHP issuers, regardless of whether they are subject to the General ECP Standard under § 156.235(a) or Alternate ECP Standard under § 156.235(b). However, SADP issuers would only be subject to such requirements as applied to provider types that offer dental services, as reflected in § 156.235(a)(2)(ii)(B).

Currently, QHPs that utilize provider networks are required to contract with at least 35 percent of available ECPs in each plan's service area to participate in the plan's provider network. In

[217] *https://www.cms.gov/newsroom/fact-sheets/rural-emergency-hospitals-proposed-rulemaking.*

addition, under § 156.235(a)(2)(ii)(B), medical QHPs must offer a contract in good faith to at least one ECP in each of the available ECP categories in each county in the plan's service area and offer a contract in good faith to all available Indian health care providers in the plan's service area. Under § 156.235(a)(2)(ii)(B), the six ECP categories currently include Federally Qualified Health Centers, Ryan White Program Providers, Family Planning Providers, Indian Health Care Providers, Inpatient Hospitals, and Other ECP Providers (currently defined to include Substance Use Disorder Treatment Centers, Community Mental Health Centers, Rural Health Clinics, Black Lung Clinics, Hemophilia Treatment Centers, Sexually Transmitted Disease Clinics, and Tuberculosis Clinics).

The proposed establishment of two new stand-alone ECP categories (Mental Health Facilities and SUD Treatment Centers) would strengthen the ECP standard in two ways: (1) by requiring that medical QHP issuers offer a contract in good faith to at least one SUD Treatment Center and at least one Mental Health Facility that qualify as ECPs in each county in the plan's service area, as opposed to being blended with other provider types in the existing ''Other ECP Provider'' category; and (2) by decreasing the number of provider types remaining in the ''Other ECP Provider'' category, thereby increasing the likelihood that remaining provider types included in the ''Other ECP Provider'' category will receive a contract offer from a medical QHP issuer to satisfy the requirement that they must offer a contract in good faith to at least one provider in each ECP category in each county in the plan's service area.

Given that the ECP standard is facility-based, if finalized as proposed, the inclusion of SUD Treatment Centers and Mental Health Facilities on the HHS ECP List would be limited to those facilities identified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and/or CMS as providing such services, in addition to fulfilling other ECP qualification requirements as specified at § 156.235(c).

If finalized as proposed, the eight available stand-alone ECP categories would consist of the following: (1) Federally Qualified Health Centers; (2) Ryan White Program Providers; (3) Family Planning Providers; (4) Indian Health Care Providers; (5) Inpatient Hospitals, (6) Mental Health Facilities; (7) SUD Treatment Centers, and (8) Other ECP Providers, to include Rural Health Clinics, Black Lung Clinics, Hemophilia Treatment Centers, Sexually Transmitted Disease Clinics, and Tuberculosis Clinics. The proposed ECP categories and ECP provider types within those categories in the FFEs for PY 2024 and beyond are set forth in Table 13.

TABLE 13: ECP Categories and Provider Types in FFEs, as proposed for PY 2024 and beyond

Major ECP category	ECP provider types
Federally Qualified Health Centers (FQHC)	FQHC and FQHC ''Look-Alike'' Clinics
Ryan White Program Providers	Ryan White HIV/AIDS Providers
Family Planning Providers	State-owned family planning service sites, governmental family planning service sites, including Title X Family Planning Clinics and Title X "Look-Alike" Family Planning Clinics, Not-for-profit family planning service sites that do not receive Federal funding under special programs, including under Title X of the PHS Act or other 340B-qualifiying funding
Indian Health Care Providers	Tribes, Tribal Organization and Urban Indian Organization Providers, Indian Health Service Facilities
Inpatient Hospitals	Disproportionate Share Hospital (DSH), Children's Hospitals, Rural Referral Centers, Sole Community Hospitals, Free-standing Cancer Centers, Critical Access Hospitals,
Substance Use Disorder Treatment Centers	Substance Use Disorder Treatment Providers
Mental Health Facilities	Community Mental Health Centers, Other Mental Health Providers
Other ECP Providers	Black Lung Clinics, Hemophilia Treatment Centers, Rural Health Clinics, Sexually Transmitted Disease Clinics, Tuberculosis Clinics, Rural Emergency Hospitals

In addition, HHS proposes to revise § 156.235(a)(2)(i) to require QHPs to contract with at least a minimum percentage of available ECPs in each plan's service area within certain ECP categories, as specified by HHS. Specifically, HHS proposes to require QHPs to contract with at least 35 percent of available FQHCs that qualify as ECPs in the plan's service area and at least 35 percent of available Family Planning Providers that qualify as ECPs in the plan's service area. Furthermore, HHS proposes to revise § 156.235(a)(2)(i) to clarify that these proposed requirements would be in addition to the existing provision that QHPs must satisfy the overall 35 percent ECP threshold requirement in the plan's service area. We note that HHS would retain its current overall ECP provider participation standard of 35 percent of available ECPs based on the applicable PY HHS ECP list, including approved ECP write-ins that would also count toward a QHP issuer's satisfaction of the 35 percent threshold.

HHS is proposing that only two ECP categories, FQHCs and Family Planning Providers, be subject to the additional 35 percent threshold in PY 2024 and beyond. These two categories were selected, in part, because they represent the two largest ECP categories; together, these two categories comprise roughly 62 percent of all facilities on the ECP List. Applying an additional 35 percent threshold to these two categories could increase consumer access in low-income areas that could benefit from the additional access to the broad range of health care services that these particular providers offer. HHS may consider applying a specified threshold to other ECP categories in future rulemaking, if HHS finds that additional ECP categories contain a sufficient number and geographic distribution of providers to allow for application of the threshold without inflicting undue burden on issuers by effectively forcing them to contract with a few specific providers.

Based on data from PY 2023, it is likely that a majority of issuers would be able to meet or exceed the threshold requirements for FQHCs and Family Planning Providers without needing to contract with additional providers in these categories. To illustrate, if these requirements had been in place for PY 2023, out of 137 QHP issuers on the FFEs, 76 percent would have been able to meet or exceed the 35 percent FQHC threshold, while 61 percent would have been able to meet or exceed the 35 percent Family Planning Provider threshold without contracting with additional providers. For SADP issuers, 84 percent would have been able to meet the 35 percent threshold requirement for FQHCs offering dental services without contracting with additional providers. In PY 2023, for medical QHPs, the mean and median percentages of contracted ECPs for the FQHC category were 74 and 83 percent, respectively. For the Family Planning Providers category, the mean and median percentages of contracted ECPs were 66 and 71 percent, respectively. For SADPs, the mean and median percentages of contracted ECPs for the FQHC category were 61 and 64 percent, respectively.

We acknowledge challenges associated with a general shortage and uneven distribution of SUD Treatment Centers and Mental Health Facilities. However, the ACA requires that a QHP's network include ECPs where available. As such, the proposal to require QHPs to offer a contract to at least one available SUD Treatment Center and one available Mental Health Facility in every county in the plan's service area does not unduly penalize issuers facing a lack of certain types of ECPs within a service area, meaning that if there are no provider types that map to a specified ECP category available within the respective county, the issuer is not penalized. Further, as outlined in prior Letters to Issuers, HHS prepares the applicable PY HHS ECP list that potential QHPs use to identify eligible ECP facilities. The HHS ECP list reflects eligible providers (that is, the denominator) from which an issuer may select for contracting to count toward satisfying the ECP standard. As a result, issuers are not disadvantaged if their service areas contain fewer ECPs. HHS anticipates that any QHP issuers falling short of the 35 percent threshold for PY 2024 and beyond could satisfy the standard by using ECP write-ins and justifications. As in previous years, if an issuer's application does not satisfy the ECP standard, the issuer would be required to include as part of its application for QHP certification a satisfactory justification.

We seek comment on these proposals.

9. Termination of Coverage or Enrollment for Qualified Individuals (§ 156.270)

a. Establishing a Timeliness Standard for Notices of Payment Delinquency

We propose to amend § 156.270(f) by adding a timeliness standard to the requirement for QHP issuers to send enrollees notice of payment delinquency. Specifically, we propose to revise § 156.270(f) to require issuers to send notice of payment delinquency promptly and without undue delay. HHS has long required issuers to send notices of non-payment of premium (77 FR 18469), so that enrollees who become delinquent on premium payments are aware and have a chance to avoid termination of coverage. In accordance with § 156.270(a), issuers may terminate coverage for the reasons specified in § 155.430(b), which under paragraph (2)(ii) includes termination of coverage due to non-payment of premiums. Enrollees who are receiving APTC and who fail to timely pay their premiums are entitled to a 3-month grace period, described at § 156.270(d), during which they may return to good standing by paying all outstanding premium before the end of the 3 months. Enrollees who are not receiving APTC may also be entitled to a grace period under State law, if applicable.

HHS has an interest in helping enrollees maintain coverage by establishing basic standards of communication between the QHP issuer and enrollee regarding premium payment status, especially at the start of an enrollment and when an enrollment has entered delinquency for failure to timely pay premium and is at risk for termination. For example, before Exchange coverage is effectuated, the Exchanges on the Federal platform generally require that the enrollee make a binder payment (first month's premium) by prescribed due dates.[218] At § 156.270(f), HHS has also regulated on communicating to an enrollee when they have become delinquent on premium payment and when their coverage has been terminated. But while the regulation at § 156.270(f) requires that issuers notify enrollees when they become delinquent on premium payments, CMS currently sets no timeliness requirements for issuers. In conducting oversight of issuers, HHS is aware that in some instances, issuers have delayed notifying enrollees of delinquency. HHS is concerned that there may be situations in which enrollees are not timely informed that they have become delinquent on premium payments, thus limiting the amount of time they have available to rectify the delinquency and avoid termination of coverage. In extreme cases, an enrollee may not become aware that they have become delinquent until termination of coverage has already occurred. For example, if an enrollee (who was not receiving APTC) failed to pay August's premium but was not informed by the issuer they had become delinquent until September, they would have already lost coverage and would not have an opportunity to

[218] *See* § 155.400(e).

restore it. There may also be uncertainty among issuers regarding their requirement to send notices of delinquency, since HHS has not provided guidance on when this notice must be sent.

Modifying § 156.270(f) to require issuers to send notices of payment delinquency promptly and without undue delay would ensure that issuers are promptly sending these notices when enrollees fail to make premium payments, so that enrollees are aware they are at risk of losing coverage, including when they are entering a grace period (either the 3-month grace period for enrollees who are receiving APTC, or a State grace period if applicable). It would also provide clarity to issuers regarding their obligation to send a notice when an enrollee becomes delinquent on premium payment. Finally, updating this regulation would serve HHS' goal of promoting continuity of coverage by ensuring enrollees are aware they have become delinquent on premium payment and have a chance to pay their outstanding premium to avoid losing coverage. To further help ensure that notices are sent in a timely and uniform manner, HHS also believes it would be important to specify the number of days within which the issuer must send notice from the time an enrollee becomes delinquent on payment. However, we also recognize that issuers have a variety of practices for sending delinquency notices, and thus we request comment on what a reasonable timeframe would be for sending notices of delinquency to enrollees.

We seek comments on this proposal.

10. Final Deadline for Reporting Enrollment and Payment Inaccuracies Discovered After the Initial 90-Day Reporting Window (§ 156.1210(c))

We propose to amend § 156.1210(c) to remove the alternate deadline at § 156.1210(c)(2) that allows an issuer to describe all data inaccuracies identified in a payment and collection report by the date HHS notifies issuers that the HHS audit process with respect to the plan year to which such inaccuracy relates has been completed, in order for these data inaccuracies to be eligible for resolution.

In prior rulemakings (78 FR 65080 through 65081, 85 FR 29254, and 86 FR 24256 through 24258), we established provisions at § 156.1210 related to the review and identification of inaccuracies in the monthly payment and collection reports provided by HHS for Exchange coverage. These reports currently include information on APTC the Federal Government is paying to the issuer for each policy listed on the report, any amounts owed by the issuer for FFE and SBE–FP user fees, as well as any adjustments from previous payments under those programs. This process is intended to confirm that accurate payments are made and to facilitate adjustments where inaccuracies are identified. The policies and standards governing this process have evolved over time as HHS, State Exchanges, and issuers have gained experience with handling payment errors and enrollment reconciliation activities for Exchange coverage. Issuers are generally required to review these detailed monthly reports against the payments they expect for each policy based on the eligibility and enrollment information transmitted by the Exchange, and any amounts it expects the Federal Government to collect for FFE and SBE–FP user fees. If an issuer identifies an inaccuracy in these amounts (including incorrect payment amounts, or extra or missing policies in the report), it must notify HHS or the State Exchange (as applicable) within certain timeframes. HHS works with issuers and State Exchanges (as applicable) to resolve any discrepancies between the amounts listed in the payment and collections report and the amounts the issuer believes it should receive for the time period(s) specified on the report. The prompt identification and correction of payment and enrollment errors protects enrollees from unanticipated tax liability that could result if the APTC is greater than the amount authorized by the Exchange and accepted by the enrollee. It also supports the efficient operation of Exchanges by aligning the Exchange's enrollment and eligibility data, payments provided by and collected by HHS for Exchange coverage, and the issuer's own records of payments due.

Section 156.1210(c) currently establishes the final deadline to report inaccuracies identified in a payment and collections report for discovered underpayments [219] as before the later of (1) the end of the 3-year period beginning at the end of the plan year to which the inaccuracy relates or (2) the date by which HHS notifies issuers that the HHS audit process with respect to the plan year to which such inaccuracy relates has been completed. The final 3-year or end of the HHS audit process deadline set forth in § 156.1210(c)(1) and (2) is significant because HHS will only provide payment to the issuer for identified data inaccuracies related to discovered underpayments reported before this deadline.[220] As we explained in part 2 of the 2022 Payment Notice (86 FR 24257), under section 1313(a)(6) of the ACA, ''payments made by, through, or in connection with an Exchange are subject to the False Claims Act (31 U.S.C. 3729, *et. seq.*) if those payments include any Federal funds.'' As such, if any issuer has an obligation to pay back APTC or pay additional user fees, the issuer could be liable under the False Claims Act for knowingly and improperly avoiding the obligation to pay. Section 156.1210(c)(3) therefore states that if a payment error is discovered after the 3-year or end of audit reporting deadline as set forth at § 156.1210(c)(1) and (2), the issuer is obligated to notify HHS and the State Exchange (as applicable) and repay any overpayment.

After further consideration of the final deadline for reporting identified data inaccuracies for discovered underpayments, we propose, beginning with adjustments to APTC and user fee payments and collections for 2015 plan year coverage,[221] to remove the alternate deadline currently set forth at § 156.1210(c)(2) to ensure HHS and Exchange processes for handling payment and enrollment disputes related to discovered underpayments are completed before the existing IRS limitation on filing corrected tax returns. We further propose to revise § 156.1210(c) to generally include the final 3-year deadline to identify and report data inaccuracies for discovered underpayments.[222] As such, the first sentence in proposed new § 156.1210(c) would provide that to be eligible for resolution under § 156.1210(b), the issuer must describe all inaccuracies identified in a payment and collections report before the end of the 3-year period beginning at the end of the plan

[219] Underpayment refers to both APTC underpayments to the issuer and user fee overpayments to HHS, for which an issuer would be entitled to additional payment from HHS.

[220] HHS will work with the issuer or the State Exchange (as applicable) to resolve the inaccuracy in these situations as long as the issuer meets other applicable requirements. For example, the issuer must demonstrate that failure to identify the inaccuracy and submit it to HHS or the State Exchange (as applicable) in a timely manner (within the 90-day reporting window under § 156.1210(a)) was not unreasonable or due to the issuer's misconduct or negligence. See 45 CFR 156.1210(b)(2). In addition, once identified, the issuer must notify HHS or the State Exchange (as applicable) within 15 days of identifying the inaccuracy. See 45 CFR 156.1210(b)(1).

[221] The 2014 plan year is excluded because the alternative deadline for reporting inaccuracies closed upon completion of the 2014 audits. See CMS. (2019, April 1). CMS Issuer Audits of the Advanced Payments of the Premium Tax Credit. *www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/2014-CMS-APTC-Audits.PDF.*

[222] See 45 CFR 156.1210(c)(1).

year to which the inaccuracy relates. By requiring all issuers in all Exchanges [223] to adhere to the final 3-year deadline for identifying and reporting discovered underpayments, HHS would be balancing the desire to continue to provide issuers flexibility to identify and report discovered underpayments after the initial 90-day reporting window at § 156.1210(a), to encourage the prompt reporting and timely resolution of data inaccuracies, and to establish a more consistent, predictable, and less operationally burdensome process for the identification and resolution of such inaccuracies for enrollees, issuers, HHS, and State Exchanges.

Under this proposal, and consistent with the deadline currently set forth in § 156.1210(c)(1), for 3 years after the end of the applicable plan year, HHS would accept and work with the issuer (or State Exchange, as applicable) to resolve the identified data inaccuracies for discovered underpayments, and would process resulting payment corrections through policy-level data, which would generate new Forms 1095–A for impacted enrollees', if other applicable requirements are met.[224] Establishing a firm 3-year timeframe to resolve data inaccuracies and make subsequent adjustments for discovered APTC underpayments ensures that new Forms 1095–A are generated and sent to enrollees and filed with the IRS with sufficient time for the enrollee to potentially amend their tax filing with the IRS. This change would therefore provide greater consistency and predictably for enrollees and reduce potential confusion caused by the receipt of Forms 1095–A outside of the allowable re-filing window with the IRS. In addition to reducing enrollee confusion, requiring adherence to a firm 3-year final deadline to report data inaccuracies for discovered APTC underpayments (or user fee overpayments) would also benefit issuers by ensuring a more consistent and predictable timeline for resolution of these data inaccuracies. Aligning the payment and enrollment final dispute timeline with the 3-year Form 1095–A timeline would limit administrative burden on issuers, State Exchanges, and HHS by standardizing these related processes for resolving errors and generating new Forms 1095–A for enrollees.

Under this proposal, beginning with the 2020 plan year coverage, HHS would not pay additional APTC payments or reimburse user fee payments for FFE, SBE–FP, and SBE issuers for data inaccuracies reported after the 3-year deadline. HHS would require issuers to adhere to the 3-year deadline to submit all disputes and address all errors, instead of utilizing the end of the audit process as an alternative timeframe to receive additional APTC or reimbursement of user fee payments beyond the 3-year deadline. Thus, HHS would not accept or take action that results in an outgoing payment on data inaccuracies or payment errors for 2020 plan year coverage that are reported after December 31, 2023. Similarly, HHS would not accept or take action that results in an outgoing payment on data inaccuracies or payment errors for 2021 plan year coverage that are reported after December 31, 2024, and so on.

Additionally, we propose that HHS would not accept or take action that results in an outgoing payment on data inaccuracies or payment errors for the 2015 through 2019 plan year coverage that are reported after December 31, 2023. If finalized, this proposal would grant issuers some additional time after this rule is finalized to submit any inaccuracies for the 2015 through 2019 plan year coverage, for which submission would no longer be permitted if this proposal was effective upon finalization.

We are not proposing any changes to the general framework outlined in § 156.1210(c)(3), which currently states that if a payment error is discovered after the final deadline set forth in § 156.1210(c)(1) and (2), the issuer must notify HHS, the State Exchange, or SBE–FP (as applicable) and repay any overpayments to HHS. We propose to retain this language as the last sentence of new proposed § 156.1210(c), except for the reference to the alternative deadline at § 156.1210(c)(2).

With regard to issuers in State Exchanges, we further affirm that this proposal would not change the requirement that issuers promptly identify and report data inaccuracies to the State Exchange.[225] Under the proposed revisions to § 156.1210(c), issuers in State Exchanges would be subject to the same final 3-year deadline to work with the State Exchange to resolve any enrollment or payment inaccuracies identified after the initial 90-day reporting window for discovered underpayments. Similarly, we also propose that HHS would not make any payments to issuers in State Exchanges on data inaccuracies or payment errors for 2015 through 2019 plan year coverage that are reported after December 31, 2023. Issuers in State Exchanges would also remain subject to the existing requirement to report data inaccuracies identified at any time when related to overpayments. We note that when HHS initially proposed the deadline of 3 years or the date by which the HHS audit process is completed, as currently described at § 156.1210(c), we requested comment on the ability of State Exchanges to resolve data inaccuracies and report payment adjustments to HHS under the 3-year deadline framework currently captured in § 156.1210(c)(1). We did not receive any comments objecting to this timeframe based on the ability of State Exchanges to resolve such disputes, and therefore, believe that the current proposal to set the final deadline to identify and report data inaccuracies for discovered underpayments at 3 years is reasonable and will not pose a challenge to State Exchanges or issuers.

We seek comment on this proposal.

11. Administrative Appeals (§ 156.1220)

As discussed in section III.A.7.d. of this preamble (HHS–RADV Discrepancy and Administrative Appeals Process), we propose amendments to § 156.1220(a)(4)(ii) to add a reference to new proposed § 153.630(d)(3). As discussed in section III.A.7.d of this preamble, under new proposed § 153.630(d)(3), we would retain the 30-calendar-day window to confirm, or file a discrepancy, regarding the calculation of the risk score error rate as a result of HHS–RADV. Under this proposal, the cross-reference to § 153.630(d)(2) in § 156.1220(a)(4)(ii) would be maintained and would capture the new proposed 15-calendar-day window to confirm, or file a discrepancy, for SVA findings (if applicable).

In addition, we propose to amend § 156.1220(b)(1) to address situations when the last day of the period to request an informal hearing does not fall on a business day. In these cases, we propose that the deadline to request an informal hearing would be extended to the next applicable business day. This proposal is consistent with our policy

[223] The requirements captured in 45 CFR 156.1210 apply to all issuers who receive APTC, including issuers in State Exchanges. See part 2 of the 2022 Payment Notice, 86 FR at 24258.

[224] For example, the issuer must demonstrate the failure to identify and promptly report the data inaccuracies and discovered underpayments within the initial 90-day reporting window, under § 156.1210(a), was not unreasonable or due to the issuer's misconduct or negligence. See § 156.1210(b)(2). In addition, once identified, the issuer must notify HHS or the State Exchange (as applicable) within 15 days of identifying the inaccuracy. See § 156.1210(b)(1).

[225] As previously noted, the requirements captured in 45 CFR 156.1210 apply to all issuers who receive APTC, including issuers in State Exchanges. Also see part 2 of the 2022 Payment Notice, 86 FR at 24258.

for other risk adjustment deadlines that do not fall on a business day.[226]

We solicit comment on these proposed amendments.

IV. Collection of Information Requirements

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. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of the agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. Wage Estimates

To derive wage estimates, we generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for the cost of fringe benefits and overhead) for estimating the burden associated with the ICRs.[227] Table 14 in this proposed rule presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 14: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr.)	Fringe Benefits and Overhead ($/hr.)	Adjusted Hourly Wage ($/hr.)
Business Operations Specialist	13-1199	$38.10	$38.10	$76.20
General and Operations Manager	11-1021	$55.41	$55.41	$110.82
Management Analyst	13-1111	$48.33	$48.33	$96.66
Insurance Sales Agent	41-3021	$33.34	$33.34	$66.68
Computer and Information Systems Manager	11-3021	$78.33	$78.33	$156.66
Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	43-6014	$19.75	$19.75	$39.50

B. ICRs Regarding Repeal of Risk Adjustment State Flexibility To Request a Reduction in Risk Adjustment State Transfers (§ 153.320(d))

We propose to repeal the flexibility for any State, including prior participant States, to request a reduction in risk adjustment State transfers in all State market risk pools beginning with the 2025 benefit year. As such, we propose several amendments to § 153.320(d).

The burden currently associated with this requirement is the time and effort for the State regulator to submit its request and supporting evidence and analysis to HHS. In the Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment information collection (OMB control number: 0938–1155), we estimated that submitting the request and supporting evidence and analysis would take a business operations specialist 40 hours (at a rate of $76.20 per hour) to prepare the request and 20 hours for a senior operations manager (at a rate of $110.82 per hour) to review the request and transmit it electronically to HHS. We estimated that each State seeking a reduction would incur a burden of 60 hours at a cost of approximately $5,264.40 per State to comply with this reporting requirement (40 hours for the operations specialist and 20 hours for the operations manager).

Since this proposal would eliminate the ability of the one prior participating State (Alabama) to request this flexibility beginning with benefit year 2025, we similarly propose to rescind this information collection beginning with the 2025 benefit year. The burden associated with this information collection estimated above would be removed if this proposal is finalized, since no State would have the opportunity to request this flexibility moving forward. This information collection is approved under OMB control number 0938–1155, and if this proposal is finalized, HHS would rescind the information collection under OMB control number 0938–1155 accordingly and provide the applicable comment periods once the policy is no longer in effect.

We seek comment on this proposed rescission.

C. ICRs Regarding Risk Adjustment Issuer Data Submission Requirements (§§ 153.610, 153.700, and 153.710)

We propose to require issuers to collect and make available for HHS' extraction from issuers' EDGE servers a new data element, a QSEHRA indicator. We propose to adopt the same transitional approach and schedule for the population of the QSEHRA indicator as was finalized for the ICHRA indicator in the 2023 Payment Notice. Under this proposal, for the 2023 and 2024 benefit years, issuers would be required to populate the QSEHRA indicator using

[226] See, for example, 45 CFR 153.730.

[227] See May 2021 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at *https://www.bls.gov/oes/current/oes_stru.htm.*

data they already collect or have accessible regarding their enrollees. Then, beginning with the 2025 benefit year, issuers that do not have an existing source to populate this field for particular enrollees would be required to make a good faith effort to collect and submit the QSEHRA indicator for these enrollees. We propose to extract this data element beginning with the 2023 benefit year and also propose to include the QSEHRA indicator in the enrollee-level EDGE limited data sets available to qualified researchers upon request, once available.

We propose to begin collection of the QSEHRA indicator with the 2023 benefit year, and estimate that approximately 650 issuers of risk adjustment covered plans would be subject to this data collection. We propose to collect a QSEHRA indicator from issuers' ESES files and risk adjustment recalibration enrollment files. We believe the burden associated with the collection of this data would be similar to that of the collection of ICHRA indicator finalized in the 2023 Payment Notice. Much like the ICHRA indicator data, we believe that some issuers already collect or have access to the relevant information to populate the QSEHRA indicator. However, we do not believe the information to populate the QSEHRA indicator is routinely collected by all issuers at this time; therefore, we anticipate that there may be administrative burden for some issuers in developing processes for collection, validation, and submission of this new data element. In recognition of the burden that collection of this new data element potentially would pose for some issuers, we propose to adopt a transitional approach for the QSEHRA indicator that mirrors the approach finalized for the ICHRA indicator in the 2023 Payment Notice and is similar to how we have handled other new data collection requirements.[228] For successful EDGE server data submission, each issuer would need to update their file creation process to include the new data element, which would require a one-time administrative cost. After incorporating the most recently updated wage estimate data, we estimate this one-time administrative cost at $579.96 per issuer (reflecting 6 hours of work by a management analyst at an average hourly rate of $96.66 per hour). Based on this, we estimate the cumulative one-time cost to update issuers' file creation process to be $376,974 for 650 issuers (3,900 total hours for all issuers). We also estimate a cost of $96.66 in total annual labor costs for each issuer which reflects 1 hour of work by a management analyst per issuer at an average hourly rate of $96.66 per hour. Based on this, we estimate $62,829 in total annual labor costs for 650 issuers (650 total hours per year for all issuers). We believe that this proposed data collection should not pose significant additional operational burden to issuers given that the operational burden associated with populating the QSEHRA indicator should be aided by the requirement finalized in the 2023 Payment Notice mandating the collection of the ICHRA indicator in the same fashion. The proposed extraction of the new proposed QSEHRA indicator should also not pose additional burden to issuers since the creation and storage of the extract—which issuers do not receive—are mainly handled by HHS. If finalized, HHS would revise the information collection request to account for the burden associated with this policy, and would provide the applicable comment periods.[229]

We also propose to amend the applicability date for the extraction of the plan ID and rating area data elements to extend the extraction of these two data elements to the 2017, 2018, 2019 and 2020 benefit year data sets. As detailed earlier and in prior rulemakings, issuers have been required to collect and submit these two data elements as part of the required risk adjustment data since the 2014 benefit year. Therefore, HHS estimates that the proposal to extract these data elements would not pose additional operational burden to the majority of issuers, since the creation and storage of the extract—which issuers do not receive—is mainly handled by HHS. However, some issuers may not have benefit year 2017, 2018, 2019, or 2020 data readily available for extraction from their EDGE servers, and therefore, there may be some burden associated with restoring past years' data to their respective EDGE servers should this be the case. Our intention with this policy proposal is to limit the burden on issuers for us to collect and extract the plan ID and rating area data elements from additional prior benefit year data. Therefore, while we broadly solicit comment on these data collection proposals, we specifically solicit comments on this burden estimate and ways that we can further limit the burden on extracting these two data elements from the 2017, 2018, 2019 and 2020 benefit year data sets.

D. ICRs Regarding Risk Adjustment Data Validation Requirements When HHS Operates Risk Adjustment (HHS–RADV) (§ 153.630)

Under § 153.630(g)(2), issuers below a materiality threshold, as defined by HHS, are exempt from the annual HHS–RADV audit requirements in § 153.630(b). While these issuers are exempt from the annual HHS–RADV audit process, they are subject to random and targeted sampling such that they undergo HHS–RADV approximately every 3 years (barring any risk-based triggers based on experience that would warrant more frequent audits). We propose, beginning with 2022 benefit year HHS–RADV, to change the materiality threshold from $15 million in total annual premiums Statewide in the benefit year being audited to 30,000 BMM Statewide in the benefit year being audited.

We estimate that this proposal will not significantly impact issuer burden relative to previous estimates for HHS–RADV and the current materiality threshold. In particular, the proposed threshold will not significantly alter the anticipated number of issuers that would fall under the materiality threshold and be subject to random and targeted sampling rather than the annual audit requirements. We estimate that each year, on average, there are 197 issuers of risk adjustment covered plans with total annual Statewide premiums below $15 million and 201 issuers of risk adjustment covered plans below 30,000 BMM Statewide. If we assume one-third of issuers below the materiality threshold would be subject to HHS–RADV each year, we estimate that the total number of issuers selected for HHS–RADV that fall under the materiality threshold would remain fairly constant. We believe that the number of issuers participating in HHS–RADV for any given benefit year under the proposed 30,000 BMM Statewide threshold will not be significantly different than the number of issuers participating under the current $15 million total annual premium Statewide threshold and reflected in our current HHS–RADV burden estimates, and therefore, we believe that there will not be an overall increase or decrease in burden. If finalized, we would revise the information collection currently approved under OMB control number 0938–1155 to account for the changes to

[228] For example, HHS did not penalize issuers for temporarily submitting a default value for the in/out-of-network indictor for the 2018 benefit year to give issuers time to make the necessary changes to their operations and systems to comply with the new data collection requirement, but required issuers to provide full and accurate information for the in/out-of-network indicator beginning with the 2019 benefit year.

[229] Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment (OMB control number 0938–1155).

the HHS definition for the materiality threshold in § 153.630(g)(2).

E. ICRs Regarding Navigator, Non-Navigator Assistance Personnel, and Certified Application Counselor Program Standards (§§ 155.210 and 155.225)

This proposal would not impose any new information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Though CMS requires Navigator grantees to track enrollment numbers on weekly, monthly, and quarterly progress reports, this is already accounted for in an existing PRA package (OMB control number 0938–1205, Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel—CAC), and they are not required to specifically track enrollments completed for door-to-door enrollments.

F. ICRs Regarding Providing Correct Information to the FFEs (§ 155.220(j))

As discussed in the preamble of this proposed rule, we are proposing amendments to § 155.220(j)(2)(ii) to require agents, brokers, and web-brokers to document that eligibility application information has been reviewed by and confirmed to be accurate by the consumer or their authorized representative prior to application submission. This proposal would require the consumer or their authorized representative to take an action that produces a record that they reviewed and confirmed the information on the eligibility application to be accurate prior to application submission. This documentation would be required to be maintained by agents, brokers, and web-brokers for a minimum of 10 years and produced upon request in response to monitoring, audit, and enforcement activities.

We estimate costs will be associated with this proposal, including those related to documenting, maintaining, and producing the documentation. Our proposal, if finalized, would not mandate any method or prescribe a template for documenting that a consumer or their authorized representative reviewed and confirmed the accuracy of their eligibility application information. It would be up to the agents, brokers, and web-brokers to determine the best way to meet these proposed regulatory requirements.

Costs related to requiring the consumer take some affirmative action to memorialize the review of application information are as follows. We estimate it would take an additional 5 minutes for an enrolling agent, broker, or web-broker to obtain documentation from a consumer or their authorized representative that they have reviewed and confirmed the accuracy of their application information. Billing at $66.68 per hour using the Insurance Sales Agent occupation code, each enrollment will have approximately $5.33 additional cost associated with it based on extra time commitment. In PY 2021, agents submitted 3,630,849 policies. This makes the yearly total cost associated with the extra time per enrollment approximately $19,352,425.17 (3,630,849 × $5.33).

Costs associated with maintaining consumer or their authorized representative's documentation would depend on the method selected by the agent, broker, or web-broker to meet the regulatory requirements. For those agents, brokers, or web-brokers currently meeting the requirements, no additional costs would be incurred. If an enrolling entity opts to use paper for documentation, they would bear the costs of paper, ink and filing cabinets to store the paperwork.

HHS would only require an agent, broker, or web-broker to produce retained records in limited circumstances related to monitoring, audit, and enforcement activities. In instances of fraud investigation, HHS typically asks for documentation associated with approximately 10 different applications, generally from the past 2 to 3 years. We estimate it would take an agent approximately 2 hours to gather consumer documentation for 10 applications. Each year, HHS generally investigates approximately 50 agents, brokers, or web-brokers. Therefore, we estimate the yearly cost of producing documentation for HHS to be approximately $6,668 (($66.68 hourly rate × 2 hours) × 50). The documentation would be able to be mailed electronically, so there would be no cost associated with printing or mailing the documentation. Agency-wide audits are not completed often by HHS but may become more widespread. In those instances, HHS would ask the agency to produce a certain number of records from the past 10 years.

We seek comment on these burden estimates.

G. ICRs Regarding Documenting Receipt of Consumer Consent (§ 155.220(j))

As discussed earlier in the preamble of this proposed rule, we are proposing amendments to § 155.220(j)(iii) to require agents, brokers, and web-brokers to document the receipt of consumer consent. This proposal would require the consumer or their authorized representative to take an action that produces a record that they provided consent. Agents, brokers, and web-brokers would be required to maintain the records for a minimum of 10 years and produce the records upon request in response to monitoring, audit, and enforcement activities.

We estimate costs will be associated with this proposal, including those related to documenting, maintaining, and producing the records of consumer consent. Our proposal, if finalized, would not mandate any method or prescribe a template for documenting receipt of consumer consent. It would be up to the agents, brokers, and web-brokers to determine the best way to meet these proposed regulatory requirements. As agents, brokers, and web-brokers are currently required to obtain consumer consent prior to assisting them, the requirement to obtain consent would not add any costs to the enrolling agent, broker, or web-broker.

Costs related to requiring that the consumer or their authorized representative take some affirmative action to memorialize that consent was provided are as follows. We estimate it would take about 5 minutes for an enrolling agent, broker or web-broker to obtain consumer, or their authorized representative, affirmation of their consent. Using the adjusted hourly wage rate of $66.68 for an Insurance Sales Agent, each enrollment will have approximately $5.33 in additional cost associated with it based on the extra time commitment from these proposed policy changes. In PY 2021, agents submitted 3,630,849 policies. Based on this number of enrollments, the total annual burden is 290,468 hours with a total annual cost of $19,352,425.17. HHS would only require an agent, broker, or web-broker to produce retained records in limited circumstances related to fraud investigation or agency audits. In instances of fraud investigation, HHS typically asks for consent records of approximately 10 different applications, generally from the past 2 to 3 years. We estimate it would take an agent approximately 2 hours to gather consent documentation for 10 applications. Each year, HHS generally investigates approximately 50 agents, brokers, or web-brokers. Therefore, we estimate the yearly cost of producing consumer consent documentation to HHS to be approximately $6,668 (($66.68 hourly rate × 2 hours) × 50). These records are able to be mailed electronically, so there would be no cost associated with printing or mailing the records. Agency-wide audits are not completed often by HHS but may become more widespread.

In those instances, HHS would ask the agency to produce a certain number of records from the past 10 years.

The estimated total annual cost of memorializing the documentation of consumer consent is $19,352,425.17, and the estimated total cost of producing the retained eligibility and consent records is $6,668.00. Combined, the total annual cost of the proposed information collection requirements is $19,359,093.17.

We seek comment on these burden estimates.

H. ICRs Regarding Failure To File and Reconcile Process (§ 155.305(f))

We are proposing to amend current regulation at § 155.305(f)(4) under which an Exchange may not find a consumer eligible for APTC where a consumer has failed to file a tax return reconciling their APTC for a previous year to provide more flexibility to Exchanges to ensure that consumers are complying with the requirement to file their Federal income tax returns and reconcile past year's APTC, while ensuring continuity of coverage in Exchange QHPs. We are proposing to provide Exchanges the option to end APTC after 1 year of a taxpayer's (or taxpayer's spouse, if married) failure to file and reconcile APTC, or only after two consecutive years of a taxpayer's failure to file and reconcile APTC.

On Exchanges on the Federal platform, FTR would otherwise be conducted in the same as manner it had previously been conducted, with minimal changes to the language of the Exchange application questions necessary to obtain relevant information; as such, we anticipate that the proposed amendment will not impact the information collection (OMB control number 0938–1191) burden for consumers.

I. ICRs Regarding Income Inconsistencies (§§ 155.315 and 155.320)

Section 155.320 requires the Exchange to generate an income DMI and proceed with the process in § 155.315(f)(1) through (4) when there is no IRS data available to verify attested projected annual household income or when such IRS data available but it is inconsistent with the projected annual household income attestation. In order to verify an applicant or enrollee's attested projected annual household income to determinate eligibility for APTC and CSRs, an applicant generally must mail or upload documentation which must then be reviewed by an HHS eligibility support staffer. We propose to amend § 155.320 to require Exchanges to accept attestation when the Exchange requests tax return data from the IRS to verify attested projected annual household income, but the IRS confirms there is no such tax return data available.

Based on historical DMI data, we estimate that HHS would conduct document verification for 1.2 million fewer households per year. Once households have submitted the required verification documents, we estimate that it takes approximately 12 minutes for an eligibility support staff person (occupation No. 43–4061), at an hourly cost of $46.70, to review and verify submitted verification documents. The proposed revisions to § 155.320 would result in a decrease in annual burden for the Federal Government of 240,000 hours at a cost of $11,208,000.

In addition to the reduced administrative burden for HHS eligibility support staff, the proposed change would reduce the time consumers spend submitting documentation to verify their income. We estimate that consumers each spend 1 hour to submit documentation and that the proposed change would decrease burden on consumers by 1.2 million hours per year.

We would revise the information collection currently approved under OMB control number 0938–1207 (Medicaid and Children's Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment) to account for this decreased burden. Given that this change entails a reduction in consumer burden, the 30-day notice soliciting public comment will be published in the **Federal Register** at a future date.

J. ICRs Regarding the Improper Payment Pre-Testing and Assessment (IPPTA) for State Exchanges (§§ 155.1500–155.1515)

As described in the preamble to § 155.1510, the IPPTA is proposed to replace the existing voluntary State engagement initiative with mandatory participation and related requirements. The IPPTA is designed to test processes and procedures that support HHS's review of determinations of APTC made by State Exchanges and to prepare State Exchanges for the planned measurement of improper payments.

In the preamble to § 155.1510(a)(1), we propose that State Exchanges provide to HHS: (1) the State Exchange's data dictionary including attribute name, data type, allowable values, and description; (2) an entity relationship diagram; and (3) business rules and related calculations. This data documentation is currently retained by State Exchanges in a digital format and can be electronically transmitted to HHS. We estimate that the burden associated with this data transfer would be no more than 22 hours.

In the preamble to § 155.1510(a)(2), we propose that HHS will provide State Exchanges with the pre-testing and assessment data request form. HHS proposes to review the form and its instructions with each State Exchange prior to the State Exchange completing and returning the form and required data to HHS. Both the pre-testing and assessment data request form and the requested source data are in an electronic format. The burden associated with completion and return of the pre-testing and assessment data request form and required data would be the time it would take each State Exchange to meet with HHS to review the form and its requirements, analyze and design the database queries based on the data elements identified in the form, electronically transmit the data to HHS, and meet with HHS to verify and validate the data.

We expect respondent costs will not substantially vary since the data being collected is largely in a digitized format and that each State Exchange will be providing the application data and consumer submitted documents for approximately 10 tax households. We seek comment on these assumptions.

We estimate that gathering and transmitting the data documentation as specified in § 155.1510(a)(1) and completion of the pre-testing and assessment data request form as specified in § 155.1510(a)(2) would take 530 hours per respondent at an estimated cost of $56,986.48 per respondent. To compile our estimates, we referenced our experience collecting data in our FFE pilot initiative and in working with State Exchanges in the existing voluntary State engagement initiative. We identified specific personnel and the number of hours that would be involved in collecting the data broken down by specific area (for example, eligibility verification, auto-re-enrollment, periodic data matching, enrollment reconciliation, plan management, and manual reviews including document retrieval).

Hourly wage rates vary from $92.92 for a Computer Programmer to $156.66 for a Computer and Information Systems Manager depending on occupation code and function. With a mean hourly rate of $111.07 for the respective occupation codes, the burden across the 18 State Exchanges equals 9,540 hours for a total

cost of up to $1,025,756. We seek comment on these burden estimates.

K. ICRs Regarding QHP Rate and Benefit Information (§ 156.210)

a. Age on Effective Date for SADPs

In this proposed rule, we propose to require issuers of Exchange-certified stand-alone dental plans (SADPs), whether they are sold on- or off-Exchange, to use the age on effective date methodology as the sole method to calculate an enrollee's age for rating and eligibility purposes, as a condition of QHP certification, beginning with Exchange certification for PY 2024. This rule does not propose to alter any of the information collection requirements related to age determination for rating and eligibility purposes during the QHP certification process in a way that would create any additional costs or burdens for issuers seeking QHP certification. This information collection is currently approved under OMB control number 0938–1187.

b. Guaranteed Rates for SADPs

The proposal to require issuers of Exchange-certified SADPs, whether they are sold on- or off-Exchange, to submit guaranteed rates, as a condition of Exchange certification beginning with Exchange certification for PY 2024, will not impose an additional burden on issuers. Exchange-certified SADP issuers already submit either guaranteed or estimated rates during QHP certification, and are therefore, familiar with the QHP certification rate submission process. This information collection is currently approved under OMB control number 0938–1187.

L. ICRs Regarding Establishing a Timeliness Standard for Notices of Payment Delinquency (§ 156.270)

The proposal to add a timeliness standard to the requirement for QHP issuers to send enrollees notice of payment delinquency would not impose an additional information burden on issuers. Per § 156.270(f), issuers are already required to send notices to enrollees when they become delinquent on premium payments, and this proposal would not require any additional information collection. We are merely proposing to add a requirement that issuers send these notices promptly and without undue delay. This information collection is currently approved under OMB control number 0938–1341 (CMS–10592).

M. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 15: Proposed Annual Recordkeeping and Reporting Requirements

Regulation Section(s)	OMB Control Number	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($)	Total Cost ($)
§ 153.320(d)	0938-1155	-1	-1	-60	-60	-$5,264.40	-$5,264.40
§§ 153.610, 153.700, and 153.710	0938-1155	650	650	1	650	$62,829	$62,829
§ 155.220(j)	0938-NEW	50	50	2	100	$6,668	$6,668
§ 155.220(j)	0938-NEW	3,630,849	3,630,849	0.08	290,467.92	$19,352,425.17	$19,352,425.17
§ 155.320	0938-1207	-1,200,000	-1,200,000	-0.2	-240,000	-$11,208,000	-$11,208,000
§ 155.1510	0938-NEW	18	18	530	9,540	$1,025,756	$1,025,756
TOTAL		2,431,566	2,431,566		60,697.92	$9,234,413.77	$9,234,413.77

This proposed rule includes one proposal—repealing risk adjustment State flexibility to request a reduction in risk adjustment State transfers (§ 153.320(d))—with information collection requests which seeks to use this rulemaking as the **Federal Register** notice through which to receive comment on its proposed revisions to the associated PRA package.

The following proposals with associated information collection requests will be submitted for PRA approval outside of this rulemaking, through separate **Federal Register** notices: risk adjustment issuer data submission requirements (§§ 153.610, 153,700, and 153.710); and income inconsistencies (§ 155.320).

The HHS–RADV, Navigator, FTR, application to SADPs, and QHP rate and benefit information proposals contain information collections which are covered by the following PRA packages: Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment, OMB control number: 0938–1155; Cooperative Agreement to Support Navigators in Federally-facilitated and State Partnership Exchanges, OMB control number: 0938–1215; Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Health Benefits Exchanges, Medicaid and CHIP Agencies, OMB control number: 0938–1191; Initial Plan Data Collection to Support QHP Certification and other Financial Management and Exchange Operations, OMB control number: OMB 0938–1187; and Establishment of Qualified Health Plans and American Health Benefit Exchanges, OMB control number: 0938–1156.

N. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB. To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule and identify the rule (CMS–9899–P), the ICR's CFR citation, CMS ID number, and OMB control number.

Comments must be received on/by February 13, 2023.

V. Regulatory Impact Analysis

A. Statement of Need

This rule proposes to improve risk adjustment and HHS–RADV policies to use the most recent data to recalibrate the risk adjustment models and reduce operational burden for HHS–RADV, and to update Navigator standards to permit door-to-door and other unsolicited means of direct contact. The rule also proposes to require agents, brokers, and web-brokers to provide correct consumer information and document consumer consent; and require Exchanges on the Federal platform to accept an applicant's or enrollee's attestation of projected annual household income when IRS data is not available and determine the applicant or enrollee eligible for APTC or CSRs in accordance with the applicant's or enrollee's attested projected household income. In addition, the rule proposes to implement the IPPTA, reduce 2024 user fee rates to 2.5 percent of premiums for FFE issuers and 2.0 percent of premiums for SBE–FP issuers, and make minor updates to standardized plan options and limit the number of non-standardized plan options issuers can offer. Finally, the rule proposes to require that QHP plan marketing names include correct information, without omission of material fact, and do not include content that is misleading; revise the network adequacy and ECP standards §§ 156.230 and 156.235 to state that all QHP issuers, including SADPs, must use a network of providers that complies with the standards described in those sections; expand access to care for low-income and medically underserved consumers by strengthening ECP standards for QHP certification; and add a timeliness standard to the requirement for QHP issuers to send enrollees notice of payment delinquency.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999).

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 significant regulatory action/s and/or with economically significant effects ($100 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold. Accordingly, we have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 16 showing the classification of the impact associated with the provisions of this proposed rule.

This proposed rule proposes standards for programs that will have numerous effects, including providing consumers with access to affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify all benefits and costs of this proposed rule. The effects in Table 16 reflect qualitative assessment of impacts and estimated direct monetary costs and transfers resulting from the provisions of this proposed rule for health insurance issuers and consumers. The annual monetized transfers described in Table 16 include changes to costs associated with the risk adjustment user fee paid to HHS by issuers.

We are proposing the risk adjustment user fee of $0.21 PMPM for the 2024 benefit year to operate the risk adjustment program on behalf of States,[230] which we estimate to cost approximately $60 million in benefit year 2024. This estimated total cost remains stable with the approximately $60 million estimated for the 2023 benefit year.

Additionally, for 2024, we are proposing an FFE and SBE–FP user fee rate of 2.5 and 2.0 percent of premiums, respectively. These user fee rates are lower than the 2023 FFE and SBE–FP user fee rates of 2.75 and 2.25 percent of premiums, respectively.

For our proposed implementation of the IPPTA program, we estimate record keeping costs for data submission to be approximately $1,025,756 beginning in PY 2024.

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[230] As noted previously in this proposed rule, no State has elected to operate the risk adjustment program for the 2024 benefit year; therefore, HHS will operate the risk adjustment program for all 50 States and the District of Columbia.

TABLE 16: Accounting Table

Benefits:	Estimate	Year Dollar	Discount Rate	Period Covered	
Annualized Monetized ($/year)	$79.52 Million		2022	7 percent	2023-2027
	$81.16 Million		2022	3 percent	2023-2027

Quantitative:

- Reduction of $5,264.40 in reporting costs associated with repealing the ability of prior participant States to request a reduction in risk adjustment State transfers starting with the 2025 benefit year.
- Annual cost savings of approximately $66 million to the Federal Government and $37 million to State Exchanges as a result of the proposed revisions to income DMIs beginning in 2024.

Qualitative:

- Improved review of rebuttal evidence and reconsideration requests based on the proposal to increase the review period for agent, broker, or web-broker suspensions or terminations to 60 days.
- Requiring a consent recordation will reduce the number of unauthorized enrollments and help resolve disputes between enrolling entities and consumers, as well as between enrolling entities.
- Requiring enrolling entities to confirm information prior to submitting an application will help reduce the number of incorrect DMIs.
- Improved consumer experience by amending the hierarchy for re-enrollment to facilitate enrollment into lower cost, higher generosity plans.
- Improved continuity of care by including provider networks in re-enrollment determinations when the enrollee's current plan is no longer available.
- Improved consumer experience as a result of reduced choice overload due to the proposal to limit the number of non-standardized plan offerings.
- Increased access to continuous health insurance coverage for individuals who qualify for a special enrollment period due to attesting to a future loss of MEC, associated with the proposal to allow earlier effective dates for individuals qualifying for such special enrollment periods.
- Increased access to continuous health insurance coverage for individuals losing Medicaid or CHIP who qualify for a special enrollment period with 60 days before or 90 days after to report such loss of MEC to an Exchange.
- Potential direct benefit of reducing improper payments, with secondary effects including a boost of issuer confidence in State Exchanges, through implementation of the proposed IPPTA.
- Reduced burden on consumers and assisters due to the proposal to require QHP plan marketing names to include correct information without omission of material fact and to not include misleading content.
- Potential increased access to coverage associated with the proposal to add a timeliness standard for payment delinquency notices for enrollees who become delinquent on premium payments by ensuring they are properly informed of their delinquency in time to avoid losing coverage.
- Increased access to more comprehensive provider networks due to the network adequacy and ECP proposals, which would better ensure that individuals have reasonable, timely access to an adequate number, type, and distribution of providers and facilities to manage their health care needs.

Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	$710.84 Million	2022	7 percent	2023-2027
	$721.71 Million	2022	3 percent	2023-2027

Quantitative:

- Cumulative additional cost estimate for the collection of one new data element for risk adjustment estimated to be approximately $62,829 annually for 650 issuers beginning in 2024, plus a one-time cost of $376,974 in 2024 to update their data collection processes to begin collecting this new data element.
- Increased APTC expenditures of $373 million per coverage year beginning in benefit year 2024 due to FTR proposal to not determine an enrollee ineligible for APTC until after two consecutive years.
- One-time costs of approximately $6.6 million in benefit year 2024 to five State Exchanges that have not fully implemented the infrastructure to run FTR operations, with annual costs to maintain FTR operations of approximately $10 million beginning in 2024.
- Recordkeeping costs incurred by State Exchanges related to IPPTA, estimated to be a total, one-time cost of approximately $1.025 million across all 18 State Exchanges during calendar years 2024 and 2025.

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• One-time cost of $500,000 in 2023 for HHS to implement a 60-day extension for households with income DMIs for Exchanges on the Federal platform and $9 million for State Exchanges to implement 60-day extension. • One-time cost of $500,000 in 2023 for HHS to accept attestation for households without IRS data for Exchanges on the Federal platform and $9 million for State Exchanges to implement accepting attestation for households without IRS data. • Increased costs of $175 million per year starting in 2024 associated with increased APTC expenditures due to the income DMI proposals. • Increased costs of $161 million per coverage year beginning in 2023 associated with increased APTC expenditures due to the proposal to modify current coverage effective date rules for qualifying individuals who qualify for a special enrollment period due to a future loss of MEC for Exchanges on the Federal platform. • Increased costs of $98 million per coverage year beginning in 2024 associated with increased APTC expenditures due to the proposal to add a new special rule permitting Exchanges on the Federal platform to allow consumers up to 60 days before and up to 90 days after to report a loss of Medicaid or CHIP. • Increased costs of $48 million per year beginning in 2024 with increased APTC spending due to the proposal to amend the re-enrollment hierarchy to allow Exchanges to direct re-enrollment for enrollees who are eligible for CSR in accordance with § 155.305(g) from a bronze QHP to a silver QHP with a lower or equivalent premium after APTC provided certain conditions are met.				
Qualitative: • Under the proposed limits to the number of non-standardized plan options that issuers of QHPs can offer through the FFEs and SBE-FPs, we estimate that approximately 60,949 of a total of 106,037 non-standardized plan option plan-county combinations (57 percent) would be discontinued in PY 2024. Relatedly, we estimate that approximately 2.72 million of the 10.21 million total enrollees on the FFEs and SBE-FPs (26.6 percent of total enrollees) would be affected by these discontinuations. • Increase in administrative burden to State Exchanges that choose to adopt the proposal to prohibit issuers from terminating coverage for policy dependent enrollees because they reached the maximum allowable age mid-plan year. • Potential administrative burden on issuers to comply with new plan marketing name standards and on SBE-FPs to support and enforce these new standards. • Increased burden for plans that do not currently use a provider network and wish to remain in the Exchanges to comply with the proposal to require all QHPs and SADPs to use a network and comply with the network adequacy standards at § 156.235 beginning with plan year 2024. • Increased burden to consumers, agent/brokers, and assisters to change enrollment to another plan if a consumer's current plan does not use a provider network and exits the Exchanges due to the proposal that all QHPs and SADPs use provider networks beginning with plan year 2024.				
Transfers:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	-$142.09 Million	2022	7 percent	2023-2027
	-$147.35 Million	2022	3 percent	2023-2027
Quantitative: • Reduction in FFE and SBE-FP user fee transfers from issuers to the Federal Government of $74 million for benefit year 2024 compared to the prior benefit year. We estimate additional reductions in FFE and SBE-FP user fee transfers from issuers to the Federal Government of $147 million in 2025, $317 million in 2026, and $219 million in 2027 if this user fee level were maintained in subsequent years. •				

This RIA expands upon the impact analyses of previous rules and utilizes the Congressional Budget Office's (CBO) analysis of the ACA's impact on Federal

spending, revenue collections, and insurance enrollment. Table 17 summarizes the effects of the risk adjustment program on the Federal budget from fiscal years 2024 through 2028, with the additional, societal effects of this proposed rule discussed in this RIA. We do not expect the provisions of this proposed rule to significantly alter CBO's estimates of the budget impact of the premium stabilization programs that are described in Table 17.[231]

TABLE 17: Estimated Federal Government Outlays and Receipts for the Risk Adjustment and Reinsurance Programs from Fiscal Year 2024-2028, in billions of dollars[231]

Year	2024	2025	2026	2027	2028	2024-2028
Risk Adjustment and Reinsurance Program Payments	6	7	7	8	8	36
Risk Adjustment and Reinsurance Program Collections	6	7	7	8	8	36

Note: Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time. Source: Congressional Budget Office. Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2022 to 2032. Table A-2. June 30, 2022. https://www.cbo.gov/system/files/2022-06/57962-health-insurance-subsidies.pdf.

1. Data for Risk Adjustment Model Recalibration for 2024 Benefit Year

We propose to use the 2018, 2019, and 2020 benefit year enrollee-level EDGE data to recalibrate the 2024 benefit year risk adjustment models with an exception for the use of the 2020 benefit year to recalibrate the age-sex coefficients for the adult models. Specifically, we propose to use only 2018 and 2019 benefit year enrollee-level EDGE data to recalibrate the age-sex coefficients in the adult models to account for the observed anomalous decreases in the unconstrained coefficients for the 2020 benefit year enrollee-level EDGE data for older adult enrollees, especially older female adult enrollees. Consistent with the approach outlined in the 2020 Payment Notice to no longer rely upon MarketScan® data for recalibrating the risk adjustment models, under this proposal, we would continue to recalibrate the risk adjustment models for the 2024 benefit year using only enrollee-level EDGE data, and would continue to use blended, or averaged, coefficients from the 3 years of separately solved models for the 2024 benefit year model recalibration, with the noted exception for recalibration of the adult models' age-sex factors. This approach seeks to maintain stability in the markets, and therefore, we anticipate that this proposal would have minimal impact on risk scores and transfers for issuers in the individual and small group (including merged) markets.

2. Repeal of Risk Adjustment State Flexibility To Request a Reduction in Risk Adjustment State Transfers (§ 153.320(d))

We propose to eliminate the flexibility for any State, including prior participant States, to request reductions of risk adjustment State transfers calculated by HHS under the State payment transfer formula beginning with the 2025 benefit year. We anticipate that this change would have a minimal impact as only one State, Alabama, is considered a prior participant and would no longer be able to request reductions in risk adjustment transfers if this policy is finalized.

3. Risk Adjustment Issuer Data Requirements (§§ 153.610, 153.700, and 153.710)

We are also proposing the collection and extraction of a new data element, the QSEHRA indicator, as part of the required risk adjustment data submissions issuers make accessible to HHS through their respective EDGE servers. For the 2023 and 2024 benefit years, similar to the transitional approach finalized for the ICHRA indicator, issuers would be required to populate the field for the QSEHRA indicator using only data they already collect or have accessible regarding their enrollees. Then, beginning with the 2025 benefit year, the transitional approach would end, and issuers would be required to populate the field using available sources (for example, information from Exchanges, and requesting information directly from enrollees) and, in the absence of an existing source for particular enrollees, to make a good faith effort to ensure collection and submission of the QSEHRA indicator for these enrollees. HHS would provide additional details on what constitutes a good faith effort to ensure collection and submission of the QSEHRA indicator beginning with 2025 benefit year data submissions in the future. An updated burden estimate associated with this policy may be found in section IV of this proposed rule, in the *ICRs Regarding Risk Adjustment Issuer Data Submission Requirements (§§ 153.610, 153.700, and 153.710)* section earlier in this rule.

In addition, we propose to extract the plan ID and rating area data elements from issuers' EDGE servers that issuers already make accessible to HHS as part of the required risk adjustment data for additional prior benefit years of data. Specifically, we propose to amend the applicability date for the extraction of these two data elements from issuers' enrollee-level EDGE data as finalized in the 2023 Payment Notice to also allow extraction of these data elements from the 2017, 2018, 2019 and 2020 benefit year data.

4. Risk Adjustment User Fee for 2024 Benefit Year (§ 153.610(f))

For the 2024 benefit year, HHS will operate a risk adjustment program in every State and the District of Columbia. As described in the 2014 Payment Notice (78 FR 15416 through 15417), HHS' operation of risk adjustment on behalf of States is funded through a risk adjustment user fee. For the 2024 benefit year, we propose to use the same methodology to estimate our

[231] Reinsurance collections ended in FY 2018 and outlays in subsequent years reflect remaining payments, refunds, and allowable activities.

administrative expenses to operate the risk adjustment program as was used in the 2023 Payment Notice. Risk adjustment user fee costs for the 2024 benefit year are expected to remain stable from the prior 2023 benefit year estimates. However, we project higher enrollment than our prior estimates in the individual and small group (including merged) markets in the 2023 and 2024 benefit years due to the enactment of the ARP,[232] and section 12001 of the IRA, which extended the enhanced PTC subsidies in section 9661 of ARP through the 2025 benefit year. We estimate that the total cost for HHS to operate the risk adjustment program on behalf of States and the District of Columbia for 2024 will be approximately $60 million, and therefore, the proposed risk adjustment user fee would be $0.21 PMPM. Because enrollment projections have increased for the 2023 and 2024 benefit year due to the IRA and the proposed 2024 risk adjustment user fee is $0.01 PMPM lower than the 2023 user fee, we expect the proposed risk adjustment user fee for the 2024 benefit year to reduce the transfer amounts collected or paid by issuers of risk adjustment covered plans.

5. Risk Adjustment Data Validation Requirements When HHS Operates Risk Adjustment (HHS–RADV) (§ 153.630)

We propose, beginning with 2022 benefit year HHS–RADV, to change the HHS definition for the materiality threshold for the HHS–RADV exemption under § 153.630(g)(2) from $15 million total annual premiums Statewide to 30,000 BMM Statewide in the benefit year being audited. The purpose of this policy is to address the estimated increase in costs to complete the IVA over the years and to ensure the materiality threshold is not eroded as costs increase. We quantify this increase in IVA cost in the Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeal of the PRA (OMB Control Number 0938–1155), which was updated in 2022.[233] We believe that the number of issuers exempt from HHS–RADV for any given benefit year under the proposed 30,000 BMM threshold will not be significantly different than the number of issuers exempt under the current $15 million total annual premium Statewide threshold, and therefore, we believe that there will not be an overall reduction in burden. However, those issuers that are exempted from HHS–RADV will have less burden and administrative costs than an issuer subject to these requirements.

We propose, beginning with 2021 benefit year HHS–RADV, to remove the policy to only make adjustments to reflect exiting outlier issuers HHS–RADV results when the issuer is a positive error rate outlier in the applicable benefit year's HHS–RADV. Under the proposal to remove this policy, exiting and non-exiting outlier issuers would be treated the same, and HHS would apply HHS–RADV adjustments to risk scores and risk adjustment State transfers for both positive and negative error rate outlier exiting and non-exiting issuers. Based on our experience, we estimate that the number of negative error rate outlier exiting issuers in any given benefit year would be very small, and therefore, we believe that changing this policy would not significantly increase burden.

We also propose to change the attestation and discrepancy reporting window to file a discrepancy report or confirm SVA findings from 30 calendar days to within 15 calendar days of the notification by HHS, beginning with the 2022 benefit year HHS–RADV. Shortening this attestation and discrepancy reporting window would improve HHS' ability to finalize SVA findings results prior to release of the HHS Risk Adjustment Data Validation (RADV) Results Memo and the Summary Report of Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers for the applicable benefit year in a timely fashion, which would support timely reporting of information on HHS–RADV adjustments to risk adjustment State transfers in issuers' MLR reports.

Based on our experience operating HHS–RADV, few issuers have insufficient pairwise agreement and receive SVA findings, and the 15-calendar-day attestation and discrepancy reporting window is consistent with the IVA sample and EDGE discrepancy reporting windows under §§ 153.630(d)(1) and 153.710(d)(1). Further, HHS believes that this shortened reporting window would not be overly burdensome to the few impacted issuers, and that any disadvantages of this shortened reporting window would be outweighed by the benefits of timely resolution of any discrepancies before the release of the applicable benefit year HHS Risk Adjustment Data Validation (RADV) Results Memo and the Summary Report of Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers for the applicable benefit year.

6. EDGE Discrepancy Materiality Threshold (§ 153.710)

We propose to amend the materiality threshold for EDGE discrepancies at § 153.710(e) to align with the materiality threshold as described in the preamble of part 2 of the 2022 Payment Notice final rule (86 FR 24194 through 24195) to reflect that the amount in dispute must equal to or exceeds $100,000 or 1 percent of the total estimated transfer amount in the applicable State market risk pool, whichever is less. HHS generally only takes action on reported material EDGE discrepancies when an issuer's submission of incorrect EDGE server premium data has the effect of increasing or decreasing the magnitude of the risk adjustment transfers to other issuers in the market (83 FR 16970 through 16971). We do not believe that the proposal related to the materiality threshold for EDGE discrepancies would impose additional administrative burden on issuers beyond the effort already required to submit data to HHS for the purposes of operating State market risk pool transfers, as previously estimated in part 2 of the 2022 Payment Notice (86 FR 24273 through 24274).

7. Exchange Blueprint Approval Timelines (§ 155.106)

As discussed in the preamble of this proposed rule, the proposed regulatory amendments would not eliminate the requirement for States seeking to transition to a different Exchange operational model (FFE to SBE–FP or SBE, or SBE–FP to SBE) to submit an Exchange Blueprint or for HHS to approve, or conditionally approve, a State's Exchange Blueprint. It would only impact the timeline, by providing additional time, for HHS to provide approval, or conditional approval.

We do not estimate any burden associated with this proposal as States are currently required to submit an Exchange Blueprint to HHS for approval, or conditional approval, and HHS is currently required to approve, or conditionally approve, a State's Exchange Blueprint.

We seek comment on this estimate.

8. Navigator, Non-Navigator Assistance Personnel, and Certified Application Counselor Program Standards (§§ 155.210 and 155.225)

As discussed in the preamble, this new language would permit enrollment assistance on initial door-to-door outreach. Currently, Assisters are permitted to go door-to-door to engage in outreach and education activities, just not enrollment assistance. Therefore, this proposed change would

[232] Public Law 117–2.

[233] Available at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202207-0938-001.*

not impose any new or additional opportunity costs on Navigators, non-Navigator assistance personnel, or CACs, and we do not anticipate any estimated burden associated with this proposal. The benefits of this proposal would be eliminating barriers to coverage access by maximizing pathways to enrollment. We believe it is important to be able to increase access to coverage for those whose ability to travel is impeded due to mobility, sensory or other disabilities, who are immunocompromised, and who are limited by a lack of transportation. We anticipate that this proposal would be a positive step toward enabling Assisters to reach a broader consumer base in a timely manner—helping to reduce uninsured rates and health disparities by removing underlying barriers to accessing health coverage.

We seek comment on these assumptions, specifically about any reduction in costs, benefits, or burdens on Navigators, non-Navigator assistance personnel, CACs, and consumers as related to this proposal.

9. Extension of Time To Review Suspension Rebuttal Evidence and Termination Reconsideration Requests (§§ 155.220(g) and 155.220(h))

As discussed in the preamble of this proposed rule, the proposed regulatory amendments would provide HHS with up to an additional 15 calendar days to review evidence submitted by agents, brokers, or web-brokers to rebut allegations that led to the suspension of their Exchange agreement(s) and up to an additional 30 calendar days to review evidence submitted by agents, brokers, or web-brokers to request reconsideration of termination of their Exchange agreement(s).

We do not estimate much burden associated with this proposal, as there is no requirement for HHS to utilize the additional 15 or 30 calendar days and this will only impact a very small percentage of enrolling agents, brokers, or web-brokers. Only those agents, brokers, or web-brokers that are reasonably suspected to have engaged in fraud or abusive conduct, or those with a specific finding of non-compliance against them or who have exhibited a pattern of non-compliance or abuse that may pose imminent consumer harm would be impacted.

As discussed in the preamble, this proposal would not impose any new requirements on agents, brokers, or web-brokers. At present, agents, brokers, or web-brokers whose Exchange agreement(s) are suspended or terminated may submit rebuttal evidence or reconsideration requests for HHS to consider. During this review, the submitting agent, broker, or web-broker remains unable to enroll consumers on the FFEs. This process would not change. While we would be increasing the amount of potential time the review process would take, which could lead to slightly longer periods during which agents, brokers, or web-brokers cannot enroll consumers through the FFEs and SBE–FPs, we would not be mandating HHS utilize the additional 15 or 30 calendars days for its reviews. For this reason, we do not expect any impact on agents, brokers, or web-brokers based on this proposal. We seek comment on this assumption.

10. Providing Correct Information to the FFEs and Documenting Receipt of Consumer Consent (§ 155.220(j))

As discussed in the preamble of this proposed rule, the proposed regulatory amendments would require agents, brokers, and web-brokers assisting with and facilitating enrollment through FFEs and SBE–FPs or assisting an individual with applying for APTC and CSRs for QHPs to document that eligibility application information has been reviewed by and confirmed to be accurate by the consumer or their authorized representative prior to application submission. The proposal would require the consumer or their authorized representative taking an action that produces a record showing the consumer or their authorized representative reviewed and confirmed the accuracy of their application information that must be maintained by the assisting agent, broker, or web-broker and produced to confirm the submitted eligibility application information was reviewed and confirmed to be accurate by the consumer or their authorized representative.

Also discussed in the preamble of this proposed rule, the proposed regulatory amendments would require agents, brokers, and web-brokers assisting with and facilitating enrollment through FFEs and SBE–FPs or assisting an individual with applying for APTC and CSRs for QHPs to document the receipt of consent from the consumer or their authorized representative, designated in compliance with § 155.227, qualified employers, or qualified employees they are assisting. The proposal would require the consumer or their authorized representative taking an action that produces a record of consent that must be maintained by the assisting agent, broker, or web-broker and produced to confirm the consumer or their authorized representative's consent was provided. As these two documentation processes would likely be occurring as part of the same consumer interaction,[234] the two proposals are discussed below together.

A potential cost to consider is the additional time it would take to process and submit each consumer's application. It currently takes approximately 30 minutes for an assisting agent, broker, or web-broker to submit a consumer's application. These proposed requirements may add approximately five minutes additional time, per proposal, to each application, making each application submission take 40 minutes under the new proposed policies. This means that for every six policies submitted under the proposed regulatory requirements, there would have been two additional applications that could have been submitted under the former regulatory requirements (10 extra minutes per application $\times$ 3 applications = 30 minutes, which is the estimated completion time for applications at present). If we assume agents, brokers, and web-brokers work traditional 8-hour days, they would have been able to enroll approximately 4 more consumers per day (1 application per 30 minutes = 16 per day; 1 application per 40 minutes = 12 per day). An approximation of commission for each submitted policy is $16.67.[235] Therefore, the proposed regulatory text may result in $66.68 lost per day per agent, broker, or web-broker. ($16.67 $\times$ 4 less applications submitted).

However, there would only be a potential loss of income if an agent, broker, or web-broker were constantly enrolling consumers and running out of time during the workday. It is unlikely agents, brokers, and web-brokers are constantly enrolling consumers non-stop throughout an 8-hour workday. During PY 2021, agents submitted 3,630,849 policies. The top 1 percent of agents[236] submitted 1,159,608 policies during PY 2021, which equals approximately 7 submitted policies per day.[237] As it was determined under the

[234] We note that obtaining documentation of consumer consent must occur before an application is completed. In contrast, obtaining documentation that a consumer has reviewed and confirmed the accuracy of their application information must necessarily take place during or after the application is completed. However, we expect generally that application completion, including the documentation we are proposing to require before and after the completion of the application, would occur as part of a single interaction in most cases.

[235] This was derived using the Insurance Sales Agent mean hourly wage from the above wage estimate table of $33.34 and dividing in-half.

[236] The current number of agents registered with the Exchange is 66,893. We looked at data from the 668 top-selling agents.

[237] This assumed an agent worked 250 days per year (50 weeks at 5 days per week).

new proposed policies that an agent could submit approximately 12 applications per day, there is no clear impact associated with this proposal as far as the number of applications being submitted. However, this could be different during Open Enrollment Period (OEP) as that generally has more activity than regular business days. During PY 2022 Open Enrollment, agents submitted 2,572,341 applications, which translates to 38 per agent. The top selling 1 percent of agents submitted 689,146 applications during Open Enrollment, which is approximately 18 applications per day.[238] Under the proposed regulatory amendments, a top-selling agent could lose approximately 6 applications per day due to time constraints. OEP runs from November 1 through January 15, which is 76 days. Under the assumption an agent is working 5 days per work for eight hours per day, an agent would submit 330 fewer applications during OEP (55 days working × 6 fewer applications per day). Using the above reference of $16.67 commission gained per submitted policy, a top-selling agent may lose $5,501.10 in commissions during OEP (330 applications × $16.67). It is likely these agents are working more hours than we accounted for, meaning the 330 fewer applications is an estimate such that the actual loss of commission would be less than we estimated. We seek comment on these burden estimates.

11. Failure To File and Reconcile Process (§ 155.305)

We propose to require that Exchanges instead determine an enrollee as ineligible for APTC if their taxpayer did not file a Federal income tax return and reconcile their APTC for two consecutive tax years, rather than one tax year as currently outlined at § 155.305(f)(4). We believe this proposal would benefit both Exchanges and consumers as it provides Exchanges with additional flexibility with their FTR operations and procedures, while ensuring continuity of coverage for consumers, that would otherwise go uninsured after losing ATPC to help pay for their Exchange QHPs.

We anticipate that this proposal would increase APTC expenditures by promoting continuous enrollment of consumers with APTC, who, absent this proposal, would likely choose to terminate their coverage altogether after losing their APTC eligibility due to having an FTR status. Based on HHS' own analysis, for Open Enrollment 2020, about 116,000 enrollees with an FTR status were automatically re-enrolled into an Exchange QHP without APTC; by March 2020, approximately 14,000 (12 percent) of those enrollees were still enrolled in an Exchange QHP. With the new 2-year FTR proposal, if those enrollees that ended their QHP coverage after losing APTC were given another year of APTC eligibility to come into compliance with the requirement to file and reconcile, we estimate that about 102,000 enrollees would have retained coverage with APTC for another coverage year; however, based on HHS' experience running FTR since 2015, we anticipate that about 20,400 (20 percent) of these enrollees are likely to receive a second FTR flag. Therefore, we estimate that this 2-year FTR proposal is likely to increase APTC expenditures by approximately $373 million per year beginning in benefit year 2024.

HHS is also aware of five States that have only recently transitioned to operating their own State Exchange and have not yet fully implemented the infrastructure to run FTR operations for plan years through 2023 due to the flexibility the Exchanges were given to temporarily pause FTR operations between 2021 and 2023 due to the COVID–19 public health emergency. We estimate the one-time costs for these five States to fully implement the functionality and infrastructure to conduct FTR operations to be approximately $6.6 million and estimate that the annual costs to maintain FTR operations to be approximately $10 million.

We invite comments from interested parties on this proposal, including regarding additional costs, burdens, and benefits to issuers, consumers, and Exchanges as a result of this proposal.

12. Income Inconsistencies (§§ 155.315 and 155.320)

We anticipate that proposed revision to § 155.315 would impose a minimal regulatory and cost burden on Exchanges using the Federal platform and State Exchanges in order to grant the 60-day extension for income DMIs. We estimate that the proposed change to grant a 60-day extension to applicants with income DMIs would result in a $500,000 one-time cost to Exchanges on the Federal platform and to each of the State Exchanges using their own platform. Therefore, we estimate that the total cost for State Exchanges would be $9 million to comply with the requirement to grant the 60-day extension, and the total cost to the Federal Government would be $500,000.

We anticipate that the proposed revisions to § 155.320 would impose a minimal regulatory burden and a one-time cost burden on the Exchanges using the Federal platform and State Exchanges using their own platform. We estimate that the proposed change to accept the income attestation for households for which the Exchange requests tax return data from the IRS to verify attested projected annual household income but for whom the IRS confirms there is no such tax return data available would result in a $500,000 one-time cost to the Federal Government and a one-time cost of $500,000 to each of the State Exchanges using their own platform. We also anticipate $175 million in increased APTC costs annually as a result of this proposal, due to applicants remaining enrolled through the end of the plan year instead of losing eligibility for APTC due to not providing sufficient documentation to verify their projected household income.

However, we do anticipate that the proposed revisions to § 155.320 would also result in some decreases in ongoing administrative costs for the Exchanges using the Federal platform and State Exchanges. The proposed change would eliminate the requirement to generate income DMIs when the Exchange requests tax return data from the IRS for an applicant or enrollee and the IRS confirms no such data is available. For Exchanges on the Federal platform, we anticipate that this will result in 1.2 million fewer households receiving an income DMI, which would result in $66 million in annual cost savings to the Federal Government. Additionally, State Exchanges using their own platform would also experience annual cost savings of $37 million due to this proposed change.

We do not anticipate that these proposed changes would impose a cost or regulatory burden on issuers. However, the proposed changes would have a financial impact on issuers via the continued enrollment of consumers who otherwise would have experienced APTC adjustment and are thus likely to disenroll.

13. Annual Eligibility Redetermination (§ 155.335(j))

We propose revising § 155.335(j) to allow the Exchange, beginning in PY 2024, to direct re-enrollment for enrollees who are eligible for CSR in accordance with § 155.305(g) from a bronze QHP to a silver QHP with a lower or equivalent premium after APTC within the same product and QHP issuer, regardless of whether their current plan is available or not. We also

[238] This assumed an agent worked 5 days per week at 8 hours per day, which is likely a low estimate.

propose to amend the Exchange re-enrollment hierarchy to allow all Exchanges (Exchanges on the Federal platform and SBEs) to ensure enrollees whose QHPs are no longer available to them and enrollees who would be re-enrolled into a silver-level QHP in order to receive income-based CSRs are re-enrolled into plans with the most similar network to the plan they had in the previous year, provided that certain conditions are met.

We propose revising paragraph (j)(2)(i) to state that if the enrollee is not CSR eligible, the Exchange will re-enroll the enrollee in a QHP at the same metal level as and with the most similar network compared to the enrollee's current QHP. We propose amending and redesignating paragraphs (j)(2)(ii) and (iii) as paragraphs (j)(2)(iv) and (v), respectively, to specify that the enrollee's provider network must also be considered in re-enrollment determinations. We also propose adding a new paragraph (j)(2)(ii) to establish that if the enrollee is CSR-eligible, in accordance with § 155.305(g), and the enrollee's current QHP is a bronze level plan, the Exchange will re-enroll the enrollee either in a bronze level QHP, or, at the option of the Exchange, in a silver level QHP that has a lower or equivalent premium after APTC and has the most similar network compared to the enrollee's current QHP in the product offered by the same issuer through the Exchange that is most similar to the enrollee's current product. Lastly, we propose to add a new paragraph (j)(2)(iii) to establish that if the enrollee is CSR-eligible, in accordance with § 155.305(g), and the enrollee's current QHP is not a bronze level plan, the enrollee will be re-enrolled in a QHP at the same metal level that has the most similar network compared to the enrollee's current QHP in the product offered by the same issuer that is the most similar to the enrollee's current product.

We anticipate that the inclusion of additional criteria in the Federal hierarchy for re-enrollment would increase costs and burden for issuer and Exchanges, although we are unable to quantify this increase. However, we believe initially limiting the scope to only CSR-eligible enrollees who are currently in a bronze QHP and have a lower cost silver CSR QHP available would allow issuers and Exchanges to incrementally update their processes, as opposed to incorporating both premium (after APTC) and out-of-pocket cost (OOPC) throughout the hierarchy in PY 2024. Additionally, we believe that allowing the Exchange to direct re-enrollment for CSR-eligible enrollees from bronze plans to silver CSR plans with lower or equivalent premium after APTC would facilitate enrollment into silver CSR plans and help reduce CSR forfeiture. We believe these proposed changes to the re-enrollment process, in combination with improved consumer notification, would further streamline the consumer shopping experience, enhance consumer understanding of plan options, and help move enrollment into more affordable, higher generosity plans, especially in cases where market conditions have substantially increased the old plan's cost. By amending the current Federal hierarchy for re-enrollment to incorporate provider networks and facilitate enrollment into lower cost, higher generosity plans, we believe we would be promoting consumer access to affordable, high-quality coverage.

We seek comment on the estimated costs and benefits described in this section, as well as any additional impacts on consumers, issuers, and Exchanges as a result of this proposal.

14. Coverage Effective Dates for Qualified Individuals Losing Other Minimum Essential Coverage (§ 155.420(b))

We propose to add paragraph (b)(2)(iv) to § 155.420(b) to provide earlier SEP coverage effective dates for qualifying individuals who attest to a future loss of MEC, such as coverage offered through an employer, Medicaid, CHIP, or Medicare., within 60 days before such loss of MEC s. Currently, the earliest start date for Exchange coverage when a qualifying individual attests to a future loss of MEC is the first day of the month following the date of loss of MEC, which may result in coverage gaps when consumers lose forms of MEC (other than Exchange coverage) mid-month. We believe that this proposed change is necessary to ensure that qualifying individuals are able to seamlessly transition from other non-Exchange MEC to Exchange coverage as quickly as possible with minimal coverage gaps. As discussed earlier in preamble, ensuring smooth and quick transitions into Exchange coverage will be especially critical once the COVID–19 PHE comes to an end and higher numbers of consumers lose their Medicaid or CHIP coverage and transition to Exchange coverage, as applicable.

Based on HHS' own analysis, for plan years 2019 through 2021, approximately 214,000 households seeking coverage on Exchanges using the Federal platform reported a future mid-month loss of MEC date and ultimately did not enroll in a QHP. In PY 2021, about 45,000 households attested to a future mid-month loss of coverage MEC date and did not enroll in QHP coverage. If these consumers had been given the opportunity for Exchange coverage to begin the first of the month in which their prior mid-month loss of MEC coverage end date occurred, rather than having to wait weeks for their coverage to start, these consumers could have avoided a gap in coverage and could have received an additional month of APTC, given our interpretation of IRS' definition of a coverage month, which we plan to codify in the final rule. Therefore, for consumers who report a future loss of MEC, especially those who reside in States that allow mid-month terminations for Medicaid or CHIP, we estimate that this proposed change could increase APTC expenditures by approximately $161 million dollars per coverage year by allowing Exchange coverage to start the first of the month in which the mid-month loss of MEC or COBRA occurs and assuming that similar volume of consumers would choose enroll in an Exchange QHP, however, this number could be slightly lower but we are unable to estimate what proportion of consumers would still elect to not enroll in an Exchange QHP. We also anticipate additional costs to certain consumers as some consumers would be required to pay for an additional month of Exchange coverage for which they would not have previously been eligible while also still possibly paying for one last month of their prior MEC coverage. However, in order to mitigate adverse selection concerns, we are not proposing that Exchanges permit consumers to select a different, prospective coverage start date, such as the first of the month following plan selection. We also seek comment from issuers regarding any additional or remaining risk regarding mid-month coverage effective dates.

We seek comment on this proposal, specifically about any additional costs, benefits, or burdens on State Exchanges, issuers, and consumers as related to this proposal.

15. Special Rule for Loss of Medicaid or CHIP Coverage (§ 155.420(c))

We propose to add paragraph (c)(6) to § 155.420(c) to provide qualifying individuals losing Medicaid or CHIP that is considered MEC in accordance with § 155.420(d)(1)(i), and who qualify for a special enrollment period, with up to 60 days before and up to 90 days after their loss of coverage to enroll in QHP coverage. We believe that this proposed change is necessary to ensure that qualifying individuals are able to seamlessly transition from Medicaid or

CHIP into Exchange coverage as quickly as possible with little to no coverage gaps. As discussed earlier in preamble, ensuring smooth and quick transitions into Exchange coverage will be especially critical once the COVID–19 PHE comes to an end and higher numbers of consumers lose their Medicaid or CHIP coverage and transition to Exchange coverage, as applicable.

Based on HHS's own analysis, in plan year 2019, about 60,000 consumers seeking coverage on Exchanges using the Federal platform attested to a Medicaid/CHIP loss or denial between 60 to 90 days prior on their *HealthCare.gov* application. We estimate that this proposed change to permit Exchanges to use a special rule to provide consumers losing Medicaid or CHIP with 90 days after their loss of Medicaid or CHIP to enroll in QHP coverage would increase APTC expenditures by approximately $98 million per year.

We seek comment on this proposal, specifically about any additional costs, benefits, or burdens on States, issuers, and consumers as related to this proposal.

16. Plan Display Error Special Enrollment Periods (§ 155.420(d))

We anticipate that revisions to § 155.420(d)(12) would maintain current regulatory burden and cost on issuers. As discussed earlier in preamble, our proposal to make necessary changes to the text of § 155.420(d)(12) is to align the policy for granting SEPs to persons who are adversely affected by a plan display error with current plan display error SEP operations. Our proposal would have minimal operational impact, as interested parties such as issuers, States, and the Exchanges on the Federal platform currently have the infrastructure to demonstrate that a material plan display error influenced a qualified individual's, enrollee's, or their dependents' enrollment and, or decision to purchase a QHP through the Exchange. This does not impose additional regulatory burden or costs because the revisions do not require the consumers, HHS, or issuers to conduct new or additional processes to existing data change requirements.

17. Termination of Exchange Enrollment or Coverage (§ 155.430)

We anticipate that the proposal to expressly prohibit issuers from terminating coverage for policy dependent children because they reached the maximum allowable age mid-plan year would benefit affected enrollees by providing clarity regarding their ability to maintain coverage. Because this prohibition has already been in place on the Exchanges on the Federal platform, we do not anticipate a financial impact to issuers or HHS. There may be some minor costs for State Exchanges that choose to implement this prohibition and have not previously done so, but we do not have adequate data to estimate these costs. We seek comment on these benefit and burden assumptions.

18. Improper Payment Pre-Testing and Assessment for State Exchanges (§ 155.1500)

This proposal would prepare HHS to implement the Payment Integrity Information Act of 2019 (PIIA) requirements for State Exchanges. As described in the preamble earlier in this proposed rule, the PIIA requires that agencies measure the improper payments rate for programs susceptible to significant improper payments. HHS already undertakes annual measurements for Medicare, Medicaid, FFEs, and SBE–FPs. This proposed rule would lay the groundwork to complete the Exchanges' measurement program by including State Exchanges and to enable HHS to estimate improper payment rates as mandated by statute.

This proposal tests State Exchanges' readiness to provide the information necessary to measure the rate of improper payments. Even slight decreases in this rate would accrue large taxpayer savings. The IPPTA incurs approximately $57,000 in costs per respondent. Nevertheless, HHS believes that the potential benefits of this regulatory action justify the present costs.

This proposal would prepare HHS to implement the statutory requirement for measurement of improper payments for programs susceptible to significant improper payments. We have quantified the costs for this proposal. Neither this IPPTA nor any follow-on program should affect transfers between parties.

19. FFE and SBE–FP User Fee Rates for the 2024 Benefit Year (§ 156.50)

We are proposing an FFE user fee rate of 2.5 percent of monthly premiums for the 2024 benefit year, which is a decrease from the 2.75 percent FFE user fee rate finalized in the 2023 Payment Notice (87 FR 27289). We also propose an SBE–FP user fee rate of 2.0 percent for the 2024 benefit year, which is a decrease from the 2.25 percent SBE–FP user fee rate finalized in the 2023 Payment Notice. Based on our estimated costs, enrollment (including anticipated transitions of States from the FFE and SBE–FP models to either the SBE–FP or State Exchange model), premiums for the 2024 benefit year, and proposed user fee rates, we are estimating that FFE and SBE–FP user fee transfers from issuers to the Federal Government would be $170 million lower compared to those estimated for the prior benefit year. We also anticipate that the lower user fee rates may exert downward pressure on premiums.

20. Standardized Plans

a. Standardized Plan Options (§ 156.201)

At § 156.201, we propose minor updates to our approach to standardized plan options for PY 2024 and subsequent PYs. In particular, in contrast to the policy finalized in the 2023 Payment Notice, HHS proposes, for PY 2024 and subsequent PYs, to no longer include a standardized plan option for the non-expanded bronze metal level. Accordingly, HHS proposes at new § 156.201(b) that for PY 2024 and subsequent PYs, FFE and SBE–FP issuers offering QHPs through the Exchanges must offer standardized QHP options designed by HHS at every product network type (as described in the definition of ''product'' at § 144.103), at every metal level except the non-expanded bronze level, and throughout every service area that they offer non-standardized QHP options.

HHS believes that maintaining the highest degree of continuity possible in the approach to standardized plan options minimizes the risk of disruption for a range of interested parties, including issuers, agents, brokers, States, and enrollees. HHS believes that making major departures from the approach to standardized plan options in the 2023 Payment Notice could result in drastic changes in these plan designs that could potentially cause undue burden for these interested parties. Furthermore, if the standardized plan options HHS creates vary significantly from year to year, those enrolled in these plans could experience unexpected financial harm if the cost-sharing for services they rely upon differs substantially from the previous year. Ultimately, HHS believes consistency in standardized plan options is important to allow both issuers and enrollees to become accustomed to these plan designs.

Thus, similar to the approach taken in the 2023 Payment Notice, HHS proposes to create standardized plan options that would continue to resemble the most popular QHP offerings that millions of consumers are already enrolled in. As such, these proposed standardized plan options are based on refreshed PY 2022

cost-sharing and enrollment data to ensure that these plans continue to reflect the most popular offerings in the Exchanges.

With HHS proposing to maintain a similar approach to standardized plan options to that taken in the 2023 Payment Notice, issuers would continue to be able to utilize many existing benefit packages, networks, and formularies, including those paired with standardized plan options for PY 2023. Furthermore, since HHS is proposing to require QHP issuers to offer standardized plan options at every product network type, at every metal level except the non-expanded bronze metal level, and throughout every service area they also offer non-standardized plan options (but not for different product network types, metal levels, and service areas where they do not also offer non-standardized plan options), issuers would continue to not be required to extend plan offerings beyond their existing service areas.

Furthermore, as discussed earlier in the preamble, HHS noted that it would continue to differentially display standardized plan options on *HealthCare.gov* per the existing authority at § 155.205(b)(1). Since HHS would continue to assume the burden for differentially displaying standardized plan options on *HealthCare.gov,* FFE and SBE–FP issuers would continue to not be subject to this burden.

In addition, as noted in the preamble, HHS would continue enforcement of the standardized plan option display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively. HHS believes that continuing the enforcement of these differential display requirements would not require significant modification of these entities' platforms and non-Exchange websites, especially since the majority of this burden already occurred when the standardized plan option differential display requirements were first finalized in the 2018 Payment Notice [239] or when enforcement of these requirements resumed beginning with the PY 2023 open enrollment period.

Finally, since HHS would continue to allow these entities to submit requests to deviate from the manner in which standardized plan options are differentially displayed on *HealthCare.gov,* the burden for these entities would continue to be minimized. HHS intends to continue providing access to information on standardized plan options to web-brokers through the Health Insurance Marketplace Public Use Files (PUFs) and QHP Landscape file to further minimize burden. Specific burden estimates for these requirements can be found in the corresponding ICR sections for §§ 155.220 and 156.265 of the 2023 Payment Notice (87 FR 698 and 699 and 87 FR 27360 and 27361).

b. Non-Standardized Plan Option Limits (§ 156.202)

At § 156.202, we propose to limit the number of non-standardized plan options that issuers of individual market medical QHPs can offer through the FFEs and SBE–FPs to two per product network type, metal level, and service area. If such a limit were adopted in PY 2024, it is estimated that the weighted average number of non-standardized plan options (which does not take into consideration standardized plan options) available to each consumer would be reduced from approximately 107.8 in PY 2022 to 37.2 in PY 2024. Furthermore, it is estimated that approximately 60,949 of a total 106,037 non-standardized plan option plan-county combinations (amounting to 57.5 percent of non-standardized plan option plan-county combinations) would be discontinued.[240] Finally, it is estimated that approximately 2.72 million of the approximate 10.21 million enrollees on the FFEs and SBE–FPs (amounting to 26.6 percent of enrollees) would be affected by these discontinuations.[241]

The total number of QHPs that would have to undergo QHP certification each year would be reduced as a result of limiting the number of non-standardized plan options. Relatedly, although issuers would be required to select another QHP to which to crosswalk affected enrollees from discontinued non-standardized plan options, the existing discontinuation notices and process as well as the current re-enrollment hierarchy and corresponding crosswalk process outlined at § 155.335(j) could accommodate crosswalking these affected enrollees, and no additional modification to these processes or to this re-enrollment hierarchy would be required. Finally, no additional action would be required from consumers to complete this crosswalking process.

We do not have sufficient data to estimate the costs associated with these proposed changes, so we seek comment from interested parties regarding cost estimates and data sources.

21. QHP Rate and Benefit Information (§ 156.210)

a. Age on Effective Date for SADPs

This rule proposes standards related to the rate submission process for Exchange-certified SADPs during QHP certification. This rule proposes to modify the rate submission process to require issuers of Exchange-certified SADPs, whether they are sold on- or off-Exchange, to use age on effective date as the sole method to calculate an enrollee's age for rating and eligibility purposes beginning with Exchange certification in PY 2024. Requiring these issuers to use the age on effective date methodology for calculating an enrollee's age, and consequently removing the less common and more complex age calculation methods, will reduce potential consumer confusion and the burden placed on Exchange interested parties (including issuers, as well as DE and EDE partners) by promoting operational efficiency.

This proposed policy change reduces the risk of consumer harm and confusion since the age on effective date method allows consumers to more easily understand the rate they are charged. This proposed policy also helps reduce enrollment blockers, which will improve the efficiency of the enrollment process and reduce the burden placed on Exchange interested parties (including issuers, as well as DE and EDE partners). Therefore, this proposed policy helps facilitate more informed enrollment decisions and enrollment satisfaction.

We also do not anticipate any negative financial impact as a result of this proposed policy, given that it would be a small operational change. If anything, this proposed policy has the potential to reduce financial burden on issuers and CMS, as removing the other age rating methods would reduce the added expense and slower development times that must account for test cases in

[239] These differential display requirements were first effective and enforced beginning with PY 2018. See 81 FR 94117 through 94118, 94148.

[240] Plan-county combinations are the count of unique plan ID and FIPS code combinations. This measure is used because a single plan may be available in multiple counties, and specific limits on non-standardized plan options may have different impacts on one county where there are four plans of the same product network type and metal level versus another county where there are only two plans of the same product network type and service area, for example.

[241] These calculations assume that the non-standardized plan options removed due to the proposed limit would be those with the fewest enrollees based on PY 2022 data, which includes individual market medical QHPs for Exchanges using the *HealthCare.gov* eligibility and enrollment platform, including SBE–FPs.

the rating engine for the less commonly used and more complex methods.

Additionally, this proposed policy change would not create any additional information submission burden, as it would apply to information that Exchange issuers already submit as part of the QHP certification process.

b. Guaranteed Rates for SADPs

This rule proposes standards related to the rate submission process for Exchange-certified SADPs during QHP certification. This rule proposes to modify the rate submission process to require issuers of Exchange-certified SADPs, whether they are sold on- or off-Exchange, to submit guaranteed rates beginning with Exchange certification in PY 2024. Requiring guaranteed rates would reduce potential consumer harm and burden associated with incorrect APTC calculation for the pediatric dental EHB portion of premiums, and the need for consumers to contact issuers who post estimated rates for final rates.

Requiring guaranteed rates would reduce the risk of consumer harm by reducing the risk of incorrect APTC calculation for the pediatric dental EHB portion of premiums. Therefore, we believe that this proposed policy change would support health equity by helping to ensure that low-income enrollees who qualify for APTC are charged the correct premium amount. Beyond reducing the potential for consumer financial harm, this proposed policy would also reduce the burden placed on consumers because it would allow them to rely on the information they see on the issuer's website and not have to contact issuers for final rates after the QHP certification process.

22. Plan and Plan Variation Marketing Name Requirements for QHPs (§ 156.225)

We propose at § 156.225 to require that QHP plan and plan variation marketing names include correct information, without omission of material fact, and do not include content that is misleading. CMS, States, and QHP issuers work together to ensure that consumers can make informed decisions when selecting a health insurance plan based on factors such as QHP benefit design, cost-sharing requirements, and available financial assistance. In PY 2022, Exchanges on the Federal platform saw a significant increase in the number of plan and plan variation marketing names using cost-sharing information and other benefit details. Following Open Enrollment for PY 2022, CMS received complaints from consumers in multiple States who misunderstood cost-sharing information in their QHP's marketing name. We believe that clear policy can result in plan and plan variation marketing names that reduce consumer confusion.

By providing standards that help ensure plan and plan variation marketing names are clear and accurate, we anticipate the proposed policy will reduce burden on consumers and on those who help consumers to enroll in Exchange coverage because it will allow them to rely on information they see during the plan selection process. In addition, we believe that the proposed standards for plan and plan variation marketing names would have an overall positive impact on other Exchange interested parties as well, by ensuring that the consumer education that plans use to compete in the individual health insurance market is clear and accurate.

This proposed policy may require additional effort during the QHP certification process on the part of Exchange issuers to comply with new plan marketing name standards. However, we would work to streamline this process by incorporating education about plan and plan variation marketing name standards into the annual QHP certification process, and proactively addressing issuer and State questions through existing outreach and education vehicles including webinars, email blasts, and regularly scheduled meetings on individual health insurance market policy and operations.

The proposed policy would not create any new information submission burden, because it would apply to information that Exchange issuers already submit as part of the QHP certification process. Additionally, while requiring increased effort initially, we believe this proposed policy would ultimately decrease issuer and State effort following QHP certification, and during and after the annual Open Enrollment Period, by reducing the number of plan and plan variation marketing name-related consumer complaints to triage and, in some cases, special enrollment periods to be provided.

We seek comment on the burden that this proposed policy would impose, and on the burden reduction it could provide. We also seek comment on how CMS can further alleviate any burden associated with this proposed policy, such as through technical assistance to Exchange interested parties, including issuers and enrollment assisters.

Finally, we also believe that the proposed policy would promote health equity by reducing the likelihood of QHP benefit misunderstanding and confusion that leads to less informed enrollment decisions, especially for consumers with low health literacy, which is disproportionately experienced among underserved communities and other vulnerable populations. For example, a 2022 study found higher self-reported low health literacy among people who are Hispanic, non-U.S. citizens, unemployed, or who have less than a high school education.[242] A 2019 study that tested participants' knowledge of health insurance terminology found statistically significant disparities based on race, ethnicity, and language preference.[243] We seek comment on this proposal and on whether this proposal would promote health equity, and on additional ways that CMS can support health insurance literacy through plan marketing guidance and technical assistance.

23. Network Adequacy (§ 156.230)

Regarding HHS's proposal to require all QHP issuers, including SADP issuers, to utilize a contracted network of providers and comply with network adequacy standards at § 156.230 and ECP standards at § 156.235, we acknowledge that SADP issuers that only offer plans that do not use a provider network and that want to be certified may initially face increased costs associated with developing contractual relationships with providers or leveraging pre-existing networks associated with their other plans. However, studies have found that provider networks allow for insurer-negotiated prices and controlled (that is, reduced) costs in the form of reduced patient cost-sharing, premiums, and service price, as compared with such services obtained out of network.[244] [245] We expect any initial increased issuer costs to differ from the costs experienced once such provider

[242] Edward J, Wiggins A, Young MH, Rayens MK. Significant Disparities Exist in Consumer Health Insurance Literacy: Implications for Health Care Reform. Health Lit Res Pract. 2019 Nov 5;3(4):e250–e258. doi: 10.3928/24748307–20190923–01. PMID: 31768496; PMCID: PMC6831506.

[243] Villagra VG, Bhuva B, Coman E, Smith DO, Fifield J. Health insurance literacy: disparities by race, ethnicity, and language preference. Am J Manag Care. 2019 Mar 1;25(3):e71–e75. PMID: 30875174.

[244] Benson NM, Song Z. Prices And Cost Sharing For Psychotherapy In Network Versus Out Of Network In The United States. Health Aff (Millwood). 2020 Jul;39(7):1210–1218. *https://www.healthaffairs.org/doi/10.1377/hlthaff.2019.01468.*

[245] Song, Z., Johnson, W., Kennedy, K., Biniek, J. F., & Wallace, J. Out-of-network spending mostly declined in privately insured populations with a few notable exceptions from 2008 to 2016. Health Aff. 2020;39(6), 1032–1041. *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2019.01776.*

contractual relationships have been established or pre-existing networks associated with their other plans have been leveraged. We request comment on whether and how to extrapolate from literature on voluntary network formation for purposes of assessing impacts of this regulatory provision.

For SADPs that do not use a provider network, this proposal would require these issuers to contract with providers in accordance with our existing network adequacy requirements or withdraw from the Exchange. The latter may create a burden for enrollees and QHP plans in the service area if no SADPs remain. However, we expect this burden to only affect a small number of consumers, given the overall small number of Exchange-certified SADPs that do not use a provider network on the FFEs. As discussed further in Table 12 in the preamble for part 156, over the last few years, fewer than 100 counties have had SADPs without provider networks, and most of these counties had SADPs with provider network options available. For PY 2022, there were only 8 Exchange-certified SADPs without provider networks in the FFEs. Similarly, the number of States with these types of plans has decreased over time. At its highest, in 2014, 9 FFE States had Exchange-certified SADPs without provider networks. Since PY 2020, this number has dropped to 4 or fewer FFE States, with only 2 FFE States having this plan type in PYs 2022 and 2023. Additionally, Exchange-certified SADPs with provider networks are becoming more available in counties that previously only had no-network SADP options: for PYs 2022 and 2023, only 2 FFE States (Alaska and Montana) offer Exchange-certified SADPs without provider networks. For Montana, all counties offering this plan type also offer Exchange-certified SADPs with provider networks. For Alaska in PYs 2022 and 2023, 90 percent of counties with Exchange-certified SADPs without provider networks have no Exchange-certified SADPs with provider networks.

We anticipate approximately 2,200 enrollees will be affected by this proposal. Enrollees in SADPs that choose not to comply with this requirement would need to select a different plan for coverage, which may cause hardship if the enrollee cannot access assistance, requires culturally and linguistically appropriate support, and/or does not have an understanding of health insurance design and benefits. In the event service areas are left without SADPs due to the provider network requirement, health plans will have to amend their benefits to include the pediatric dental benefit EHB. This change may require costs for issuers to build the benefit and contract with providers.

These impacts may be mitigated if we finalize a limited exception to allow SADPs to not use a provider network in areas where it is prohibitively difficult for the SADP issuer to establish a network of dental providers that complies with §§ 156.230 and 156.235.

Finally, we do not anticipate any impact as a result of this proposal on health plans that do not use a network, given our understanding that no such plan is currently certified as a QHP by an Exchange, but solicit comment to inform that understanding.

24. Essential Community Providers (§§ 156.235(a)(2)(i) and 156.235(a)(2)(ii)(B))

Regarding HHS's proposal to strengthen the ECP standards under § 156.235(a)(2)(i) by requiring QHPs to contract with at least 35 percent of available FQHCs that qualify as ECPs in the plan's service area and at least 35 percent of available Family Planning Providers that qualify as ECPs in the plan's service area, we acknowledge that issuers whose provider networks do not currently include such a percentage of these provider types that qualify as ECPs may face increased costs associated with complying with the proposed policies. However, we do not expect this increase to be prohibitive. Based on data from PY 2023, it is likely that a majority of issuers would be able to meet or exceed the threshold requirements for FQHCs and Family Planning Providers without needing to contract with additional providers in these categories.

To illustrate, if these requirements had been in place for PY 2023, out of 137 QHP issuers on the FFEs, 76 percent would have been able to meet or exceed the 35 percent FQHC threshold, while 61 percent would have been able to meet or exceed the 35 percent Family Planning Provider threshold without contracting with additional providers. For SADP issuers, 84 percent would have been able to meet the 35 percent threshold requirement for FQHCs offering dental services without contracting with additional providers. In PY 2023, for medical QHPs, the mean and median ECP percentages for the FQHC category were 74 and 83 percent, respectively. For the Family Planning Providers category, the mean and median ECP percentages were 66 and 71 percent, respectively. For SADPs, the mean and median ECP percentages for the FQHC category were 61 and 64 percent, respectively.

Regarding HHS's proposal to strengthen the ECP standards under § 156.235(a)(2)(ii)(B) by establishing two additional stand-alone ECP categories to include SUD Treatment Centers and Mental Health Facilities, we acknowledge challenges associated with a general shortage and uneven distribution of SUD Treatment Centers and mental health providers. However, the ACA requires that a QHP's network include ECPs where available. As such, the proposal to require QHPs to offer a contract to at least one available SUD Treatment Center and one available Mental Health Facility in every county in the plan's service area does not unduly penalize issuers facing a lack of certain types of ECPs within a service area, meaning that if there are no provider types that map to a specified ECP category available within the respective county, the issuer is not penalized. Further, as outlined in prior Letters to Issuers, HHS prepares the applicable PY HHS ECP list that potential QHPs use to identify eligible ECP facilities. The HHS ECP list reflects the total supply of eligible providers (that is, the denominator) from which an issuer may select for contracting to count toward satisfying the ECP standard. As a result, issuers are not disadvantaged if their service areas contain fewer ECPs. HHS anticipates that any QHP issuers falling short of the 35 percent threshold for PY 2024 could satisfy the standard by using ECP write-ins and justifications. As in previous years, if an issuer's application does not satisfy the ECP standard, the issuer would be required to include as part of its application for QHP certification a satisfactory justification.

25. Termination of Coverage or Enrollment for Qualified Individuals (§ 156.270)

We propose to amend § 156.270(f) by adding a timeliness standard to the requirement for QHP issuers to send enrollees notice of payment delinquency. Specifically, we propose to revise § 156.270(f) to require issuers to send notice of payment delinquency promptly and without undue delay. We anticipate that this proposal would be beneficial to enrollees who become delinquent on premium payments by ensuring they are properly informed of their delinquency in time to avoid losing coverage. It may be especially beneficial to enrollees who are low income, who would be especially negatively impacted by disruptions in coverage. We expect some minimal costs to issuers associated with updating their internal processes to ensure compliance with the finalized

timeliness standard, but do not have adequate data to estimate these costs. We seek comment on the benefit and cost assumptions of this proposal.

26. Final Deadline for Reporting Enrollment and Payment Inaccuracies Discovered After the Initial 90-Day Reporting Window (§ 156.1210(c))

We propose to amend § 156.1210(c) to remove the alternate deadline at § 156.1210(c)(2), which requires an issuer to describe all data inaccuracies identified in a payment and collection report by the date HHS notifies issuers that the HHS audit process with respect to the plan year to which such inaccuracy relates has been completed, in order for these data inaccuracies to be eligible for resolution. Under this proposal, we would retain only the deadline at § 156.1210(c)(1), which requires that issuers describe all inaccuracies identified in a payment and collections report within 3 years of the end of the applicable plan year to which the inaccuracy relates to be eligible to receive an adjustment to correct an underpayment. Under this proposal, beginning with the 2020 plan year coverage, HHS would not pay additional APTC payments or reimburse user fee payments for FFE, SBE–FP, and SBE issuers for data inaccuracies reported after the 3-year deadline. Further, we propose that HHS would not accept or take action that results in an outgoing payment on data inaccuracies or payment errors for the 2015 through 2019 plan year coverage that are reported after December 31, 2023. We anticipate that this proposed change would result in a less operationally burdensome process for the identification and resolution of these data inaccuracies for issuers, State Exchanges, and HHS, and a slight reduction in associated burdens, such as resolution of data inaccuracies for discovered underpayments. However, we anticipate the impact would be minimal, if any, and result in no significant financial impact.

27. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed or 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 last year's proposed rule (465) will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $115.22 per hour, including overhead and fringe benefits.[246] Assuming an average reading speed, we estimate that it would take approximately 1 hour for the staff to review half of this proposed or final rule. For each entity that reviews the rule, the estimated cost is $115.22 (1-hour × $115.22). Therefore, we estimate that the total cost of reviewing this regulation is $53,577.30 ($115.22 × 465).

D. Regulatory Alternatives Considered

With respect to the inclusion or exclusion of the 2020 benefit year enrollee-level EDGE data in the recalibration of 2024 benefit year risk adjustment models, we considered a variety of alternative options to our proposal to use 2018, 2019, and 2020 enrollee-level EDGE data with an exception to exclude 2020 benefit year data from recalibration of the age-sex coefficients for the adult models, which is the fourth option outlined above. The first option considered was to maintain current policy, recalibrating the risk adjustment models using 2018, 2019, and 2020 enrollee-level EDGE data (without any adjustment). The second option involved using 2018, 2019, and 2020 enrollee-level EDGE data, but assigning a lower weight to the 2020 data. The third option we considered would utilize 4 years of enrollee-level EDGE data, instead of three, to recalibrate the risk adjustment models using 2017, 2018, 2019, and 2020 data. The fifth option would exclude the 2020 enrollee-level EDGE data and use the 2017, 2018, and 2019 enrollee-level EDGE data in recalibration for the 2024 benefit year or to use the final 2023 models as the 2024 risk adjustment models. The sixth and final option we considered would use 2 years of enrollee-level EDGE data for 2024 benefit year recalibration—only 2018 and 2019 data.

Our analyses found that the 2019 and 2020 benefit year enrollee-level EDGE recalibration data were largely comparable, however, there were observed anomalous decreases in the unconstrained coefficients for the 2020 benefit year enrollee-level EDGE recalibration data for older adult enrollees, especially older female enrollees. Option 1 therefore would not address the identified anomalous trend that is not expected to continue in future benefit years.

The second option would represent a compromise between those who wish to include 2020 data in model recalibration and those who wish to exclude 2020 data, by capturing the utilization and spending patterns underlying the 2020 data while dampening its effects in the model. However, we were concerned this approach would require finding an appropriate weighting methodology, and we are further concerned that broadly dampening the effect of the 2020 benefit year data in the models defeats the purpose of adding the next available benefit year of data as part of model recalibration because doing so would prevent the models from reflecting changes in utilization and cost of care that are unrelated to the impact of the COVID–19 PHE. There are similar concerns with option 3 and the inclusion of an additional prior benefit year (that is, 2017) to recalibrate the 2024 benefit year models to dampen the impact of the 2020 benefit year data. We do not believe that such a broad dampening is necessary because the anomalous coefficient changes identified from the 2020 benefit year data were largely limited to the adult model age-sex coefficients, and incorporating an additional prior benefit year of data would dampen the impact of the 2020 benefit year data on other factors and would prevent the models from reflecting changes in utilization and cost of care that are unrelated to the impact of the COVID–19 PHE.

We are similarly concerned about options 5 and 6, which would involve the complete exclusion of 2020 benefit year data, because both of these options would result in reliance on data that may not be the most reflective data set of the utilization and spending trends. Furthermore, there are questions about whether there is a sufficient justification to completely exclude 2020 benefit year

[246] *https://www.bls.gov/oes/current/oes_nat.htm.*

enrollee-level EDGE recalibration data in the recalibration of the risk adjustment models. The sixth option has the same limitations and would also have the additional drawback of decreasing the stabilizing effect of using multiple years of data in model recalibration. More specifically, because this option would reduce the number of years of data used, a change in a coefficient occurring in just 1 year of the data that is actually included in recalibration (that is, the 2018 or 2019 benefit years of enrollee-level EDGE recalibration data) would have a greater impact on the risk adjustment model coefficients due to the increase in the reliance of the blended coefficients on the remaining 2 years of data.

We solicit comment on all of these alternatives for the use of the 2020 enrollee-level EDGE data in the 2024 benefit year risk adjustment model recalibration.

In developing the updated materiality threshold for HHS–RADV proposed in this rule, we sought to ensure the materiality threshold would ease the burden of annual audit requirements for smaller issuers of risk adjustment covered plans that do not materially impact risk. To do this, we considered the costs associated with hiring an initial validation auditor and submitting IVA results and the relative growth of issuers' total annual premiums Statewide and total BMM. We also evaluated the benefits of shifting to a threshold based on BMM rather than annual premiums, and we are proposing changing the materiality threshold from $15 million in total annual premiums Statewide to 30,000 BMM Statewide. As an alternative option, we considered increasing the threshold to $17 million in total annual premiums Statewide and maintaining a cutoff based on premium dollars (instead of BMMs). However, we were concerned that a premium threshold would fail to capture small issuers overtime as PMPM premiums grow and would require more regular updates to the materiality threshold to maintain the current balance. The use of a BMM threshold avoids this issue. We invite comment on our proposed materiality threshold and on the potential alternative option to update the threshold to $17 million annual premiums Statewide for the benefit year being audited, and we also invite comment on the applicability date for when the new materiality threshold should begin to apply.

Regarding our proposal to require Exchanges to determine an enrollee as ineligible for APTC after having failed to file and reconcile for two consecutive tax years rather than after one tax year, we considered multiple alternatives. One alternative we considered was extending the current pause on FTR operations through plan year 2024, while HHS continued to examine the current FTR process, and explore ways in which the FTR process could promote continuity of coverage, while maintaining its critical program integrity function to ensure that only enrollees eligible for APTC continue to do so. Another alternative we considered was repealing the requirement under 45 CFR 155.305(f)(4) that a taxpayer(s) must file a Federal income tax return and reconcile their APTC for any tax year in which they or their tax household received APTC in order to continue their eligibility for APTC. However, we wanted to maintain the program integrity benefits of the FTR process, and believe there is still value in ensuring that only people who are filing and reconciling remain eligible to receive APTC. Because of this, we have amended our proposal and are instead proposing requiring that Exchanges end APTC only after two consecutive years of FTR status rather than ending APTC after a single year.

We considered two alternatives to accepting attestation to determine household income for households for which IRS does not return any data and expanding the amount of time to resolve income DMIs to meet the goal of increased consumer service and advancing health equity. We considered establishing a threshold when adjusting APTC following an income inconsistency period. Under this alternative, HHS would continue current operations but would not eliminate APTC eligibility completely if consumers are unable to provide sufficient documentation. While this alternative would require fewer changes to implement, our current proposal would create better outcomes for more consumers and decrease administrative burden. Additionally, we considered eliminating income DMIs for all consumers, including those for whom the Exchanges have IRS data, due to the large burden the income verification process places on consumers, but we found that the verification process was required for consumers with IRS data, and that consumers with other IRS data would have their household income adjusted based on that data as opposed to those without IRS data who would instead lose all of their APTC.

In developing the proposal for re-enrollment hierarchy, we considered a variety of alternatives, including making no modifications. We also considered revising the policy, beginning in PY 2024, such that the Exchange could direct re-enrollment for income-based CSR-eligible enrollees from a bronze QHP to a silver QHP with a $0 net premium within the same product and QHP issuer, regardless if the enrollee's current plan is available. Under this alternative we considered revising the policy to allow the Exchange to ensure the enrollee's coverage retained a similar provider network throughout the Federal hierarchy for re-enrollment. While we believe this may slightly reduce operational complexity, we believe income-based CSR-eligible enrollees who have a de minimis or non-zero-dollar premium would still greatly benefit from having their coverage renewed into a silver CSR QHP with a lower or equivalent net premium and OOPC, by saving thousands in care costs.

We also considered revising the policy, beginning in PY 2024, such that the Exchange could: (1) direct re-enrollment, for income-based CSR-eligible enrollees, from a bronze QHP to a silver QHP with a lower or equivalent net premium and total OOPC within the same product and QHP issuer regardless if their current plan is available; (2) if their current plan is available and the enrollee is not income-based CSR eligible, re-enroll the enrollee's coverage in the enrollee's same plan; (3) if their current plan is not available and the enrollee is not income-based CSR eligible, direct re-enrollment to a plan at the same metal level that has a lower or equivalent net premium and total out-of-pocket cost compared to the enrollee's current QHP within the same product and QHP issuer; and (4) if a plan at the same metal level as their current QHP is not available and the enrollee is not income-based CSR eligible, direct re-enrollment to a QHP that is one metal level higher or lower than the enrollee's current QHP and has a lower or equivalent net premium and total OOPC compared to the enrollee's current QHP within the same product and issuer. Under this alternative, we considered revising the policy to allow the Exchange to ensure the enrollee's coverage retained a similar provider network throughout the Federal hierarchy for re-enrollment. While we believe this alternative would be beneficial for all enrollees, we understand this would pose a substantial operational burden and complexities for issuers and Exchanges to shift from the current policy to this revised alternative. We believe an incremental change would help issuers and Exchanges diligently and appropriately adjust their re-enrollment operations. We solicit comment on all

aspects of the re-enrollment proposal at § 155.335(j).

HHS considered taking no action related to the two technical corrections to the regulatory text at § 155.420(a)(4)(ii)(A) and (B). However, HHS felt these changes were necessary to make it explicitly clear that when a qualified individual or enrollee, or his or her dependent, experiences the special enrollment period triggering event, all members of a household may enroll in or change plans together in response to the event experienced by one member of the household. These proposed technical corrections should eliminate any confusion surrounding special enrollment period triggering events and may help Exchanges and other interested parties more effectively communicate and message rules that determine eligibility for special enrollment periods and how plan category limitations may apply for certain special enrollment periods as outlined under § 155.420(a).

We considered taking no action related to our proposal to revise paragraph § 155.420(b)(2)(iv), to provide Exchanges with more flexibility by allowing Exchanges the option to provide consumers with earlier coverage effective dates so that consumers are able to seamlessly transition from one form of coverage to Exchange coverage as quickly as possible with no coverage gaps. However, we believe that many consumers would benefit from this proposed change, especially those consumers whose States allow for mid-month terminations for Medicaid/CHIP or those consumers whose COBRA coverage ends mid-month and who report their coverage loss to the Exchange before it happens. We also considered allowing consumers the option to request a prospective coverage start date rather than the day following loss of MEC or COBRA coverage but we determined that this could introduce adverse selection as consumers could choose to delay enrolling in Exchange coverage and paying premiums until coverage was necessary. Finally, we also considered for consumers attesting to a past loss of MEC and who also report a mid-month coverage loss that Exchange coverage would be effective retroactively back to the first day after the prior coverage loss date. For example, if a consumer lost coverage on July 15, coverage would be effective retroactively back to July 16. We decided against this option as it would require a statutory change to allow for mid-month PTC for consumers losing MEC mid-month, in addition to being too operationally complex for both Exchanges and issuers to implement.

We considered taking no action related to our proposal to add new paragraph § 155.420(c)(6), to ensure that qualifying individuals losing Medicaid or CHIP coverage are able to seamlessly transition to Exchange coverage as quickly as possible with little to no coverage gaps. However, we believe that many consumers will benefit from this proposed change, especially during the PHE unwinding period, where many consumers will need to seamlessly transition off Medicaid or CHIP and into Exchange coverage. We also considered whether this proposed change should be broadened to include consumers in other disadvantaged groups such as those impacted by natural disasters or other exceptional circumstances, consumers losing Medicaid or CHIP that is not considered MEC, and consumers who are denied Medicaid or CHIP coverage. We decided not to include other groups, such as those residing in a Federal Emergency Management Agency (FEMA) declared disaster area, as current CMS guidance requires that an SEP be made available for an additional 60 days after the end of a FEMA declaration.[247] Additionally, for other exceptional circumstances, there is flexibility under § 155.420(d)(9) that CMS may offer impacted consumers more time to enroll under an SEP depending on the type of exceptional circumstance, like a national PHE such as COVID–19. Finally, regarding the population that is denied Medicaid or CHIP coverage, we also considered whether to extend the SEP window length from 60 days to 90 days for the population that is denied Medicaid or CHIP, however, we chose not to extend the SEP window length for this population as there is no 90 day reconsideration period that needs alignment for consumers denied Medicaid or CHIP as there is for consumers who have lost eligibility for Medicaid or CHIP as described earlier in preamble.

We considered taking no action regarding our proposal to modify § 155.430(b) to expressly prohibit issuers from terminating coverage for policy dependent enrollees because they reached the maximum allowable age mid-Plan Year. However, we believe it is important to provide clarity to issuers and consumers regarding this policy so that coverage is not prematurely disrupted.

In developing the IPPTA policies contained in this proposed rule (§ 155.1500), we requested to meet individually with each State Exchange currently participating in the voluntary State engagement initiative in order to gather State-specific information regarding options for data collection that would impose the least burden on State Exchanges. Based on information provided by those State Exchanges that were able to participate in the meetings, we considered several data collection options but chose the option that provides State Exchanges with the greatest amount of control in aligning their source data to the requested data elements. In addition, the proposed data collection option requests that the State Exchange provide no fewer than 10 sampled tax households that we propose the State Exchange would identify based upon fulfilling the scenarios described in the preamble. An alternative option consisted of allowing the State Exchange to provide to HHS all of the source data in an unstructured format for the respective, sampled tax households. HHS using its own resources would then map the State Exchange source data to the required data elements that are necessary for performing the pre-testing and assessment. The mapping process would require consultative sessions with each State Exchange and a validation process to ensure the accurate mapping of the data. While the proposed pre-testing and assessment data request form also entails a process to validate the data with the State Exchanges, the consultative process associated with this alternative data collection mechanism would entail more frequency and a higher level of intensity.

We invite comment on this proposed data collection option and invite comment on potential alternative data collection options.

With respect to standardized plan options, we considered a range of options for the proposed policy approach at § 156.201, such as modifying the methodology used to create the standardized plan options for PY 2024 and subsequent PYs. Specifically, we considered including more than four tiers of prescription drug cost-sharing in the standardized plan option formularies. We also considered lowering the deductibles in these plan designs and offsetting this increase in plan generosity by increasing cost-sharing amounts for several benefit categories. We also considered simultaneously maintaining the current cost-sharing structures and decreasing the deductibles for these plan designs, which would have increased the AVs of these plans to be at the ceiling of each AV de minimis range. Ultimately, we

[247] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/8-9-natural-disaster-SEP.pdf.*

decided to maintain the AVs of these plans near the floor of each de minimis range by largely maintaining the cost-sharing structures and deductible values from the standardized plan options from PY 2023, as well as by increasing the MOOP values for these plan designs. We believe this proposed approach would strike the greatest balance in providing enhanced pre-deductible coverage while ensuring competitive premiums for these standardized plan options.

We invite comment on this proposed approach.

With respect to non-standardized plan option limits, we considered a range of options for the proposed policy approach at § 156.202. Specifically, we considered limiting the number of non-standardized plan options to three, two, or one per issuer, product network type, metal level, and service area combination. We also considered no longer permitting non-standardized plan options to be offered through the Exchanges.

We also considered redeploying the meaningful difference standard, which was previously codified at § 156.298, either in place of or in conjunction with imposing limits on the number of non-standardized plan options that issuers can offer through the Exchanges. In this scenario, we considered selecting from among several combinations of the criteria in the original version of the meaningful difference standard to determine whether plans are ''meaningfully different'' from one another.[248] Specifically, we considered using only a difference in deductible type (that is, integrated or separate medical and drug deductible), as well as a $1,000 difference in deductible to determine whether plans are ''meaningfully different'' from one another.

We believe the proposed approach of limiting the number of non-standardized plan options to two per issuer, product network type, service area, and metal level would most significantly reduce the risk of plan choice overload, streamlining the plan selection process and enhancing choice architecture for consumers on the Exchanges.

We invite comment on this proposed approach.

With respect to plan and plan variation marketing names, we considered issuing sub-regulatory guidance in lieu of proposed rulemaking to require that marketing names include correct information, without omission of material fact, and not include content that is misleading. However, given the important role that plan and plan variation marketing names play in facilitating plan competition through consumer education on Exchanges, we are proposing this requirement in regulation to allow interested parties the opportunity to comment.

We considered leaving the ECP provider participation threshold and major ECP categories unchanged from PY 2023, but elected to propose these changes to ECP policy in an effort to increase access to care, particularly mental health care and SUD treatment, for low-income and medically underserved consumers. We invite comment on these proposals.

We considered not introducing a proposal to require all QHP issuers, including stand-alone dental plans, to utilize a contracted network of providers, but elected to propose this change to network adequacy policy in an effort to ensure that consumers have access to insurer-negotiated prices and reduced costs in the form of reduced cost-sharing, premiums, and service price, as compared with cost-sharing, premiums, and service prices obtained from plans with no network of contracted providers. We invite comment on this proposal.

We considered not proposing an amendment to § 156.270(f) to add a timeliness standard to the requirement for QHP issuers to send enrollees notices of payment delinquency. However, because there is currently no timeliness standard for delinquency notices, we are concerned that there is a risk that enrollees may not receive sufficient notice of their delinquency in order to avoid termination of coverage. We also considered proposing requirements on how much advance notice issuers must provide on premium bills after coverage is effectuated, but have declined to propose regulation here, determining that our focus on delinquency notice timeliness will have the desired impact without creating potential conflicts with the existing pattern of State rules and issuer practices that have long applied in the individual market.

E. Regulatory Flexibility Act (RFA)

The RFA 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, we estimate that small businesses, nonprofit organizations, and small governmental jurisdictions are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, we believe that health insurance issuers and group health plans would be classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $41.5 million or less would be considered small entities for these NAICS codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $35 million or less.[249] We believe that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report submissions for the 2020 MLR reporting year, approximately 78 out of 480 issuers of health insurance coverage nationwide had total premium revenue of $41.5 million or less.[250] This estimate may overstate the actual number of small health insurance issuers that may be affected, since over 76 percent of these small issuers belong to larger holding groups, and many, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding $41.5 million.

In this proposed rule, we propose standards for the risk adjustment and HHS–RADV programs, which are intended to stabilize premiums and reduce incentives for issuers to avoid higher-risk enrollees. Because we believe that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for ''small entities'' established by the SBA, we do not

[248] Under the original meaningful difference standard, a plan was considered to be ''meaningfully different'' from other plans in the same product network type, metal level, and service area combination if the plan had at least one of the following characteristics: difference in network ID, difference in formulary ID, difference in MOOP type, difference in deductible, multiple in-network provider tiers rather than only one, a difference of $500 or more in MOOP, a difference of $250 or more in deductible, or any difference in covered benefits.

[249] *https://www.sba.gov/document/support--table-size-standards.*

[250] Available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

believe that an initial regulatory flexibility analysis is required for such firms. Furthermore, the proposals related to IPPTA at §§ 155.1500–155.1515 will affect only State Exchanges. As State governments do not constitute small entities under the statutory definition, and as all State Exchanges have revenues exceeding $5 million, an impact analysis for these provisions is not required under the RFA.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this proposed rule. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. While this rule is not subject to section 1102 of the Act, we have determined that this proposed rule would not affect small rural hospitals. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. 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 2022, that threshold is approximately $165 million. Although we have not been able to quantify all costs, we expect the combined impact on State, local, or Tribal governments and the private sector does not meet the UMRA definition of unfunded mandate.

G. 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.

In compliance with the requirement of E.O. 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, we have engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the NAIC, and consulting with State insurance officials on an individual basis.

While developing this rule, we attempted to balance the States' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, we complied with the requirements of E.O. 13132.

Because States have flexibility in designing their Exchange and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment program. For States that elected previously to operate an Exchange, those States had the opportunity to use funds under Exchange Planning and Establishment Grants to fund the development of data. Accordingly, some of the initial cost of creating programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the State. Current State Exchanges charge user fees to issuers.

In our view, while this proposed rule would not impose substantial direct requirement costs on State and local governments, this regulation has Federalism implications due to potential direct effects on the distribution of power and responsibilities among the State and Federal Governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. For example, the repeal of the risk adjustment State flexibility policy may have Federalism implications, but they are mitigated because States have the option to operate their own Exchange and risk adjustment program if they believe the HHS risk adjustment methodology does not account for State-specific factors unique to the State's markets.

As previously noted, the proposals in this rule related to IPPTA would impose a minimal unfunded mandate on State Exchanges to supply data for the improper payment calculation. Accordingly, E.O. 13132 does not apply to this section of the proposed rule. In addition, statute requires HHS to determine the amount and rate of improper payments. Finally, States have the option to choose an FFE or SBE–FP, each of which place different Federal burdens on the State. As the IPPTA section of the proposed rule should not conflict with State law, HHS does not anticipate any preemption of State law. We invite State Exchanges to submit comments on this section of the proposed rule if they believe it would conflict with State law.

In addition, we believe this proposed regulation does have Federalism implications due to our proposal that Exchanges offer earlier effective dates for consumers attesting to future mid-month loss of MEC or COBRA coverage. However, the Federalism implications are mitigated as Exchanges would have the flexibility to continue offering the current coverage effective dates as described at § 155.420(b)(2)(iv) or the new proposed earlier effective dates for consumers attesting to a future loss of MEC as described earlier in preamble. In addition, through the cross-references in § 147.104(b)(5), the new proposed earlier coverage effective dates for consumers attesting to a future loss of MEC would be applicable market-wide at the option of the applicable State authority.

Additionally, we believe this proposed regulation does have Federalism implications due to our proposal that Exchanges provide consumers losing Medicaid or CHIP with a 90-day special enrollment period window to enroll in an Exchange QHP rather than the current 60-day window. However, the Federalism implications are mitigated as Exchanges will have the flexibility to decide whether to continue providing 60 days before or 60 days after for consumers losing Medicaid or CHIP to enroll in a QHP plan as described at § 155.420(c)(1) or to implement the proposed new special rule providing consumers with 60 days before or 90 days after their loss of Medicaid or CHIP to enroll in QHP coverage.

List of Subjects

45 CFR Part 153

Administrative practice and procedure, Health care, Health insurance, Health records, Intergovernmental relations, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers,

Conflict of interests, Consumer protection, Grants administration, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

For the reasons set forth in the preamble, under the authority at 5 U.S.C. 301, the Department of Health and Human Services proposes to amend 45 CFR subtitle A, subchapter B, as set forth below.

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 1. The authority citation for part 153 continues to read as follows:

Authority: 42 U.S.C. 18031, 18041, and 18061 through 18063.

■ 2. Amend § 153.320 by revising paragraphs (d) introductory text, (d)(1)(iv), and (d)(4)(i)(B) to read as follows:

§ 153.320 Federally certified risk adjustment methodology

* * * * *

(d) *State flexibility to request reductions to transfers.* For the 2020 through 2023 benefit years, States can request to reduce risk adjustment transfers in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool by up to 50 percent in States where HHS operates the risk adjustment program. For the 2024 benefit year, only prior participants, as defined in paragraph (d)(5) of this section, may request to reduce risk adjustment transfers in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool by up to 50 percent in States where HHS operates the risk adjustment program.

(1) * * *

(i) * * *

(iv) For the 2024 benefit year only, a justification for the requested reduction demonstrating the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

* * * * *

(4) * * *

(B) For the 2024 benefit year only, that the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

* * * * *

■ 3. Section 153.630 is amended by—

■ a. Revising paragraph (d)(2);

■ b. Redesignating paragraph (d)(3) as paragraph (d)(4); and

■ c. Adding new paragraph (d)(3).

The revision and addition read as follows:

§ 153.630 Data validation requirements when HHS operates risk adjustment.

* * * * *

(d) * * *

(2) Within 15 calendar days of the notification of the findings of a second validation audit (if applicable) by HHS, in the manner set forth by HHS, an issuer must confirm the findings of the second validation audit (if applicable), or file a discrepancy report to dispute the findings of a second validation audit (if applicable).

(3) Within 30 calendar days of the notification by HHS of the calculation of a risk score error rate, in the manner set forth by HHS, an issuer must confirm the calculation of the risk score error rate as a result of risk adjustment data validation, or file a discrepancy report to dispute the calculation of a risk score error rate as a result of risk adjustment data validation.

* * * * *

■ 4. Section 153.710 is amended by revising paragraphs (e) and (h)(1) introductory text to read as follows:

§ 153.710 Data requirements.

* * * * *

(e) *Materiality threshold.* HHS will consider a discrepancy reported under paragraph (d)(2) of this section to be material if the amount in dispute is equal to or exceeds $100,000 or 1 percent of the total estimated transfer amount in the applicable State market risk pool, whichever is less.

* * * * *

(h) * * *

(1) Notwithstanding any discrepancy report made under paragraph (d)(2) of this section, any discrepancy filed under § 153.630(d)(2) or (3), or any request for reconsideration under § 156.1220(a) of this subchapter with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees and risk adjustment data validation adjustments; reinsurance payment; cost-sharing reduction payment or charge; or risk corridors payment or charge, unless the dispute has been resolved, an issuer must report, for purposes of the risk corridors and MLR programs:

* * * * *

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 5. The authority citation for part 155 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083.

■ 6. Section 155.106 is amended by revising paragraphs (a)(3) and (c)(3) to read as follows:

§ 155.106 Election to operate an Exchange after 2014.

(a) * * *

(3) Have in effect an approved, or conditionally approved, Exchange Blueprint and operational readiness assessment prior to the date on which the Exchange would begin open enrollment as a State Exchange;

* * * * *

(c) * * *

(3) Have in effect an approved, or conditionally approved, Exchange Blueprint and operational readiness assessment prior to the date on which the Exchange proposes to begin open enrollment as an SBE–FP, in accordance with HHS rules, as a State Exchange utilizing the Federal platform;

* * * * *

§ 155.210 [Amended]

■ 7. Section 155.210 is amended by removing and reserving paragraph (d)(8).

■ 8. Section 155.220 is amended by—

■ a. Revising paragraphs (g)(5)(i)(B), (h)(3), and (j)(2)(ii) introductory text;

■ b. Redesignating paragraphs (j)(2)(ii)(A) through (D) as paragraphs (j)(2)(ii)(B), through (E), respectively;

■ c. Adding new paragraph ((j)(2)(ii)(A); and

■ d. Revising paragraph (j)(2)(iii).

The revisions and additions read as follows:

§ 155.220 Ability of States to permit agents and brokers and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling QHPs.

* * * * *

(g) * * *

(5) * * *

(i) * * *

(B) The agent, broker, or web-broker may submit evidence in a form and manner to be specified by HHS, to rebut the allegation during this 90-day period. If the agent, broker, or web-broker submits such evidence during the suspension period, HHS will review the evidence and make a determination whether to lift the suspension within 45 calendar days of receipt of such evidence. If the rebuttal evidence does not persuade HHS to lift the suspension, or if the agent, broker, or web-broker fails to submit rebuttal evidence during the suspension period, HHS may terminate the agent's, broker's, or web-broker's agreements required under paragraph (d) of this section and under § 155.260(b) for cause under paragraph (g)(5)(ii) of this section.

* * * * *

(h) * * *

(3) *Notice of reconsideration decision.* The HHS reconsideration entity will provide the agent, broker, or web-broker with a written notice of the reconsideration decision within 60 calendar days of the date it receives the request for reconsideration. This decision will constitute HHS' final determination.

* * * * *

(j) * * *

(2) * * *

(ii) Provide the Federally-facilitated Exchanges with correct information, and document that eligibility application information has been reviewed by and confirmed to be accurate by the consumer, or the consumer's authorized representative designated in compliance with § 155.227, prior to the submission of information under section 1411(b) of the Affordable Care Act, including but not limited to:

(A) Documenting that eligibility application information has been reviewed by and confirmed to be accurate by the consumer or the consumer's authorized representative must require the consumer or their authorized representative to take an action that produces a record that can be maintained by the individual or entity described in paragraph (j)(1) of this section and produced to confirm the consumer or their authorized representative has reviewed and confirmed the accuracy of the eligibility application information. Non-exhaustive examples of acceptable documentation include obtaining the signature of the consumer or their authorized representative (electronically or otherwise), verbal confirmation by the consumer or their authorized representative that is captured in an audio recording, a written response (electronic or otherwise) from the consumer or their authorized representative to a communication sent by the agent, broker, or web-broker, or other similar means or methods specified by HHS in guidance.

(*1*) The documentation required under paragraph (j)(2)(ii)(A) of this section must include the date the information was reviewed, the name of the consumer or their authorized representative, an explanation of the attestations at the end of the eligibility application, and the name of the assisting agent, broker, or web-broker.

(*2*) An individual or entity described in paragraph (j)(1) of this section must maintain the documentation described in paragraph (j)(2)(ii)(A) of this section for a minimum of ten years, and produce the documentation upon request in response to monitoring, audit, and enforcement activities conducted consistent with paragraphs (c)(5), (g), (h), and (k) of this section.

* * * * *

(iii) Obtain and document the receipt of consent of the consumer or their authorized representative designated in compliance with § 155.227, employer, or employee prior to assisting with or facilitating enrollment through a Federally-facilitated Exchange or assisting the individual in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs;

(A) Obtaining and documenting the receipt of consent must require the consumer, or the consumer's authorized representative designated in compliance with § 155.227, to take an action that produces a record that can be maintained and produced by an individual or entity described in paragraph (j)(1) of this section to confirm the consumer's or their authorized representative's consent has been provided. Non-exhaustive examples of acceptable documentation of consent include obtaining the signature of the consumer or their authorized representative (electronically or otherwise), verbal confirmation by the consumer or their authorized representative that is captured in an audio recording, a response from the consumer or their authorized representative to an electronic or other communication sent by the agent, broker, or web-broker.

(B) The documentation required under paragraph (j)(2)(iii)(A) of this section must include a description of the scope, purpose, and duration of the consent provided by the consumer or their authorized representative designated in compliance with § 155.227, the date consent was given, name of the consumer or their authorized representative, and the name of the agent, broker, web-broker, or agency being granted consent, as well as a process through which the consumer or their authorized representative may rescind the consent.

(C) An individual or entity described in paragraph (j)(1) of this section must maintain the documentation described in paragraph (j)(2)(iii)(A) of this section for a minimum of 10 years, and produce the documentation upon request in response to monitoring, audit, and enforcement activities conducted consistent with paragraphs (c)(5), (g), (h), and (k) of this section.

* * * * *

§ 155.225 [Amended]

■ 9. Section 155.225 is amended by removing and reserving paragraph (g)(5).

■ 10. Section 155.305 is amended by revising paragraph (f)(4) to read as follows.

§ 155.305 Eligibility standards.

* * * * *

(f) * * *

(4) *Compliance with filing requirement.* Beginning January 1, 2024, the Exchange may not determine a tax filer eligible for APTC if the IRS notifies HHS and HHS notifies the Exchange as part of the process described in § 155.320(c)(3) that APTC payments were made on behalf of the tax filer or either spouse if the tax filer is a married couple for two consecutive years for which tax data would be utilized for verification of household income and family size in accordance with § 155.320(c)(1)(i), and the tax filer or his or her spouse did not comply with the requirement to file an income tax return for that year and for the previous year as required by 26 U.S.C. 6011, 6012, and their implementing regulations and reconcile APTC for that period.

* * * * *

■ 11. Section 155.315 is amended by adding paragraph (f)(7) to read as follows:

§ 155.315 Verification process related to eligibility for enrollment in a QHP through the Exchange.

* * * * *

(f) * * *

(7) Must extend the period described in paragraph (f)(2)(ii) of this section by a period of 60 days for an applicant if the applicant is required to present satisfactory documentary evidence to verify household income.

* * * * *

■ 12. Section 155.320 is amended by adding paragraph (c)(5) to read as follows:

§ 155.320 Verification process related to eligibility for insurance affordability programs.

* * * * *

(c) * * *

(5) Notwithstanding any other requirement described in this paragraph (c) to the contrary, when the Exchange requests tax return data and family size from the Secretary of Treasury as described in § 155.320(c)(1)(i)(A) but no such data is returned for an applicant, the Exchange will accept that applicant's attestation of income and family size without further verification.

* * * * *

■ 13. Section 155.335 is amended by revising paragraphs (j)(1)(i), (j)(1)(ii), (j)(1)(iii)(A) and (B), (j)(1)(iv), (j)(2)(i) through (iii) and adding paragraphs (j)(2)(iv) and (v) to read as follows:

§ 155.335 Annual eligibility redetermination.

* * * * *

(j) * * *

(1) * * *

(i) If the enrollee's current QHP is available through the Exchange and –

(A) The enrollee is not CSR-eligible, in accordance with § 155.305(g), the Exchange will re-enroll the enrollee in the same plan as the enrollee's current QHP.

(B) The enrollee is CSR-eligible, in accordance with § 155.305(g), and the enrollee's current QHP is a bronze level plan, the Exchange will re-enroll the enrollee either in the same plan as the enrollee's current QHP, or, at the option of the Exchange, in a silver level QHP within the same product that has a lower or equivalent premium after APTC and that has the most similar network compared to the enrollee's current QHP;

(C) The enrollee is CSR-eligible, in accordance with § 155.305(g), and the enrollee's current QHP is not a bronze level plan, the Exchange will re-enroll the enrollee in the same plan as the enrollee's current QHP.

(ii) If the enrollee's current QHP is not available through the Exchange and –

(A) The enrollee is not CSR-eligible, in accordance with § 155.305(g), the Exchange will re-enroll the enrollee in a QHP within the same product, at the same metal level and that has the most similar network compared to the enrollee's current QHP.

(B) The enrollee is CSR-eligible, in accordance with § 155.305(g), and the enrollee's current QHP is a bronze level plan, the Exchange will re-enroll the enrollee either in a bronze level QHP within the same product, or, at the option of Exchange, in a silver level QHP within the same product that has a lower or equivalent premium after APTC and that has the most similar network compared to the enrollee's current QHP;

(C) The enrollee is CSR-eligible, in accordance with § 155.305(g), and the enrollee's current QHP is not a bronze level plan, the Exchange will re-enroll the enrollee in a QHP within the same product at the same metal level and that has the most similar network compared to the enrollee's current QHP;

(iii) * * *

(A) The enrollee's current QHP is a silver level plan, the Exchange will re-enroll the enrollee in a silver level QHP under a different product offered by the same QHP issuer that is most similar to and that has the most similar network compared to the enrollee's current product. If no such silver level QHP is available for enrollment through the Exchange, the Exchange will re-enroll the enrollee in a QHP under the same product that is one metal level higher or lower than the enrollee's current QHP and that has the most similar network compared to the enrollee's current QHP;

(B) The enrollee's current QHP is not a silver level plan, the Exchange will re-enroll the enrollee under the same product that is one metal level higher or lower than the enrollee's current QHP and that has the most similar network compared to the enrollee's current QHP and ; or

(iv) If the enrollee's current QHP is not available through the Exchange and the enrollee's product no longer includes a QHP that is at the same metal level as, or one metal level higher or lower than the enrollee's current QHP, the Exchange will re-enroll the enrollee in any other QHP offered under the product in which the enrollee's current QHP is offered in which the enrollee is eligible to enroll that has the most similar network compared to the enrollee's current QHP.

(2) * * *

(i) If the enrollee is not CSR eligible, the Exchange will re-enroll the enrollee in a QHP in the product offered by the same issuer that is the most similar to the enrollee's current product at the same metal level as and with the most similar network compared to the enrollee's current QHP;

(ii) If the enrollee is CSR-eligible, in accordance with § 155.305(g), and the enrollee's current QHP is a bronze level plan, the Exchange will re-enroll the enrollee either in a bronze level QHP, or, at the option of the Exchange, in a silver level QHP that has a lower or equivalent premium after APTC and that has the most similar network compared to the enrollee's current QHP in the product offered by the same issuer through the Exchange that is most similar to the enrollee's current product;

(iii) If the enrollee is CSR-eligible, in accordance with § 155.305(g), and the enrollee's current QHP is not a bronze level plan, the Exchange will re-enroll the enrollee in a QHP at the same metal level that has the most similar network compared to the enrollee's current QHP in the product offered by the same issuer that is the most similar to the enrollee's current product;

(iv) If the issuer does not offer another QHP at the same metal level as the enrollee's current QHP, the Exchange will re-enroll the enrollee in a QHP that is one metal level higher or lower than the enrollee's current QHP and that has the most similar network compared to the enrollee's current QHP in the product offered by the same issuer through the Exchange that is the most similar to the enrollee's current product; or

(v) If the issuer does not offer another QHP through the Exchange at the same metal level as, or one metal level higher or lower than the enrollee's current QHP, the Exchange will re-enroll the enrollee in any other QHP offered by the same issuer in which the enrollee is eligible to enroll in the product that is most similar to the enrollee's current product and in a QHP within that product that has the most similar network to the enrollee's current QHP.

* * * * *

■ 14. Section 155.420 is amended by—

■ a. Revising paragraphs (a)(4)(ii)(A) and (B), (b)(2)(iv), and (c)(2);

■ b. Adding paragraph (c)(6); and

■ c. Revising paragraph (d)(12).

The revisions and addition read as follows:

§ 155.420 Special enrollment periods.

(a) * * *

(4) * * *

(ii) * * *

(A) If an enrollee or his or her dependents become newly eligible for cost-sharing reductions in accordance with paragraph (d)(6)(i) or (ii) of this section and the enrollee or his or her

dependents are not enrolled in a silver-level QHP, the Exchange must allow the enrollee and his or her dependents to change to a silver-level QHP if they elect to change their QHP enrollment; or

(B) Beginning January 2022, if an enrollee or his or her dependents become newly ineligible for cost-sharing reductions in accordance with paragraph (d)(6)(i) or (ii) of this section and the enrollee or his or her dependents are enrolled in a silver-level QHP, the Exchange must allow the enrollee and his or her dependents to change to a QHP one metal level higher or lower if they elect to change their QHP enrollment;

* * * * *

(b) * * *

(2) * * *

(iv) If a qualified individual, enrollee, or dependent, as applicable, loses coverage as described in paragraphs (d)(1) or (d)(6)(iii) of this section, or is enrolled in COBRA continuation coverage for which an employer is paying all or part of the premiums, or for which a government entity is providing subsidies, and the employer contributions or government subsidies completely cease as described in paragraph (d)(15) of this section, gains access to a new QHP as described in paragraph (d)(7) of this section, becomes newly eligible for enrollment in a QHP through the Exchange in accordance with § 155.305(a)(2) as described in paragraph (d)(3) of this section, becomes newly eligible for advance payments of the premium tax credit in conjunction with a permanent move as described in paragraph (d)(6)(iv) of this section, and if the plan selection is made on or before the day of the triggering event, the Exchange must ensure that the coverage effective date is the first day of the month following the date of the triggering event. If the plan selection is made after the date of the triggering event, the Exchange must ensure that coverage is effective in accordance with paragraph (b)(1) of this section or on the first day of the following month, at the option of the Exchange. Notwithstanding the requirements of this paragraph (b)(2)(iv), and at the option of the Exchange, if the plan selection is made on or before the last day of the month preceding the triggering event, the Exchange must ensure that the coverage effective date is the first of the month in which the triggering event occurs for losses of coverage as described in paragraphs (d)(1), (d)(6)(iii), and (d)(15) of this section.

* * * * *

(c) * * *

(2) *Advanced availability.* A qualified individual or his or her dependent who is described in paragraph (d)(1), (d)(6)(iii), or (d)(15) of this section has 60 days before and, unless the Exchange exercises the option in paragraph (c)(6) of this section, 60 days after the triggering event to select a QHP. At the option of the Exchange, a qualified individual or his or her dependent who is described in paragraph (d)(7) of this section; who is described in paragraph (d)(6)(iv) of this section becomes newly eligible for advance payments of the premium tax credit as a result of a permanent move to a new State; or who is described in paragraph (d)(3) of this section and becomes newly eligible for enrollment in a QHP through the Exchange because he or she newly satisfies the requirements under § 155.305(a)(2), has 60 days before or after the triggering event to select a QHP.

* * * * *

(6) *Special rule for individuals losing Medicaid or CHIP.* Beginning January 1, 2024, at the option of the Exchange, a qualified individual or his or her dependent(s) who is described in paragraph (d)(1)(i) of this section and whose loss of coverage is a loss of Medicaid or CHIP coverage shall have 90 days after the triggering event to select a QHP.

* * * * *

(d) * * *

(12) The enrollment in a QHP through the Exchange was influenced by a material error related to plan benefits, service area, cost-sharing, or premium. A material error is one that is likely to have influenced a qualified individual's, enrollee's, or their dependent's enrollment in a QHP.

* * * * *

■ 15. Section 155.430 is amended by adding paragraph (b)(3) to read as follows:

§ 155.430 Termination of Exchange enrollment or coverage.

* * * * *

(b) * * *

(3) *Prohibition of issuer-initiated terminations due to aging-off.* Exchanges on the Federal platform must, and State Exchanges using their own platform may, prohibit QHP issuers from terminating dependent coverage of a child before the end of the plan year in which the child attains age 26, or before the end of the plan year in which the child attains the maximum age a QHP issuer is required to make available dependent coverage of children under applicable State law, on the basis of the child's age, unless otherwise permitted.

* * * * *

■ 16. Section 155.505 is amended by revising paragraph (g) to read as follows:

§ 155.505 General eligibility appeals requirements.

* * * * *

(g) *Review of Exchange Eligibility Appeal Decisions.* An appellant may seek review of Exchange eligibility appeal decisions issued under paragraph (b) of this section as follows:

(1) *Administrative Review.* The Administrator may review an Exchange eligibility appeal decision as follows:

(i) *Request by a party to the appeal.* (A) Within 14 calendar days of the date of the Exchange eligibility appeal decision issued by an impartial official as described in § 155.535(c)(4), a party to the appeal may request review of the Exchange eligibility appeal decision by the CMS Administrator. Such a request may be made even if the CMS Administrator has already at their initiative declined review as described in paragraph (g)(1)(ii)(B) of this section. If the CMS Administrator accepts that party's request for a review after having declined review, then the CMS Administrator's initial declination to review the eligibility appeal decision is void.

(B) Within 30 days of the date of the party's request for administrative review, the CMS Administrator may:

(1) Decline to review the Exchange eligibility appeal decision;

(2) Render a final decision as described in § 155.545 (a)(1) based on their review of the eligibility appeal decision; or

(3) Choose to take no action on the request for review.

(C) The Exchange eligibility appeal decision of the impartial official as described in § 155.535(c)(4) is final as of the date of the Exchange eligibility appeal decision if the CMS Administrator declines the party's request for review or if the CMS Administrator does not take any action on the party's request for review by the end of the 30-day period described in paragraph (a)(ii).

(ii) *Review at the discretion of the CMS Administrator.* (A) Within 14 calendar days of the date of the Exchange eligibility appeal decision issued by an impartial official as described in § 155.535(c)(4), the CMS Administrator may initiate a review of an eligibility appeal decision at their discretion.

(B) Within 30 days of the date the CMS Administrator initiates a review, the CMS Administrator may:

(1) Decline to review the Exchange eligibility appeal decision;

(2) Render a final decision as described in § 155.545 (a)(1) based on their review of the eligibility appeal decision; or

(3) Choose to take no action on the Exchange eligibility appeal decision.

(C) The eligibility Exchange appeal decision of the impartial official as described in § 155.535(c)(4) is final as of the date of the Exchange eligibility appeal decision if the CMS Administrator declines to review the eligibility appeal decision or chooses to take no action by the end of the 30-day period described in paragraph (g)(1)(i)(B) of this section.

(iii) *Effective dates.* If a party requests a review of an Exchange eligibility appeal decision by the CMS Administrator or the CMS Administrator initiates a review of an Exchange eligibility appeal decision at their own discretion, the eligibility appeal decision is effective as follows:

(A) If an Exchange eligibility appeal decision is final pursuant to paragraphs (g)(1)(ii)(B) of this section and (g)(1)(ii)(C) in this section, the Exchange eligibility appeal decision of the impartial official as described in § 155.535(c)(4) is effective as of the date of the official's decision.

(B) If the CMS Administrator renders a final decision after reviewing an Exchange eligibility appeal decision as described in paragraphs (g)(1)(i)(B)(*2*) and (1)(ii)(B)(*2*) of this section, the CMS Administrator may choose to change the effective date of the Exchange eligibility appeal decision as described in § 155.545 (a)(5).

(iv) Informal resolution decisions as described in § 155.535(a)(4) are not subject to administrative review by the CMS Administrator.

(2) *Judicial Review.* To the extent it is available by law, an appellant may seek judicial review of a final Exchange eligibility appeal decision.

* * * * *

■ 17. Add subpart P to read as follows:

Subpart P—Improper Payment Pre-Testing and Assessment (IPPTA) for State Exchanges

Sec.

Subpart P—Improper Payment Pre-Testing and Assessment (IPPTA) for State Exchanges

§ 155.1500 Purpose and scope.

(a) This subpart sets forth the requirements of the IPPTA. The IPPTA is an initiative between HHS and the State Exchanges. These requirements are intended to:

(1) Prepare State Exchanges for the planned measurement of improper payments.

(2) Test processes and procedures that support HHS's review of determinations of APTC made by State Exchanges.

(3) Provide a mechanism for HHS and State Exchanges to share information that will aid in developing an efficient measurement process.

(b) [Reserved]

§ 155.1505 Definitions.

As used in this subpart—

Business rules means the State Exchange's internal directives defining, guiding, or constraining the State Exchange's actions when making eligibility determinations and related APTC calculations.

Entity relationship diagram means a graphical representation illustrating the organization and relationship of the data elements that are pertinent to applications for QHP and associated APTC payments.

Pre-testing and assessment means the process that uses the procedures specified in § 155.1515 to prepare State Exchanges for the planned measurement of improper payments of APTC.

Pre-testing and assessment checklist means the document that contains criteria that HHS will use to review a State Exchange's ability to accomplish the requirements of the IPPTA.

Pre-testing and assessment data request form means the document that specifies the structure for the data elements that HHS will require each State Exchange to submit.

Pre-testing and assessment period means the one calendar year timespan during which HHS will engage in pre-testing and assessment procedures with a State Exchange.

Pre-testing and assessment plan means the template developed by HHS in collaboration with each State Exchange enumerating the procedures, sequence, and schedule to accomplish pre-testing and assessment.

Pre-testing and assessment report means the summary report provided by HHS to each State Exchange at the end of the State Exchange's pre-testing and assessment period that will include, but not be limited to, the State Exchange's status regarding completion of each of the pre-testing and assessment procedures specified in § 155.1515, as well as observations and recommendations that result from processing and reviewing the data submitted by the State Exchange to HHS.

§ 155.1510 Data submission.

(a) *Requirements.* For purposes of the IPPTA, a State Exchange must submit the following information in a form and manner specified by HHS:

(1) *Data documentation.* The State Exchange must provide to HHS the following data documentation:

(i) The State Exchange's data dictionary including attribute name, data type, allowable values, and description;

(ii) An entity relationship diagram, which shall include the structure of the data tables and the residing data elements that identify the relationships between the data tables; and

(iii) Business rules and related calculations.

(2) *Data for processing and testing.* The State Exchange must use the pre-testing and assessment data request form, or other method as specified by HHS, to submit to HHS the application data associated with no fewer than 10 tax household identification numbers and the associated policy identification numbers that address scenarios specified by HHS to allow HHS to test all of the pre-testing and assessment processes and procedures.

(b) *Timing.* The State Exchange must submit the information specified in paragraph (a) of this section within the timelines in the pre-testing and assessment plan specified in § 155.1515.

§ 155.1515 Pre-testing and assessment procedures.

(a) *General requirement.* The State Exchanges are required to participate in the IPPTA for a period of one calendar year. The State Exchange and HHS will execute the pre-testing and assessment procedures in this section within the timelines in the pre-testing and assessment plan.

(b) *Orientation and planning processes.* (1) As a part of the orientation process, HHS will provide State Exchanges with an overview of the pre-testing and assessment procedures and identify documentation that a State Exchange must provide to HHS for pre-testing and assessment.

(2) As a part of the planning process, HHS, in collaboration with each State Exchange, will develop a pre-testing and assessment plan that takes into consideration relevant activities, if any, that were completed during a prior,

voluntary State engagement. The pre-testing and assessment plan will include the pre-testing and assessment checklist.

(3) At the conclusion of the pre-testing and assessment planning process, HHS will issue the pre-testing and assessment plan specific to that State Exchange. The pre-testing and assessment plan will be for HHS and State Exchange internal use only and will not be made available to the public by HHS unless otherwise required by law.

(c) *Notifications and updates.* (1) *Notification*s. As needed throughout the pre-testing and assessment period, HHS will issue notifications to State Exchanges concerning information related to the pre-testing and assessment processes and procedures.

(2) *Updates regarding changes.* Throughout the pre-testing and assessment period, the State Exchange must provide HHS with information regarding any operational, policy, business rules, information technology, or other changes that may impact the ability of the State Exchange to satisfy the requirements of the pre-testing and assessment.

(d) *Submission of required data and data documentation.* As specified in § 155.1510, HHS will inform State Exchanges about the form and manner for State Exchanges to submit required data and data documentation to HHS in accordance with the pre-testing and assessment plan.

(e) *Data processing.* (1) HHS will coordinate with each State Exchange to track and manage the data and data documentation submitted by a State Exchange as specified in § 155.1510(a)(1) and (2).

(2) HHS will coordinate with each State Exchange to provide assistance in aligning the data specified in § 155.1510(a)(2) from the State Exchange's existing data structure to the standardized set of data elements.

(3) HHS will coordinate with each State Exchange to interpret and validate the data specified in § 155.1510(a)(2).

(4) HHS will use the data and data documentation submitted by the State Exchange to execute the pre-testing and assessment procedures.

(f) *Pre-testing and assessment checklist.* HHS will issue the pre-testing and assessment checklist as part of the pre-testing and assessment plan. The pre-testing and assessment checklist criteria will include but are not limited to:

(1) A State Exchange's submission of the data documentation as specified in § 155.1510(a)(1).

(2) A State Exchange's submission of the data for processing and testing as specified in § 155.1510(a)(2); and

(3) A State Exchange's completion of the pre-testing and assessment processes and procedures related to the IPPTA program.

(g) *Pre-testing and assessment report.* Subsequent to the completion of a State Exchange's pre-testing and assessment period, HHS will issue a pre-testing and assessment report specific to that State Exchange. The pre-testing and assessment report will be for HHS and State Exchange internal use only and will not be made available to the public by HHS unless otherwise required by law.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ The authority citation for part 156 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

■ 18. Section 156.201 is revised to read as follows:

§ 156.201 Standardized plan options.

A QHP issuer in a Federally-facilitated Exchange or a State-based Exchange on the Federal platform, other than an issuer that is already required to offer standardized plan options under State action taking place on or before January 1, 2020, must:

(a) For the plan year 2023, offer in the individual market at least one standardized QHP option, defined at § 155.20 of this subchapter, at every product network type, as the term is described in the definition of ''product'' at § 144.103 of this subchapter, at every metal level, and throughout every service area that it also offers non-standardized QHP options, including, for silver plans, for the income-based cost-sharing reduction plan variations, as provided for at § 156.420(a); and

(b) For plan year 2024 and subsequent plan years, offer in the individual market at least one standardized QHP option, defined at § 155.20 of this subchapter, at every product network type, as the term is described in the definition of ''product'' at § 144.103 of this subchapter, at every metal level except the non-expanded bronze metal level, and throughout every service area that it also offers non-standardized QHP options, including, for silver plans, for the income-based cost-sharing reduction plan variations, as provided for at § 156.420(a)

(c) With respect to covered drugs:

(1) Place all covered generic drugs in the standardized plan options' generic drug cost-sharing tier, or the specialty drug tier if there is an appropriate and non-discriminatory basis in accordance with § 156.125 for doing so; and

(2) Place all covered brand drugs in either the standardized plan options' preferred brand or non-preferred brand drug cost-sharing tier, or the specialty drug cost-sharing tier if there is an appropriate and non-discriminatory basis in accordance with § 156.125 for doing so.

■ 19. Section 156.202 is added to read as follows:

§ 156.202 Non-standardized plan option limits.

For the plan year 2024 and subsequent plan years, a QHP issuer in a Federally-facilitated Exchange or a State-based Exchange on the Federal platform is limited to offering two non-standardized plan options per product network type, as the term is described in the definition of ''product'' at § 144.103 of this subchapter, and metal level (excluding catastrophic plans), in any service area.

■ 20. Section 156.210 is amended by adding paragraph (d) to read as follows:

The addition reads as follows:

§ 156.210 QHP rate and benefit information.

(d) *Rate requirements* for *stand-alone dental plans.* For benefit and plan years beginning on or after January 1, 2024:

(1) *Age on effective date.* The premium rate charged by an issuer of stand-alone dental plans may vary with respect to the particular plan or coverage involved by determining the enrollee's age. Any age calculation for rating and eligibility purposes must be based on the age as of the time of policy issuance or renewal.

(2) *Guaranteed rates.* An issuer of stand-alone dental plans must set guaranteed rates.

■ 21. Section 156.225 is amended by —

■ a. In paragraph (a) removing ''and'' from the end of the paragraph; and

■ b. In paragraph (b) removing ''.'' from the end of the paragraph and replacing it with ''; and''; and

■ c. By adding paragraph (c).

The addition reads as follows:

§ 156.225 Marketing and Benefit Design of QHPs.

* * * * *

(c) *Plan marketing names.* Offer plans and plan variations with marketing names that include correct information, without omission of material fact, and

do not include content that is misleading.

* * * * *

■ 22. Section 156.230 is amended by—

■ a. Revising paragraphs (a)(1) introductory text and (e) introductory text; and

■ b. Removing and reserving paragraph (f).

The revisions read as follows:

§ 156.230 Network adequacy standards.

(a) *General requirement.* (1) Each QHP issuer must use a provider network and ensure that the provider network consisting of in-network providers, as available to all enrollees, meets the following standards:

* * * * *

(e) *Out-of-network cost-sharing.* Beginning for the 2018 and later benefit years, for a network to be deemed adequate, each QHP must:

* * * * *

■ 23. Section 156.235 is amended by revising paragraphs (a)(1), (a)(2)(i) and (a)(2)(ii)(B) to read as follows:

§ 156.235 Essential community providers.

(a) * * *

(1) A QHP issuer must include in its provider network a sufficient number and geographic distribution of essential community providers (ECPs), where available, to ensure reasonable and timely access to a broad range of such providers for low-income individuals or individuals residing in Health Professional Shortage Areas within the QHP's service area, in accordance with the Exchange's network adequacy standards.

(2) * * *

(i) The QHP issuer's provider network includes as participating providers at least a minimum percentage, as specified by HHS, of available ECPs in each plan's service area collectively across all ECP categories defined under paragraph (ii)(B) of this section, and at least a minimum percentage of available ECPs in each plan's service area within certain individual ECP categories, as specified by HHS. Multiple providers at a single location will count as a single ECP toward both the available ECPs in the plan's service area and the issuer's satisfaction of the ECP participation standard. For plans that use tiered networks, to count toward the issuer's satisfaction of the ECP standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. For plans with two network tiers (for example, participating providers and preferred providers), such as many PPOs, where cost-sharing is lower for preferred providers, only preferred providers will be counted towards ECP standards.; and

(ii) * * *

(B) At least one ECP in each of the eight (8) ECP categories in each county in the service area, where an ECP in that category is available and provides medical or dental services that are covered by the issuer plan type. The ECP categories are: Federally Qualified Health Centers, Ryan White Program Providers, Family Planning Providers, Indian Health Care Providers, Inpatient Hospitals, Mental Health Facilities, Substance Use Disorder Treatment Centers, and Other ECP Providers. The Other ECP Providers category includes the following types of providers: Rural Health Clinics, Black Lung Clinics, Hemophilia Treatment Centers, Sexually Transmitted Disease Clinics, Tuberculosis Clinics, and Rural Emergency Hospitals

* * * * *

■ 24. Section 156.270 is amended by revising paragraph (f) to read as follows:

§ 156.270 Termination of coverage or enrollment for qualified individuals

* * * * *

(f) *Notice of non-payment of premiums.* If an enrollee is delinquent on premium payment, the QHP issuer must provide the enrollee with notice of such payment delinquency promptly and without undue delay.

* * * * *

■ 25. Section 156.1210 is amended by revising paragraph (c) to read as follows:

§ 156.1210 Dispute submission.

* * * * *

(c) *Deadline for describing inaccuracies.* To be eligible for resolution under paragraph (b) of this section, an issuer must describe all inaccuracies identified in a payment and collections report before the end of the 3-year period beginning at the end of the plan year to which the inaccuracy relates. For plan years 2015 through 2019, to be eligible for resolution under paragraph (b) of this section, an issuer must describe all inaccuracies identified in a payment and collections report before January 1, 2024. If a payment error is discovered after the timeframe set forth in this paragraph, the issuer must notify HHS, the State Exchange, or SBE–FP (as applicable) and repay any overpayments to HHS.

■ 26. Section 156.1220 is amended by revising paragraphs (a)(4)(ii) and (b)(1) to read as follows:

§ 156.1220 Administrative appeals.

(a) * * *

(4) * * *

(ii) Notwithstanding paragraph (a)(1) of this section, a reconsideration with respect to a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error may be requested only if, to the extent the issue could have been previously identified, the issuer notified HHS of the dispute through the applicable process for reporting a discrepancy set forth in §§ 153.630(d)(2) and (3), 153.710(d)(2), and 156.430(h)(1) of this subchapter, it was so identified and remains unresolved.

* * * * *

(b) * * *

(1) *Manner and timing for request.* A request for an informal hearing must be made in writing and filed with HHS within 30 calendar days of the date of the reconsideration decision under paragraph (a)(5) of this section. If the last day of this period is not a business day, the request for an informal hearing must be made in writing and filed by the next applicable business day.

* * * * *

Dated: December 12, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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Part III

Department of Housing and Urban Development

24 CFR Parts 58 and 1005
Strengthening the Section 184 Indian Home Loan Guarantee Program; Proposed Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 58 and 1005

[Docket No. FR–5593–P–01]

RIN 2577–AD01

Strengthening the Section 184 Indian Home Loan Guarantee Program

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, U.S. Department of Housing and Urban Development (HUD).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the regulations governing the Section 184 Indian Home Loan Guarantee Program (''Section 184 Program'') to fiscally strengthen the program by clarifying rules for Lenders, Tribes, and Borrowers. As the program has experienced an increase in demand, it now requires an update to the implementing regulations to minimize potential risk and increase program participation by financial institutions. This proposed rule strives to modernize and enhance the Section 184 Program by adding participation and eligibility requirements for Lenders and other financial institutions. This proposed rule would also clarify the rules governing Tribal participation in the program, establish underwriting requirements, specify rules on the closing and endorsement process, establish stronger and clearer servicing requirements, establish program rules governing claims submitted by Servicers and paid by HUD, and add standards governing monitoring, reporting, sanctions and appeals. This rule would add new definitions and make statutory conforming amendments, including the categorical exclusion of the Section 184 program in HUD's environmental review regulations. Ultimately, the changes made by this proposed rule would promote program sustainability, increase Borrower protections, and provide clarity for new and existing Lenders who participate in the program.

DATES: *Comment Due Date:* March 17, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule. All submissions and communications must refer to the above docket number and title. To receive consideration as public comments, comments must be submitted through one of two methods, specified below.

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500. Due to security measures at all Federal agencies, however, submission of comments by mail often results in delayed delivery. To ensure timely receipt of comments, HUD recommends that comments submitted by mail be submitted at least two weeks in advance of the public comment deadline.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (fax) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m., weekdays, at the above address. Due to security measures at the HUD Headquarters building, an appointment to review the public comments must be scheduled in advance by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of all comments submitted by the due date will be available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Krisa Johnson, Director, Office of Loan Guarantee, Office of Native American Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW, Room 4108, Washington, DC 20410; telephone number 202–402–4978 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 184 of the Housing and Community Development Act of 1992 (Pub. L. 102–550, approved October 28, 1992) (12 U.S.C. 1715z–13a), as amended by the Native American Housing Assistance and Self-Determination Act of 1996 (Pub. L. 104–330, approved October 26, 1996), the 2013 Consolidated and Further Continuing Appropriations Act (Pub. L. 113–6, approved March 26, 2013), the 2015 Consolidated and Further Continuing Appropriations Act (Pub. L. 113–235, approved December 16, 2014), and the Consolidated Appropriations Act, 2021 (Pub. L. 116–260, approved December 27, 2020) (Section 184 statute), authorize the Section 184 Program to provide access to sources of private financing to Indian families, Tribes and Tribally Designated Housing Entities (TDHEs) who otherwise could not acquire housing financing because of the unique legal status of Trust Land. The Section 184 Program provides HUD with the authority to provide access to sources of private financing for Indian families, Tribes and TDHEs that otherwise could not obtain private financing because of the unique legal status of Trust Lands by guaranteeing loans to eligible persons and entities. Since its inception, the number of loans guaranteed under the Section 184 Program has significantly increased. At the same time, the program regulations have never been substantially revised to accommodate the exponential growth of the program. Generally, improvements on Trust Land, are alienable, but conditions and restrictions apply. Consequently, financial institutions may struggle with utilizing the land interest as Security in mortgage lending transactions. To address this concern, the Section 184 Program provides a loan guarantee to approved Direct Guarantee lenders in the event of Borrower default. The guarantee is paid from the Section 184 Loan Guarantee Fund (Fund) for up to 100 percent of the unpaid principal balance as well as any reasonable fees

and expenses approved by the Secretary.

Following the enactment of Section 184 on August 18, 1994, HUD published an interim rule (59 FR 42732) codifying regulations for the Section 184 Program at 24 CFR part 955, and on March 6, 1996, HUD published a final rule (61 FR 9052). With the enactment of the Native American Housing Assistance and Self-Determination Act of 1996 (NAHASDA), HUD published a final rule on March 12, 1998, implementing NAHASDA amendments to the Section 184 Program as well as re-designating 24 CFR part 995 as 24 CFR part 1005 (63 FR 12334). On September 11, 1998, HUD published an interim final rule (63 FR 48988) establishing a direct guarantee procedure similar to that in the Direct Endorsement Program under the Federal Housing Authority (FHA) single family mortgage insurance program. The interim final rule adopted procedures that permitted HUD to review and guarantee a loan after loan closing and made minimum changes to allow for any necessary administrative actions against approved Direct Guarantee Lenders. The final rule making these changes permanent was issued on April 19, 2002 (67 FR 19491).

The Fund receives annual appropriations to cover some of the program costs and charges and an upfront and annual fee to the borrower to support the remaining program costs. The demand for the program has increased steadily each year. In 1995, the first year of the program, HUD guaranteed less than 20 Section 184 Guaranteed Loans. Over the last 10 years, HUD has consistently guaranteed thousands of loans worth hundreds of millions of dollars annually. To date, the Fund has guaranteed over $7.5 billion in loans. While the program has grown exponentially, the program regulations have not been substantially revised to reflect this significant growth. As the volume in the program increases, so does the risk to the Fund. The proposed regulations will help to mitigate the risk associated with this increased volume.

The 2013 Consolidated and Further Continuing Appropriations Act (Pub. L. 113–6, approved March 26, 2013) (2013 Appropriations Act) amended section 184(d) of the Housing and Community Development Act of 1992 to authorize HUD to increase the fee for the guarantee of loans up to 3-percent of the principal obligation of the loan and to establish and collect annual premium payments in an amount not exceeding one percent of the remaining guaranteed balance (excluding the portion of the remaining balance attributable to the fee collected at the time of the issuance of the guarantee). On March 5, 2014, HUD published a **Federal Register** Notice (79 FR 12520) announcing an increase in the one-time Loan Guarantee Fee that Borrowers pay at loan closing from a then-existing 1 percent to 1.5 percent of Guaranteed Loan amount. By **Federal Register** Notice published on October 7, 2014 (79 FR 60492), HUD exercised its new annual premium authority to implement an annual premium to the Borrower in the amount of 0.15 percent of the remaining loan balance until the unpaid principal balance, excluding the Upfront Loan Guarantee Fee, reaches 78 percent of the lower of the initial sales price or appraised value based on the initial Amortization Schedule. By **Federal Register** Notice published on November 1, 2016 (81 FR 75836), HUD once again exercised its new annual premium authority to implement an annual premium to the Borrower in the amount of 0.25 percent of the remaining loan balance. These new fees allowed HUD to meet the current demands of the Section 184 Program.

The Consolidated and Further Continuing Appropriations Act (Pub. L. 113–235) (approved December 16, 2014) (2015 Appropriations Act) amended Section 184(h)(1)(B) of the Housing and Community Development Act of 1992 to require the exhausting of all reasonable possibilities of collection by the Holder of the guarantee, to include a good faith consideration of loan modification, and to meet standards for servicing Section 184 Guaranteed Loans in default, as determined by the Secretary.

The Office of Audit of the HUD Office of Inspector General (OIG) audited the Section 184 Program and issued Audit Report Number: 2015–LA–0002 on July 6, 2015. The report found that HUD did not adequately monitor, track, and evaluate participating Direct Guarantee and Non-Direct Guarantee Lenders to ensure that loans guaranteed by the program were being underwritten in accordance with the Section 184 processing guidelines. The OIG gave many recommendations, including: HUD develop and implement policies and procedures for monitoring, tracking, underwriting, and evaluating the Section 184 Program; standardize monthly delinquency reports; deny payments for claims on loans that have material underwriting deficiencies; take enforcement actions against certain Direct Guarantee and Non-Direct Guarantee Lenders; and ensure that only underwriters that are approved by HUD are underwriting Section 184 Guaranteed Loans. The corrective action plan proposed by OIG and agreed upon by HUD includes the development of new regulations to provide additional structure to the program and a platform for policies and procedures to manage the program and address these findings.

II. This Proposed Rule

As the Section 184 Program assists more eligible Borrowers and entities, the Fund faces more program expenses and increased risk. HUD is proposing these regulatory changes to make the program sustainable, protect Borrowers, address weaknesses identified by the OIG, provide clarity for new and existing Direct Guarantee and Non-Direct Guarantee Lenders, and reduce and eliminate inappropriate and unreasonable Claim payment requests from Servicers. This proposed rule is designed to strengthen and modernize the Section 184 Program, as well as protect the Fund. This proposed rule would enhance and fill the gap in the existing regulations by modifying and adopting industry standards and best practices, as well as relevant FHA regulations and guidance.

This proposed rule would reorganize the Section 184 Program's regulations by removing outdated sections and replacing them with the following: definitions, eligibility requirements for Lenders, rules governing participation by Indian Tribes, underwriting requirements, rules on the closing and endorsement process, loan fees, servicing requirements submission of Claims, and standards governing monitoring, reporting, sanctions and appeals.

Proposed Organization of New Part 1005

This rule proposes to divide HUD's regulations in 24 CFR part 1005 in nine subparts: Subpart A would comprise of general program requirements; subpart B would discuss Lender and eligibility requirements; subpart C would cover requirements for Tribal participation; subpart D would contain underwriting requirements for eligible Borrowers, eligible Properties, and loan types; subpart E would include requirements for closing a Section 184 Guaranteed Loan and receiving endorsement approval from HUD; subpart F would provide the requirements for calculation, collection, and submission of the Section 184 Guaranteed Loan fees; subpart G would cover the requirements for Servicers to manage Section 184 Guaranteed Loans and steps to take when a Section 184 Guaranteed Loan is in default; subpart H would contain the requirements to submit Claims on Section 184 Guaranteed Loans; and subpart I would include report requirements and sanctions to for

noncompliance with Section 184 Program regulations. Unless otherwise noted in this proposed rule, HUD is proposing to codify current practices. Where a section is a new requirement, it is noted.

A. General Program Requirements (Subpart A)

Purpose § 1005.101. Section 1005.101 would address the purpose of the part 1005 regulations and provide that the regulations in part 1005 implement the Section 184 Program.

Definitions § 1005.103. The proposed rule includes definitions for the terms found in the existing Section 184 Program regulations, which HUD has revised to better reflect how the terms are currently used by the Section 184 Program or to reflect policy shifts: ''default,'' ''Indian,'' ''property,'' ''Section 184,'' and ''Trust or Restricted Land''. In the proposed regulations, the term ''Section 184'' is further revised to ''Section 184 Guaranteed Loan,'' and the term ''Trust or Restricted Land'' is further revised to ''Trust Land''.

The proposed rule does not include the terms ''Mortgage'' and ''Mortgagee'', which were previously used in the existing regulation, because the terms are no longer used in the program and are obsolete. These terms are replaced by the terms ''Loan'' and ''Lender,'' respectively, as currently proposed in § 1005.103.

Additionally, HUD has included new terms that are commonly used by the Section 184 Program in practice. This regulation would formalize these definitions for the program. The following terms would provide clarity and ensure consistency in the implementation of the various parts of the Section 184 Program regulations: ''Acquisition Cost,'' ''Amortization,'' ''Amortization Schedule,'' ''Annual Loan Guarantee Fee,'' ''BIA,'' ''Borrower,'' ''Claim,'' ''Conflict of Interest,'' ''Date of default,'' ''day,'' ''Direct Guarantee Lender,'' ''Eligible Nonprofit Organization,'' ''Financial Statements'' ''Firm Commitment,'' ''First Legal Action,'' ''Good and Marketable Title,'' ''Holder,'' ''Identity of Interest,'' ''Indian Family,'' ''Indian Housing Loan Guarantee Fund,'' ''lease or leasehold interest,'' ''Lender,'' ''Loan,'' ''Loan Guarantee Certificate,'' ''Loan Guarantee Fee,'' ''Loss Mitigation,'' ''month or monthly,'' ''Non-Direct Guarantee Lender,'' ''Origination or originate,'' ''Owner of Record,'' ''Partial Payment,'' ''Section 184 Guaranteed Loan,'' ''Section 184 Approved Program Area,'' ''Section 184 Program Guidance,'' ''Security,'' ''Servicer,'' ''Sponsor,'' ''Sponsored Entity,'' ''Tax-exempt bond financing,'' ''Title Status Report,'' ''Tribe,'' ''Tribally Designated Housing Entity (TDHE),'' ''Trust Land,'' and ''Upfront Loan Guarantee Fee.''

B. Lender Eligibility & Requirements (Subpart B)

This subpart includes Lender eligibility and the application process to participate in the Section 184 Program as a Non-Direct Guarantee or Direct Guarantee Lender.

Lender approval and participation § 1005.201. This section describes the two types of Lenders approved to participate in the Section 184 Program: Lenders deemed approved by statute and Lenders approved by HUD. This section would require that Lenders submit to HUD an application for participation in accordance with the level of activity a Lender wants to engage in, as prescribed by Section 184 Program Guidance. This proposed section is consistent with current program policy, practice, and/or procedure.

Lenders deemed approved by statute § 1005.203. This section is a restatement of what is an eligible Lender under the statute. In response to comments received during Tribal consultation, this section specifically references Community Development Financial Institutions (CDFIs) as being included as a 'Lender approved by statute.' This proposed section is consistent with current program policy, practice, and/or procedure.

Lenders required to obtain Secretarial approval § 1005.205. This section addresses qualifications for participation in HUD's Section 184 Program if a Lender is not approved under the statutory approved listed in § 1005.203. A Lender would be required to submit an application, as prescribed by Section 184 Program Guidance, for HUD to determine the capacity of the financial institution to participate in the Section 184 Program. This application would include establishing a Lender's qualifications based on the following: business formation verification, certifications related to employees and officers, Financial Statements, quality control plan, identification of branch offices, certification of conflict and interest, licensing certification, verification of minimum net worth, and identification of operating area. HUD will review documentation submitted under this section and make a determination if the requesting financial institution is qualified to be a Lender under the Section 184 Program. If a Lender is approved to participate in the Section 184 Program, HUD would send written notification of approval. If HUD determines that the Lender does not meet the requirements of subpart B, HUD would send written notice of the denial, which may be appealed to HUD in accordance with the appeal procedure set forth in the regulation.

Lender participation options § 1005.207. This section describes the two levels of Lender participation in the Section 184 Program, Non-Direct Guarantee Lender and Direct Guarantee Lender, along with the allowed eligible activities for each level of participation. This section proposes to establish a new requirement that eligible Lenders must select their desired participation level by submitting an application to HUD. A participation level must be selected by the Lender and approved by HUD before initiating any Section 184 program activities.

Direct Guarantee Lender application process § 1005.209. This section details the application requirements for Lenders to apply to become a Direct Guarantee Lender in the Section 184 Program. These proposed requirements HUD believes are necessary to ensure that Direct Guarantee Lenders meet certain minimum requirements including having a certain level of experience in origination, underwriting, and servicing of mortgage loans. Additionally, Lenders must submit a quality control plan.

Direct Guarantee Lender approval § 1005.211. This section addresses what constitutes HUD approval for Lenders applying to participate in the Section 184 Program as a Direct Guarantee Lender under § 1005.209. This section addresses the process HUD would follow to notify Lenders of their approval as Direct Guarantee Lenders under the program. HUD would provide written notification to the Lender, and the Lender would need to certify to being in compliance with all program requirements and agree to ensure that any Sponsored Entities also comply with all program requirements. This section is an addition to HUD's current practice.

Non-Direct Guarantee Lender application, approval, and Direct Guarantee Lender sponsorship § 1005.213. This section describes the sponsorship relationship between a Direct Guarantee Lender and a Non-Direct Guarantee Lender and the general responsibilities of a Direct Guarantee Lender as the Sponsor. Each Sponsor is responsible to HUD for the actions of the Sponsored Entity and must ensure that HUD records remain up to date by informing HUD regarding any changes of the Sponsored Entity. This section

seeks to align with HUD's current practice.

Annual reporting requirements § 1005.215. This section would require annual reporting on Section 184 Guaranteed Loan performance data from Direct Guarantee Lenders, their Sponsored Entities. It also provides for HUD to establish additional annual reporting requirements as provided in Section 184 Program Guidance. The section would be a new requirement to track the performance of the program and participating Direct and Non-Direct Guarantee Lenders to ensure the protection of the Fund.

Quality control plan § 1005.217. This section proposes to implement the requirement that Lenders participating in the Section 184 Program have a written quality control plan and the contents of that plan. The purpose of the quality control plan is to ensure Lender compliance with Section 184 Program requirements and protect HUD and the Lenders from unacceptable risks. A Lender would be required to adopt and implement a quality control plan that fully complies with Section 184 Program Guidance. This requirement incorporates existing Quality Control Plan policies and adds new requirements, such as paragraphs (c) and (d) in § 1005.217.

Other requirements § 1005.219. This section describes proposed additional Direct Guarantee Lender and Non-Direct Guarantee Lender requirements, including compliance with pertinent Tribal, Federal, and State, and laws, dual employment, reporting requirements, records retention, all of which are proposed to place in regulations current program policy, practice, and/or procedure.

This section also includes a proposed new requirement that HUD may set for lenders a minimum level of lending on Trust Land. While this program was designed to bring mortgage capital to Trust Lands, the majority of loans guaranteed by the Program are made on fee simple land. In order to address this concern, this rule proposes to set forth a new requirement for lenders participating in the program to actively market, originate, and underwrite loans on Trust Land. HUD is interested in increasing lending on Trust Land to further the objectives of the Section 184 Program and provide additional homeownership opportunities on Trust Lands. In this section, HUD proposes to set, by **Federal Register**, a minimum lending amount for direct guarantee lenders on Trust Lands. All Lenders would be required to ensure that they comply with these additional requirements to remain as a participant in the program. While HUD is not proposing a specific minimum level of lending on Trust Land in this proposed rule, HUD is interested in receiving feedback on what this minimum level of lending should be and if such minimum requirement would help with the underlying goal of the provision.

Business change reporting § 1005.221. This section would require Lenders participating in the Section 184 Program to notify HUD within a timeframe as prescribed by Section 184 Program Guidance of any changes in a Lender's legal structure or staffing or any new sanctions against the Lender. HUD is proposing to require this notification to reduce risk and monitor the stability of the lender.

Annual recertification § 1005.223. This section would implement the mandatory submission of an annual recertification by all Direct Guarantee and Non-Direct Guarantee Lenders, as prescribed by Section 184 Program Guidance. HUD is proposing to require recertification to ensure that Direct Guarantee and Non-Direct Guarantee Lenders continue to meet program eligibility requirements and to reduce the risk to HUD and the Fund. This section also would require the Direct Guarantee Lender and Non-Direct Guarantee Lender to submit Financial Reports and updated contact information. This section is consistent with HUD's current practice.

Program ineligibility § 1005.225. This section describes the circumstances under which HUD would determine that a Direct Guarantee Lender or Non-Direct Guarantee Lender is ineligible to participate the Section 184 Program. This section is intended to reduce risk to the Fund as well and align with current industry standards.

C. Lending on Trust Land (Subpart C)

This subpart proposes requirements for Tribal participation in the Section 184 Program when Tribes want to make Trust Land or Restricted Fee Land available under the Section 184 Program. This section requires a partnership between HUD, the Tribe, the Direct Guarantee Lender, Servicer and the Borrower. The Tribe is a critical partner in the ability of the program to operate on Tribal Lands. For the program to operate on Trust Lands, certain Tribal ordinances must be in place. Tribes interested in participating in the Program would be required to submit to HUD evidence of the required legal and administrative framework necessary to ensure HUD or the Servicer have the ability to enforce the lien in case of default.

Tribal legal and administrative framework § 1005.301. This section outlines the legal and the administrative framework necessary when a Tribe seeks to allow eligible Borrowers place a mortgage lien on Trust Land under the Section 184 Program. The proposed rule would specify requirements governing foreclosure and assignments, property disposition, eviction procedures, lien priority, and leasing, which are an addition to the regulation to codify current policy, practice and/or procedure. These requirements are necessary to protect Borrowers, Tribes, TDHEs, Lenders and the Fund from unnecessary financial risks. This section proposes new language to be included in the Tribal lease that would allow a Tribe to assign the lease to HUD, and HUD would transfer the lease to a successor lessee, as approved by the Tribe. This language has been added because there have been instances when a Borrower is in default, their Section 184 Guaranteed Loan has been assigned to HUD, and the Borrower has vacated the property before foreclosure. The Tribe, THDE or a trial member is interested in purchasing the property, but the sale cannot happen because the defaulted Borrower remains on the lease. The proposed language gives the Tribe the authority to assign the lease to HUD so the sale of the property can move forward without having to wait until HUD obtains the lease through foreclosure.

Tribal application § 1005.303. This section includes the application requirements for Tribes interested in bringing the Section 184 Program to their Trust Lands. The application must include a copy of documents related to the Tribe's legal and administrative framework, including but not limited to a Tribe's foreclosure, eviction, lease, and priority lien ordinances, all cross-referenced ordinances in those sections, and any other documents in accordance with Section 184 Program Guidance. HUD is proposing this section to ensure that Tribes have the necessary legal structure in the event of a default on Trust Land and to ensure that HUD is provided first lien priority.

Approval of Tribal application § 1005.305. This section would specify that HUD will provide written notification to Tribes upon the completion of its review of a Tribe's application submitted in accordance with § 1005.303 and would provide the opportunity for Tribes to resubmit missing, incomplete, or deficient applications. This proposed section is consistent with current program policy, practice, and/or procedure.

Tribal recertification § 1005.307. This section would implement the mandatory submission of an annual recertification by all Tribes participating in the Section 184 Program and the contents of such recertification, in accordance with Section 184 Program Guidance. HUD proposes to require recertification to ensure that the Tribe continues to meet program eligibility requirements. This section would also require the Tribe to update contact information. This proposed section is intended to keep current on Tribal contacts and to confirm that there have been no changes to relevant ordinances and the Tribal lease.

Duty to report changes § 1005.309. This section would require Tribes participating in the Section 184 Program to report to HUD any current changes in the Tribe's contact information, or proposed changes to foreclosure, eviction lease and lien priority ordinances. This section is a new requirement to ensure HUD notification of these changes and to reduce the risk to HUD and the Fund.

HUD Notification of any lease default § 1005.311. This section would mandate, when there is any default of the lease by the Borrower, including a nonpayment of leasehold rent, the lessor shall notify HUD within 30 days of default, or as set forth in the lease agreement. This section is proposed to ensure notification of a delinquency to HUD and allow HUD to explore early Loss Mitigation actions and to reduce the risk of potential loss to the Fund.

Tribal reporting requirements § 1005.313. This section provides HUD with the ability to require Section 184 program-related reports from Tribes approved under § 1005.305. HUD intends to use this new requirement as a placeholder in the event, at a future date, HUD is in need of Section 184 Program information from approved Tribes that is not anticipated in §§ 1005.307 and 1005.309. If HUD determines additional information the Section 184 Program from Tribes is needed, it would publish these requirements in Section 184 Program Guidance and complete the necessary Paperwork Reduction Act process requesting input on the additional burden associated with the requested reports.

D. Underwriting (Subpart D)

This subpart includes the requirements for a loan to be guaranteed by the Section 184 program. The subpart is organized into four sections: eligible Borrowers, eligible Properties, eligible loans, and underwriting.

Eligible Borrowers § 1005.401. This section provides that to be eligible to participate in the Section 184 Program, a Borrower must be an Indian Family, Indian Tribe, or TDHE. This section would require an Indian Family to document its status as American Indian or Alaska Native through evidence as prescribed by Section 184 Program Guidance. This section is a revision of the language found in § 1005.105(b) of the current regulations; the existing regulation is proposed to be moved into a new section and aligns with current procedures.

Principal Residence § 1005.403. This section sets forth the occupancy requirements for Borrowers in relation to the property interest that secures the Section 184 Guaranteed Loan. HUD also defines the qualifications for a non-occupant Co-Borrower. As the program has evolved, it has allowed for non-occupant co-Borrowers as a way to expand homeownership opportunities for Borrowers who may need assistance with their mortgage and have a family member willing to take on the financial responsibility for the Section 184 Guaranteed Loan. Non-occupant co-Borrowers must be related by blood, or be able to document a family-type, longstanding, and substantial relationship not arising out of the loan transaction. This section is a revision of existing § 1005.105(b)(1).

Borrower residency status § 1005.405. This section describes the residence status requirements to be considered an eligible Borrower in the Section 184 Loan Guarantee program. In addition to the requirements set forth in § 1005.401, an eligible Borrower must be a U.S. citizen; lawful permanent resident alien; or a non-permanent resident alien. Documentation to support the lawful residency status must be provided. This proposed section is consistent with current program policy, practice, and/or procedure.

Relationship of income to loan payments § 1005.407. This section provides that a Borrower's income must be sufficient to cover the costs of Section 184 Guaranteed Loan payments plus any other long-term obligations. This section also describes the requirement for a minimum qualifying threshold when an eligible Borrower has a co-Borrower that will not occupy the home. Additionally, HUD also would require that the determination of the adequacy of a Borrower's income be free from discrimination. In particular, this section adds new language requiring that the determination of adequacy of Borrower income shall be made without regard to, among other things, Borrower's source of income or location of the property. HUD believes these two proposed non-discrimination provisions further the statutory purpose of the program to ''provide access to sources of private financing to Indian families, Indian housing authorities, and Indian tribes, who otherwise could not acquire housing financing because of the unique status of Indian lands.'' 12 U.S.C. 1715z–13a(a). With respect to the proposed prohibition of discrimination based on the Borrower's source of income, HUD seeks to address instances where lenders may disapprove of the Borrower's income streams related to Borrower's Tribal status (such as Tribal payments a Borrower may receive from his or her Tribe or from traditional tribal income sources). With respect to the proposed prohibition of discrimination based on property location, HUD seeks to address instances where lenders may decide to only approve loans involving fee simple properties and uniformly reject loan applications solely because Borrower chooses to finance a home on Tribal trust property. Other than the newly added provisions regarding non-discrimination based on property location and sources of income, this section is consistent with current practice, policy, and/or procedure.

Credit standing § 1005.409. This section is proposing, consistent with current policy and practice, that no minimum credit score is required to qualify for a Section 184 Guaranteed Loan. However, Direct Guarantee Lenders are required to analyze the Borrower's credit history and payment patterns to determine credit worthiness. This section also revises the existing guidance that if a Borrower previously defaulted on a Section 184 Guaranteed Loan, they are ineligible to apply for another Section 184 Guaranteed Loan. To conform with industry practice, HUD is proposing that these Borrowers may apply for a Section 184 Guaranteed Loan after a waiting period as prescribed by HUD.

Disclosure and verification of Social Security and Employer Identification Numbers or Tax Identification Number § 1005.411. This section would require that Borrowers must meet the requirements for the disclosure and verification of social security, employer and tax identification numbers. Disclosure and verification of this information minimizes fraud and adds protections for the Fund and is consistent with HUD's current practice, policy, and/or procedure.

Acceptable title § 1005.413. To be considered acceptable title, a Section 184 Guaranteed Loan must be on real estate held in fee simple land or Trust Land. Where title evidences a lease that

is used in conjunction with the Section 184 Guaranteed Loan, the lease must comply with § 1005.301, and must have a remaining term which exceeds the maturity date of the Section 184 Guaranteed Loan by ten years. This proposed section is consistent with current program policy, practice, and/or procedure.

Sale of property § 1005.415. This section would require that the property be purchased from the Owner of Record and that the Direct Guarantee Lender provide evidence of ownership. Additionally, this section would establish the requirements for documentation and timing restrictions on property re-sales to prevent flipping of the property for financial gain by the Borrower. This proposed section is consistent with current program policy, practice, and/or procedure.

Location of property § 1005.417. This section would establish that a property must be used for residential purposes and be located within an approved Section 184 Approved Program Area to be eligible for a Section 184 Guaranteed Loan. This proposed section is consistent with current program policy, practice, and/or procedure.

Requirements for standard housing § 1005.419. This proposed section lists the minimum required property standards for properties under the Section 184 Program. This section also explains environmental review requirements and responsibilities and includes requirements for flood insurance, the Coastal Barrier Resource System and Special Airport Hazards. With respect to minimum required property standards, this proposed section requires the property to be: decent, safe, sanitary and modest in size and design, conform with applicable general construction standards for the region, containing a heating system, contain a plumbing system, contain an electrical system, meet minimum square footage requirements, and conform with energy performance requirements for new construction. This proposed section revises existing § 1005.111(a) consistent with current practices, policies, and/or procedures.

Certification of appraisal amount § 1005.421. This section would require the contract for sale to be satisfactory to HUD and where the seller agrees to provide a certification of appraisal establishing the amount of the appraised value of the property. This protects the Borrower and the Fund by ensuring the guaranteed loan is secured by a property where the true value has been established. This proposed section is consistent with current program policy, practice, and/or procedure.

Legal restrictions on Conveyance § 1005.423. This section proposes to define and establish permitted legal restrictions that may be placed on a property guaranteed by a Section 184 loan. This section would allow for restrictions on Conveyance only to enrolled Tribal members when the property is located on Trust Land, the acceleration of a mortgage subject to tax exempt bond funding where it no longer meets the Federal requirements, and property with approved restrictions established for occupancy for the elderly. This regulation would provide Tribes with the maximum flexibility available to best serve their Tribal members. This proposed section is consistent with current program policy, practice, and/or procedure.

Rental properties § 1005.425. This section proposes the conditions under which a Section 184 Guaranteed Loan may be used to purchase a one- to four-family unit property where one unit will be owner occupied and the additional units may be rented. This section clarifies that one- to four-family unit Properties owned by the Tribe or TDHE will not be subject to the same conditions. This section clarifies the two allowable exceptions to the Principal Residence requirements in § 1005.403 and is consistent with current program policy, practice, and/or procedure.

Refinancing § 1005.427. This section proposes to include the criteria to refinance a qualified loan under the Section 184 Program and presents the three types of allowable refinance transactions: Rate and Term, Streamline and Cash Out. This section would require a maximum term for the new loan to be 30 years and a payment history on the existing loan that meets the standards established by HUD. It would also prohibit Lenders from requiring a minimum outstanding principal amount on the existing loan and clarifies the treatment of financed Upfront Loan Guarantee Fees. This proposed section is consistent with current program policy, practice, and/or procedure.

Eligibility of Loans covering manufactured homes § 1005.429. This section provides eligibility requirements for the financing of one-family manufactured homes. This section would establish the minimum square footage for a unit, the requirement to meet the National Manufactured Home Construction and Safety Standards and have a certification label, and the requirement of siting on a permanent foundation that meets the applicable installation standards and adheres to the manufacturer's installation instructions. This regulation is required to ensure the safety of the Borrower and the value of the collateral. This proposed section is consistent with current program policy, practice, and/or procedure and would align with FHA standards.

Acceptance of individual residential water purification § 1005.431. This section proposes requirements for properties that do not have access to a continuing supply of safe and potable water, without use of a water purification system. It would require the applicable official's specification of the water purification equipment approval standard, certification by Tribal, State or health authority, and Borrower notices and certification. This section would require a certification by a Tribal, State, or local health authority that it has determined the water supply meets the entity's quality standards for drinking water. Additionally, this section would require written notification to the Borrower when the contract is ratified that the property does not have access to a continuing supply of safe and potable water without a purification system, a water safety report identifying contaminants and associated health hazards, and a good faith estimate of maintenance and replacement costs. The Borrower must sign a certification they have received all of this information prior to underwriter approval. This regulation would provide the Borrower with full disclosure of maintenance and upkeep costs of an individual water purification system and health and safety provisions. This proposed section is consistent with current program policy, practice, and/or procedure and would align with industry standards.

Builder warranty § 1005.433. This section proposes that a builder must submit a warranty that the property is constructed in substantial conformity with the plans and specifications for newly constructed Properties guaranteed by the Section 184 Program. This proposed section is consistent with current program policy, practice, and/or procedure and would align with industry standards.

Eligible collateral § 1005.435. This section proposes what collateral is acceptable for a Section 184 Guaranteed Loan. The proposed section would require that the collateral be authorized and not prohibited by Tribal, Federal, State, or local law and must be sufficient to cover the amount of the loan as determined by the Direct Guarantee Lender and approved by HUD. This section would revise existing § 1005.107 of the current regulations and be consistent with current practices, policies, and/or procedures.

Loan provisions § 1005.437. This proposed section provides the details for loan provisions required for a Section 184 Guaranteed Loan, including loan form, loan multiples, loan payments, loan maturity, property standards, disbursements and prepayment. This section would revise existing § 1005.105(a).

Loan lien § 1005.439. This section proposes lien requirements for a Section 184 Guaranteed Loan. After the loan offered for guarantee has been recorded, the property must be free and clear of any other liens, unless prior approval has been granted by HUD for a junior lien. This section proposes conditions for a junior lien, which covers periodic payments, ability to pay considerations, loan to value limitations, prohibition of balloon payments earlier than 10 years, requirement for the junior lien to be due and payable upon sale or refinance of the Section 184 Guaranteed Loan, and the acceptability of prepayments at any time without the requirement for a prepayment penalty. In addition, a junior lien may be provided as a means to reduce that Borrower's monthly payments. This type of junior lien would require pre-approval from HUD, shall not require the payment of any principal or interest until the property securing the junior lien is sold or the Section 184 Guaranteed Loan is refinanced, and shall not require principal and interest payments, so long as the property is owner occupied and, where applicable, shall provide forgiveness of the junior lien at the end of the term. Lastly, if a junior lien is related to tax exempt bond financing or low-income housing tax credits, HUD approval is also required. This proposed section is consistent with current program policy, practice, and/or procedure.

Section 184 Guaranteed Loan limit § 1005.441. This section would establish HUD's authority to set the maximum loan limits for Section 184 Approved Program Areas. HUD may revise these maximum limits periodically. This proposed section is consistent with current program policy, practice, and/or procedure.

Loan amount § 1005.443. This section proposes the minimum required investment from the Borrower based on the difference between the sales price and the base loan amount. It also would provide the methodology for calculating the base loan amount and would establish the maximum and minimum principal loan amounts. This investment must come from the Borrower's own funds, gifts, or Tribal, State, or local funds awarded to the Borrower. The regulation is required to balance the risk to the Fund and the unique requirements of Native American Borrowers. This proposed section is consistent with current program policy, practice, and/or procedure.

Case numbers § 1005.445. This section explains when and how to obtain a Section 184 case number. Direct Guarantee Lenders must have an active loan application for a Borrower and a specific property. The case number request must include proof of Tribal enrollment or Alaska Native status, verification that the property is located in a Section 184 Approved Program Area, confirmation that the Loan does not exceed the Section 184 Loan Limit, and be submitted in manner prescribed in the Section 184 Program Guidance. Case numbers will be automatically cancelled after a period identified by HUD if a reservation of funds request is not received and processed by HUD. HUD may allow for the extension as prescribed. This proposed section is consistent with current program policy, practice, and/or procedure.

Maximum age of Loan documents § 1005.447. This section proposes the maximum age of loan documents at the time of underwriting and loan closing. Documents reviewed at underwriting may not be older than 60 days and all documents may not be more than 120 days old at closing. Certain documents will be exempt from these time frames if they are not affected by the passage of time. This proposed section is consistent with current program policy, practice, and/or procedure.

Qualified mortgage § 1005.449. This section explains that Section 184 Guaranteed Loans are afforded safe harbor as qualified mortgages that meet the ability-to-pay requirements. This section is a revision of the existing § 1005.120 and conforms to current practices, policies, and/or procedures.

Agreed interest rate § 1005.451. This section would require that a Loan must have an interest rate that is agreed upon by the Direct Guarantee Lender and Borrower and is determined by HUD to be reasonable. This regulation is necessary to ensure Borrowers are not being charged inflated interest rates attributable to risk-based pricing for minimum loan amounts, credit scores, or other risks, when the Direct Guarantee Lender is receiving a 100 percent guarantee against any loss due to default. This risk-based pricing requirement would be a new requirement and is intended to protect the Borrower from inflated interest rates, which may impact loan performance and the Fund.

Amortization provisions § 1005.453. This section proposes that a Loan's Amortization provisions be satisfactory to HUD, monthly payments by the Borrower, and that the principal and interest payments each month shall be substantially the same. This section is a revision of existing § 1005.105(a) and is consistent with current practices, policies, and/or procedures.

Direct guarantee underwriting § 1005.455. This section outlines proposed requirements for direct guarantee underwriting including underwriter due diligence, evaluation of the Borrower, and assumptions. This section is a revision of the existing § 1005.106(a), outlining the direct guarantee procedure. Direct Guarantee underwriters must exercise the same level of due diligence as if they were entirely dependent on the property as Security to protect their investment. An acceptable quality control plan and compliance with HUD prescribed underwriting guidelines are the minimum standard of due diligence. Direct Guarantee underwriters shall evaluate the Borrower's credit characteristics, adequacy, and stability of income to make payments on all obligations and the available assets. This section also would require all assumptions of an existing Section 184 Guaranteed Loan be underwritten using the same Borrower eligibility and underwriting standards in this subpart. This section is consistent with current program policy, practice, and/or procedure.

Appraisal § 1005.457. This section would establish the requirement for the appraisal of a property to be used to obtain a Section 184 Guaranteed Loan, the selection of an appraiser, appraisal standards, validity period for appraisals, possible extensions of the validity period, and possible sanctions when the requirements listed under the section are not met. A property appraisal for the Section 184 Program must be done in accordance with the Uniform Standards of Professional Appraisal Practice and the Fair Housing Act (42 U.S.C. 3601–19); however, HUD may establish alternative requirements in Section 184 Program Guidance. The Direct Guarantee Lender must select an appraiser currently on the FHA Appraiser Roster and the Direct Guarantee Lender must not discriminate in its selection of the appraiser. The appraiser must be knowledgeable in the market where the property is located. The appraisal and related documents must satisfy FHA, Fannie Mae, or Freddie Mac requirements. In addition, the Direct Guarantee Lender may be subject to sanctions permitted under

§ 1005.907 for submitting an appraisal that does not meet the requirements described. This proposed section would codify current program policy, practice, and/or procedure and aligns with industry standards.

Loan submission to HUD for Direct Guarantee § 1005.459. This section proposes a 60-day timeframe in which an endorsement case binder must be sent to HUD after closing. This section also outlines the additional documentation required for a late submission greater than 60 days after closing. The Direct Guarantee Lender would be required to submit a late endorsement request with documentation affirming the loan is not currently in default, all escrow accounts are current, all loan guarantee fees are current, and a statement that neither the Direct Guarantee Lender nor its agents have provided funds to bring or keep the loan current or bring about the appearance of a satisfactory payment history. This proposed section is consistent with current practices, policies, and procedures. This section does propose an exception to the proposed current endorsement practice, which provides that with prior approval from HUD, consistent with Section 184 program guidance, the Direct Guarantee Lender or Servicer may provide funds to bring or keep the Section 184 Guaranteed Loan current in the event the Borrower agrees to Loss Mitigation before HUD provides endorsement, as the case with some Borrowers during the COVID–19 National Emergency.

HUD issuance of Firm Commitment § 1005.461. This section proposes that HUD may underwrite, consistent with specific underwriting criteria, and issue a Firm Commitment. This proposed section is consistent with HUD's current practice, policy, and/or procedure.

E. Closing and Endorsement (Subpart E)

This subpart includes requirements for closing a Section 184 Guaranteed Loan and receiving endorsement approval from HUD. The subpart is organized into two sections: closing, and endorsement and post-closing.

Direct Guarantee Lender closing requirements § 1005.501. This section would provide the required documentation for closing a loan under the program, including: chain of ownership, title search and Title Status Report, closing in compliance with Direct Guarantee Lender approval, closing in the Lender's name, required forms and language in documents, projected escrow, closing costs and fees, per diem interest and interest credits, Borrower authorization of Tribal notice, signatures, and other requirements. This documentation is necessary to ensure that the Loan may be eligible for a Loan Guarantee under the program. This proposed section is consistent with current program policy, practice, and/or procedure.

Contents of endorsement case binder § 1005.503. This section proposes HUD requirements for the contents of the endorsement case binder. The endorsement case binder is required by HUD and includes certain documentation necessary for HUD to determine program compliance and to issue a Loan Guarantee Certificate to the Lender. The actual contents of the endorsement case binder shall be in a format as prescribed by Section 184 Program Guidance. This proposed section is consistent with current program policy, practice, and/or procedure.

Payment of Upfront Loan Guarantee Fee § 1005.505. This section would require the Direct Guarantee Lender to provide evidence of the remittance of the Upfront Loan Guarantee Fee, as required under § 1005.607. This proposed section is consistent with current program policy, practice, and/or procedure.

Borrower's payments to include other charges and escrow payments § 1005.507. This section proposes the charges and escrow payments that the Direct Guarantee Lender must include as part of the Section 184 Guaranteed Loan monthly payment. This section also proposes how these payments should be managed by the Lender and disallows the recovery from the Borrowers of payment of additional premiums to protect the interest of the Lender. This proposed section is consistent with current program policy, practice, and/or procedure.

Application of payments § 1005.509. This section would require that all monthly payments made by the Borrower to the Servicer shall be aggregated into a single monthly payment, and that the Servicer shall apply the Borrower's funds in accordance with § 1005.715. This proposed section is consistent with current program policy, practice, and/or procedure.

Late fee § 1005.511. This section would establish the ability for a Servicer to charge a late charge to the Borrower when a Section 184 Guaranteed Loan payment is 15 or more days in arrears. It also would establish maximum late charge of four percent of the overdue payment of principal and interest, or any other amount as established by HUD through public notice with an opportunity for comment. This section is intended to provide a deterrent for the Borrower to make payments outside of the applicable payment period and to reduce risk to the Direct Guarantee Lender and the Fund. This proposed section is consistent with current program policy, practice, and/or procedure.

Borrower's payments when Section 184 Guaranteed Loan is executed § 1005.513. This section outlines what payments from what parties are required upon execution of the Section 184 Guaranteed Loan, including the one-time Upfront Loan Guarantee Fee or any portion payable pursuant to § 1005.603; and all other applicable monthly charges pursuant to § 1005.507, including the annual Section 184 Guaranteed Loan fee pursuant to § 1005.607, covering the period from the closing date to the due date of the first installment payment under the Section 184 Guaranteed Loan. This proposed section is consistent with current program policy, practice, and/or procedure.

Charges, fees, or discounts § 1005.515. This section proposes a list of allowable charges, fees, or discounts a Direct Guarantee Lender may collect from the Borrower at Origination of a Section 184 Guaranteed Loan. These charges/fees include costs to cover origination and closing; recording fees and recording taxes; credit report; survey; title examination; title insurance premium and any appraisal or inspection; such other reasonable and customary charges as may be authorized by HUD; reasonable and customary charges in the nature of discounts; and interest calculations in accordance with § 1005.501. Before the Loan may be guaranteed by the Section 184 Program, the Direct Guarantee Lender must provide HUD a listing of all charges, fees, or discounts collected from the Borrower by the Lender.

For an assumption of an existing Section 184 Guaranteed Loan, processing fees must be based on actual costs and the Direct Guarantee Lender may not charge more than the reasonable and customary allowable cost without HUD approval. Fees for assumptions may include, but are not limited to, credit report, verification of employment and the execution of additional release of liability forms. Additional fees over and above assumption fees cannot be assessed for Section 184 Guaranteed Loans on Trust Lands. HUD may establish limitations on the amount charged for origination, closing, and assumptions. This proposed section is consistent with current program policy, practice, and/or procedure.

Certificate of nondiscrimination by the Direct Guarantee Lender § 1005.517. This section would require that Direct Guarantee Lenders, when applicable, certify to HUD specific nondiscrimination practices required of Direct Guarantee Lenders, including: nondiscrimination based on race, color, religion, sex, disability, familial status, or national origin, except as provided by law; and prohibiting any restrictive covenant, other than permissible restrictions on Trust Land, on such property relating to race, color, religion, sex, disability, familial status, or national origin and recognizing such prohibited restrictive covenants as being illegal, void, and disclaimed. A civil action for preventative relief may be brought by the Attorney General in any appropriate U.S. District Court against any person responsible for a violation of this certification. This section is intended to protect the Borrower from discrimination, and is consistent with current program policy, practice, and/or procedure.

Creation of the contract § 1005.519. This section describes when a Loan shall be considered guaranteed under the program and that the Direct Guarantee Lender and HUD are bound by the requirements set forth in this regulation as if the two parties were in an executed contract relating to the loan. This proposed section is consistent with current program policy, practice, and/or procedure.

Lender *pre-endorsement review and requirements § 1005.521.* This section would require a pre-endorsement review of the endorsement case binder by the Direct Guarantee Lender prior to the submission of the endorsement case binder to HUD and describes the parameters of this review. This review must be conducted by Direct Guarantee Lender staff not involved in the origination, processing, or underwriting of the loan, and the case binder must include all documentation the Direct Guarantee Lender used to approve the loan. Upon finalizing the pre-endorsement review, the Direct Guarantee Lender must certify that all required documents were submitted and meet the requirements of § 1005.503. This proposed new requirement would provide additional assurances that the Direct Guarantee Lender is making prudent judgements when approving the loans and following HUD program polices, practice, and procedures.

HUD pre-endorsement review § 1005.523. This section proposes Lender's submission deadline and HUD's process for a pre-endorsement review. Before endorsement, HUD will review the endorsement case binder submitted by the Direct Guarantee Lender to ensure that the loan meets all statutory, regulatory, and administrative requirements. Following this review, if the loan is determined to be eligible, HUD will issue a Loan Guarantee Certificate. HUD may reject an endorsement case binder if HUD finds that the certification or documentation is false, misleading, or constitutes fraud or is a misrepresentation on the part of any party, or that the loan fails to meet a statutory or regulatory requirement. HUD will inform the Direct Guarantee Lender in writing the reasons for the determination and any corrective actions that may be taken. The HUD pre-endorsement review is intended to reduce the risk for fraud and program non-compliance that could negatively impact the Fund, and is consistent with current program policy, practice, and/or procedure.

Loan Guarantee Certificate § 1005.525. This section proposes the conditions under which HUD will issue a Loan Guarantee Certificate. The Loan Guarantee Certificate is evidence of the HUD guarantee and is issued after HUD completes a review of the Lender's endorsement case binder and determines the case binder is in compliance with all applicable Section 184 requirements. HUD may issue a Loan Guarantee Certificate for a loan on Trust Land before HUD receives all required Trailing Documents, provided that the Direct Guarantee Lender agrees to indemnify HUD. The indemnification agreement between HUD and the Direct Guarantee Lender will terminate once all required documentation is received in a form and manner that is acceptable by HUD. This proposed section is consistent with current program policy, practice, and/or procedure.

Post-endorsement review § 1005.527. This section proposes the process for HUD to conduct a post-endorsement review of the endorsement case binder, including, but not limited to a quality control review. Following the issuance of the Loan Guarantee Certificate, HUD may review all documents required by § 1005.503. Based upon this review, if HUD determines that the Loan does not satisfy the requirements of the program, HUD may cancel the Section 184 Loan Guarantee Certificate, may request indemnification from the Direct Guarantee Lender, or sanction the Direct Guarantee Lender pursuant to § 1005.907. This proposed section is consistent with current program policy, practice, and/or procedure.

Indemnification § 1005.529. This section proposes that an Originating Direct Guarantee Lender must indemnify HUD when a claim has been filed or when HUD discovers an underwriting deficiency in a pre- or post-endorsement review. In this instance, the Originating Direct Guarantee Lender shall indemnify HUD or HUD may deny the Claim. Underwriting deficiencies may include, but not limited to, fraud or misrepresentation by the Originating Direct Guarantee Lender. If indemnification is necessary, HUD will request indemnification in writing that the Originating Direct Guarantee Lender will reimburse HUD if a subsequent holder of the loan files a Claim and HUD suffers a financial loss. This proposed section is intended to protect HUD from financial risk from possible underwriting deficiencies and aligns with industry standards.

F. Section 184 Guaranteed Loan Fees (Subpart F)

This subpart includes the requirements for calculation, collection, and submission of the Section 184 Loan Guarantee Fee.

Scope and method of payment § 1005.601. This section includes the statutory requirements of a one-time, Upfront Loan Guarantee Fee and a recurring Annual Loan Guarantee Fee, for all Section 184 Guaranteed Loans. This section revises existing § 1005.109 of the current regulations and is consistent with current program policy, practice, and/or procedure.

Upfront Loan Guarantee Fee § 1005.603. This section mandates that an Upfront Loan Guarantee Fee, not exceeding three percent of the principal obligation of the loan, as determined by HUD, is to be paid at closing. The amount of the Upfront Fee will be prescribed by HUD through a notice in the **Federal Register**. This fee is statutorily required and necessary to credit the Fund to provide for payments under the guarantee, in addition to congressional appropriation.

Remittance of Upfront Loan Guarantee Fee § 1005.605. This section would require the Direct Guarantee Lender to submit to HUD the Upfront Loan Guarantee Fee within 15 days of loan closing. Additionally, this section would require the Direct Guarantee Lender to provide an account reconciliation of the Upfront Loan Guarantee Fee in the time and manner as may be prescribed by HUD. This proposed section codifies current program practices, policy, and/or procedure.

Annual Loan Guarantee Fee § 1005.607. This section would require an Annual Loan Guarantee Fee to be collected from the Borrower on a monthly basis, as determined by HUD

and published in the **Federal Register**. This section would also authorize the Servicer to collect monthly payments from the Borrower in an amount equal to one-twelfth of the annual loan guarantee premium and the ability for the Borrower to prepay their Section 184 Guaranteed Loan. These payments are included in the Amortization Schedule issued with the Loan approval. The Annual Loan Guarantee Fee is statutorily required and necessary to credit the Fund to provide for payments under the guarantee, in addition to congressional appropriation. This proposed section is consistent with current program policy, practice, and/or procedure.

Remittance of Annual Loan Guarantee Fee § 1005.609. This section would require the Servicer to submit to HUD the Annual Loan Guarantee Fees collected from the Borrower no later than the 15th day of each month, beginning in the month in which the Borrower is required to make the first monthly loan payment. If the Servicer is late submitting the monthly installment of the Annual Loan Guarantee Fee, the Servicer must pay a penalty in accordance with § 1005.611. The Annual Loan Guarantee Fee no longer applies when the loan to value ratio equals an amount less than 78 percent, in accordance with § 1005.607. The Servicer must refund to the Borrower any excess Annual Loan Guarantee Fees collected when the loan-to-value ratio is less than 78 percent, within 30 days of the overpayment.

This section also would require that the Servicer continue to collect the Annual Loan Guarantee Fee on a monthly basis without regard to delinquent payments, prepayments, agreements to postpone payments, or agreements to recast the loan. When transferring a Section 184 Guaranteed Loan to another Servicer, this section would require an account reconciliation of the Upfront Guarantee Fee and Annual Loan Guarantee to the new Servicer. When transfer of servicing between Servicers results in a missed monthly payment(s) of the Annual Loan Guarantee Fee to HUD, the acquiring Servicer shall pay the overdue payment(s) in a lump sum to HUD within 30 days of acquisition of the loan and include any applicable penalties in accordance with § 1005.611. This section clarifies the circumstances of the on-going payment of the monthly payment of the Annual Loan Guarantee Fee and sets a timeframe for submission of this payment even when the loan is sold between Direct Guarantee Lenders or to a Servicer. This proposed section is consistent with current program policy, practice, and/or procedure.

HUD imposed penalties § 1005.611. This section proposes the circumstances in which HUD may impose civil monetary penalties on Direct Guarantee Lenders and Servicers related to the collection and submission of Loan Guarantee Fees. This section also prohibits seeking recovery of the penalty from the Borrower. Direct Guarantee Lenders may incur penalties for failure to timely remit Upfront Loan Guarantee Fee. Servicers may incur penalties for failure to timely remit the monthly installment of the Annual Loan Guarantee Fee to HUD, failure to adjust the amount of the Annual Loan Guarantee Fee, and failure to cease collection of the Annual Loan Guarantee Fee. A reasonable penalty or fee will be prescribed by HUD in Section 184 Program Guidance. HUD is proposing allowing a monetary penalty for the late or non-submission of the Annual Loan Guarantee Fee to encourage Lenders and Servicers to pay on a timely basis.

G. Servicing (Subpart G)

This subpart includes the requirements for Servicers to manage Section 184 Guarantee Loans and steps to take when a Borrower defaults on a Section 184 Guaranteed Loan. The subpart is organized into four sections: servicing loans generally, servicing defaulted loans, Loss Mitigation and assignment, foreclosure and Conveyance.

Section 184 Guaranteed Loan servicing generally § 1005.701. This proposed section provides an overview of subpart G, HUD servicing expectations and requirements for servicing Section 184 Guaranteed Loans.

Servicer eligibility and application process § 1005.703. This section proposes that a Direct Guarantee Lender, Non-Direct Guarantee Lenders or other financial institution must be an approved mortgage Servicer for FHA or another agency of the Federal Government. Direct Guarantee Lenders, and Non-Direct Guarantee Lenders are required to apply to be a Servicer, in accordance with Section 184 Program Guidance. This proposed section is intended to ensure that Servicers have the experience and qualifications and have the processes in place to properly service Section 184 Guaranteed Loans to provide quality customer service to Native American Borrowers.

Servicer approval § 1005.705. This section proposes what constitutes HUD approval for a Direct Guarantee Lenders, Non-Direct Guarantee Lenders and other financial institutions applying to be Servicers in the Section 184 Program under § 1005.703. This section addresses the process HUD will follow to notify interested Non-Director Guarantee Lenders and financial institutions seeking HUD approval to be a Servicer under the program. HUD will provide written notification of its approval and the approved Servicer must agree to comply with all program requirements. This includes the notification by the Servicer to HUD of any acquisition or sale of Section 184 Guaranteed Loans. This proposed section would be complimentary to the new requirement under § 1005.703.

Responsibility for servicing § 1005.707. This section proposes a Servicer's responsibilities under the Section 184 Program, which includes, program compliance, using a sub-Servicer, changing Servicers, transferring servicing rights, reporting requirements, program ineligibility, and records retention. This section proposes new requirements for the Servicer in the areas of annual recertification and business change reporting. HUD is proposing these new requirements to reduce risk and monitor the stability of the Servicer.

Providing information to Borrower and HUD § 1005.709. This section proposes Servicer requirements for providing information to the Borrower on the Section 184 Guaranteed Loan. Servicers must provide loan information to Borrowers and arrange for individual loan consultation on request. The Servicer must establish written procedures and controls to assure prompt responses to inquiries. All Borrowers must be informed annually of the system available for obtaining answers to loan inquiries and the office to which requests may be presented. Within 30 days after the end of each calendar year, the Servicer must furnish to the Borrower a statement of the interest paid, and of the taxes disbursed from the escrow account during the preceding year. At the Borrower's request, the Servicer must furnish a statement of the escrow account sufficient to enable the Borrower to reconcile the account. Each Servicer must deliver to the Borrower a written notice of any transfer of the servicing rights of the loan. Finally, Servicers must respond to HUD requests for information concerning individual accounts within a timeframe prescribed by Section 184 Program Guidance. HUD is proposing these requirements to ensure that acceptable procedures exist so that Servicers can readily provide loan information to Borrowers and HUD. This proposed section is consistent with current program policy, practice, and/or procedure.

Assumption and release of personal liability § 1005.711. This section proposes the requirements and the process for assumption of a Section 184 Guaranteed Loan. Eligible Borrowers may assume a Section 184 Guaranteed Loan. The new Borrower must be determined to be creditworthy under subpart D. For loans securing Properties on Trust Lands, the lease document may require Tribal and Bureau of Indian Affairs (BIA) approval of the assignment of the lease to the new Borrower. Servicers should not proceed to closing on the assumption until and unless the Tribe has assigned the leasehold to the new Borrower, and it has been approved by the BIA. Servicers may only collect fees for an assumption in accordance with this section. With respect to release of liability, this section would provide that at closing, the Servicer must release the existing Borrower from any personal liability on a form approved by HUD and the new Borrower assumes personal liability of the loan. Finally, upon completion of an assumption, a Servicer is required to provide copies of the documents to HUD. HUD will issue a revised Loan Guarantee Certificate and additional processing instructions. These changes ensure clear guidelines exist to govern the assumption and associated release of personal liability, such as ensuring that Borrowers that assume loans meet minimum creditworthiness standards. This proposed section is consistent with current program policy, practice, and/or procedure.

Due-on-sale provision § 1005.713. This section mandates a due-on-sale clause permitting acceleration for all Section 184 Guaranteed Loans. The Servicer must accelerate the loan, subject to HUD prior approval, so long as the acceleration is permitted by applicable Tribal, Federal, or State law This proposed section is consistent with current program policy, practice, and/or procedure.

Application of Borrower payments § 1005.715. This section would establish the order in which the Servicer applies Borrower payments authorized under § 1005.509 and the proposal is consistent with current program policy, practice, and/or procedure.

Administering escrow accounts § 1005.717. This section would establish the requirements for administering escrow accounts and deposits from a Section 184 Guaranteed Loan. The Servicer may not use escrow funds for any purpose other than that for which they were received. It must segregate escrow commitment deposits, work completion deposits, and all periodic payments received on account of leasehold rents on Trust Land, taxes, assessments, monthly installments of Section 184 annual loan guarantee fees and insurance charges or premiums and must deposit such funds with one or more financial institutions in a special account or accounts that are fully insured by the Federal Deposit Insurance Corporation or the National Credit Union Administration. The Servicer must also adhere to the requirements as prescribed by Section 184 Program Guidance for escrow funds related to leasehold rents on Trust Lands. The Servicer is responsible for making escrow disbursements before bills become delinquent and must establish controls to ensure that bills payable from the escrow fund or the information needed to pay such bills is obtained on a timely basis. Penalties for late payments for items payable from the escrow account must not be charged to the Borrower unless the penalty was the direct result of the Borrower's error or omission. This section also mandates that the Servicer use the procedures set forth in the Consumer Financial Protection Bureau's (CFPB) Real Estate Settlement Procedures Act (RESPA) regulations at 12 CFR 1024.17 to compute the amount of the escrow, the methods of collection and accounting, and the payment of the bills for which the money has been escrowed. The Servicer is prohibited from initiating foreclosure for a default related to escrow payment shortfalls resulting from an adjustment pursuant to this section. Finally, when a Section 184 Guaranteed Loan is terminated voluntarily or because of Borrower's prepayment in full of the unpaid principal balance, amounts in the escrow account designated to pay any HUD required program fees must be remitted to HUD. When a loan is prepaid in full, amounts held in escrow for taxes, hazard insurance, or rents due under a tribal lease must be promptly released to the Borrower. HUD is proposing this section to ensure clear guidelines on how Servicers must administer escrow accounts. This proposed section is consistent with current practices, policies and/or procedures, aligns with industry standards, and cross references RESPA requirements, as implemented in CFPB regulations.

Fees and costs after endorsement § 1005.719. This section sets forth the allowable fees and charges from the Servicer to the Borrower after HUD's endorsement of the Section 184 Guaranteed Loan. Permissible fees and charges include certain late charges, charges for processing or reprocessing a check returned as uncollectible, fees for processing a change of ownership of the mortgaged property, fees and charges for arranging a substitution of liability in connection with the sale or transfer of the Section 184 property, charges for processing a request for credit approval on behalf of an assumption or substitute Borrower, charges for substitution of a hazard insurance policy, charges for modification of the Section 184 Guaranteed Loan involving a recorded agreement for extension of term or re-Amortization, fees and charges for processing a partial release of the property, certain attorney's and trustee's fees and expenses actually incurred, escrow charges, a trustee's fee, property preservation expenses incurred, fees permitted for providing a beneficiary notice under applicable Tribal or State law, and such other reasonable and customary charges as may be authorized by HUD. This section also would provide that reasonable and customary fees must be based upon the actual cost of the work performed, including out-of-pocket expenses. HUD may establish maximum fees and charges, which are reasonable and customary in different areas. Unless otherwise provided, no fee or charge may be based on a percentage of either the face amount of the loan or the unpaid principal balance due on the Section 184 Guaranteed Loan. This section proposes to clarify the range of fees and charges that can and cannot be charged by Servicers participating in the program proposes change consistent with HUD's current practice, policy, and/or procedure.

Enforcement of late fees § 1005.721. This section proposes when and how late charges must be applied by a Servicer. It would provide that Servicers are prohibited from commencing foreclosure when the Borrower's only default is his or her failure to pay a late charge or charges. A late charge attributable to a particular installment payment due may not be deducted from that installment. However, if the Servicer notifies the Borrower of the obligation to pay a late charge, that charge may be deducted from any subsequent payment. This section also would provide that a payment may be returned because of failure to include a late charge only if the Servicer notifies the Borrower before imposition of the charge of the amount of the monthly payment, the date when the late charge will be imposed and either the amount of the late charge or the total amount due when the late charge is included. This section prohibits a late charge from being imposed on the Borrower with respect to any payment on the Section

184 Guaranteed Loan during the 60 day period beginning on the effective date of transfer of the servicing rights of a Section 184 Guaranteed Loan. This section would provide that if a payment is received by the old Servicer prior to the due date, no late charges may be assessed by the new Servicer. Finally, this section would provide that a Servicer is prohibited from imposing a late fee for failure to pay a late fee, consistent with CFPB regulations. HUD is proposing this addition to consistent with current program practices, policies, procedures, to conform the regulations to CFPB's Truth in Lending regulations, and to ensure that Servicers comply with fair rules governing late charges and is intended align with industry standards.

Partial payments § 1005.723. This proposed section provides that a Servicer must have a written policy available to the public on how it handles Partial Payments and outlines the acceptable actions when a Servicer receives a Partial Payment from a Borrower. It also proposes to provide that upon receipt of a Partial Payment, a Servicer must provide to the Borrower a copy of the Servicer's written Partial Payment policy and a letter explaining how it will handle the received Partial Payment. The Servicer may accept a Partial Payment and apply it to the Borrower's account, identify it with the Borrower's account number and hold it in a trust account pending disposition, or return the Partial Payment to the Borrower. This proposal is necessary to ensure clear guidelines on how Servicers are to manage Partial Payments and would provide Servicers with various options and is intended to codify current practice, policy, and/or procedure.

Handling prepayments § 1005.725. This section would require that a Servicer accept pre-payment at any time and details how the interest on the debt is calculated for prepayments. This proposed section is consistent with codifies current practices, policies, and/or procedures, and ensures that Borrowers who want to make prepayments on their Section 184 Guaranteed Loans have the option to do so.

Substitute Borrowers § 1005.727. This section proposes when a Borrower requests the substitution of a co-Borrower on the Section 184 Guaranteed Loan. A remaining original Borrower must still be on the loan. It would provide that where an original Borrower requests the substitution of a co-Borrower on the loan, a Non-Direct Guarantee Servicer must obtain HUD approval for the substitution. A Direct Guarantee Lender may approve an eligible substitute Borrower who meets program eligibility requirements and need not obtain further specific approval from HUD. This proposed section is meant to provide clear guidelines to Servicers and Borrowers on how to manage the substitution of Borrowers consistent with current practice, policy, and/or procedure.

Section 184 Guaranteed Loan collection action § 1005.729. This section would require the Servicer to take prompt action to collect amounts due from Borrowers and to exhaust all reasonable possibilities of collection before initiating foreclosure or assignment. This proposed regulation is necessary to ensure that Servicers meet standards for serving Section 184 Guaranteed in default and provide Borrowers with a good faith consideration of available Loss Mitigation options to avoid default, foreclosure, or both. This section is designed to ensure that risks to the Fund are minimized, and that all available reasonable loan collection and Loss Mitigation options have been considered by the Servicer. This proposed section is consistent with current program policy, practice, and/or procedure.

Default notice to Borrower § 1005.731. This section outlines the proposed requirements for contacting a defaulted Borrower, including live contact and written notice. This includes a requirement to contact all Borrowers, whether they live in the same or different locations. Servicers are required to establish or make good faith efforts to establish live contact with a defaulting Borrower no later than the 36th day of the Borrower's default and promptly inform the Borrower about the availability of Loss Mitigation options. This section also would provide that Servicers must give written notice to each Borrower in default no later than the end of the 45th day of a Borrower's default. This section also governs what must be included in the required written notice and would provide that nothing in this section shall require a Servicer to communicate with a Borrower in a manner otherwise prohibited by applicable Tribal, Federal, or State law. This section is necessary to ensure that Servicers present a minimum level of notice of default and consider Loss Mitigation options to prevent foreclosure and other unnecessary losses and risks to the Fund. HUD is proposing this addition consistent with current program practices, policies, and/or procedures and to conform to CFPB regulations and industry standards.

Loss mitigation application, timelines, and appeals § 1005.733. This section would provide specific expectations when a Servicer processes a Borrower's Loss Mitigation application. It proposes to provide five days to acknowledge receipt of the application, determine if the application is complete or incomplete, and, if incomplete, notify the Borrower of documentation that is still required and inform the Borrower that submission of the missing documents must occur within fourteen days. Within fourteen days of receipt of a complete application, the Servicer must evaluate the application.

This section also would provide that Servicers are required to provide written notification: (1) of all available Loss Mitigation options; (2) to encourage Borrowers to review all available Loss Mitigation options and to contact the Servicer with any questions; (3) to encourage Borrowers to consider pursuing simultaneous Loss Mitigation options; (4) to inform Borrowers that if no Loss Mitigation option is elected or if they fail, the Servicer may proceed with filing of the First Legal Action at 180 days of default; and (5) to inform Borrowers that at the filing of first legal action or the assignment of the loan to HUD, the Servicer will no longer offer or allow a pre-foreclosure sale as an alternative to foreclosure, and that the only available and remaining alternative to foreclosure will be a lease-in-lieu or deed-in-lieu of foreclosure, subject to applicable Tribal, Federal, or State law. Borrowers may appeal within 14 days of receipt of the Servicer's Loss Mitigation determination, in writing, that the Servicer re-evaluate the Borrower's Loss Mitigation application. The Servicer will be required to re-evaluate the Borrower's Loss Mitigation application within 30 days, but may not use the same staff that made the initial Loss Mitigation determination and must notify the Borrower of its appeal decision. If the Borrower submits a timely written appeal, the 180-day deadline to initiate foreclosure will be suspended during the appeal process. This section is being proposed to provide clear guidelines to both Servicers and Borrowers on the Loss Mitigation application process and associated appeals, to minimize risks and losses to the Fund, and to avoid foreclosure when possible. This proposed section is consistent with current program policy, practice, and/or procedure.

Occupancy inspection § 1005.735. This section proposes occupancy inspection as a visual inspection by the Servicer, defines occupancy follow-up as an attempt to communicate with the

Borrower through various means to determine occupancy status, and would provide the requirements for occupancy inspections and occupancy follow-ups while a Borrower is in default. It also governs occupancy inspections conducted during a Borrower's bankruptcy.

HUD is proposing this regulation to ensure that clear guidelines exist for Servicers governing occupancy inspections. Servicers may find the need to conduct occupancy inspections to determine whether a property has become vacant or abandoned, and to confirm the identity of any occupants. HUD is requiring Servicers to conduct occupancy follow-ups and to attempt to conduct continuing inspections, if necessary, every 25–35 days from the last inspection until the occupancy status is determined. This is designed to ensure that Servicers proactively work to determine the status of each property subject to a loan guaranteed under the program, that is in default, and to minimize costs and risks to the Fund. This proposed section is consistent with current program policy, practice, and/or procedure.

Vacant property procedures § 1005.737. This section would set forth the requirements when a property has been determined vacant or abandoned based on an occupancy or occupancy follow-up inspection. This provision includes a notice requirement to the Borrowers of determination of vacancy or abandonment, which is sent to the property address and all known addresses of Borrowers. If occupancy is found through the delivery confirmation process, the Servicer must continue pursuing Loss Mitigation efforts until the Servicer can proceed to First Legal Action. On the other hand, if the Servicer verifies through the delivery confirmation process or other method that the property is vacant or abandoned, then the Servicer must secure and maintain the property through appropriate property preservation actions, initiate the First Legal Action or assign a Trust Land loan to HUD within 120 days after date of default, continue to perform vacant property inspections every 25–35 days, and retain documentation in the servicing file.

HUD is proposing this section to ensure that clear guidelines exist for Servicers who manage vacant or abandoned Properties. While not common, a small number of Properties assisted under the Section 184 Program have previously been abandoned. In such cases, it is critical that Servicers remain proactive in verifying the occupancy status of such Properties and ensuring that they are processed and disposed of in a timely manner. Vacant or abandoned Properties can attract criminal activity and serve as an additional blight to Trust Land. These guidelines will also help preserve collateral and prevent unnecessary losses and risks to the Fund. This proposed section is consistent with current program policy, practice, and/or procedure, and aligns with industry standards.

Loss mitigation § 1005.739. This section proposes the Loss Mitigation options and review requirements when a Borrower defaults on a Section 184 Guaranteed Loan. This section would require that Servicers utilize various Loss Mitigation options, if practical, within 180 days of the date of default. Loss mitigation options include: (1) forbearance plan, (2) assumption, (3) trial payment plan agreement for a loan modification, (4) pre-foreclosure sale, or (5) deed-in-lieu or lease-in-lieu of foreclosure. Within 180 days of default, if the Borrower is offered a Loss Mitigation option other than loan modification and fails to meet the Loss Mitigation requirements, the Servicer is required, within 5 days of the Loss Mitigation default, to determine whether the Borrower should continue with the current Loss Mitigation option or reassess the Borrower. If no time or very limited time remains within 180 days of default, the Servicer will not be required to reassess the Borrower for another Loss Mitigation option.

This section also would provide that if a Borrower is performing under a Loss Mitigation option that does not reinstate the loan at 180 days of default but subsequently fails to perform, the Servicer must take First Legal Action within 5 days of the Loss Mitigation option default. Servicers must maintain documentation of all evaluations and Loss Mitigation actions. Finally, Servicers that fail to engage in and comply with required Loss Mitigation may be subject to enforcement action by HUD, including possible sanctions.

HUD is proposing this addition to the regulation to ensure Servicers review Loss Mitigation options to prevent foreclosures, to maintain Native American Borrowers in their homes, to the extent practicable, and to minimize any resulting losses and risks to the Fund. This proposed section is consistent with current program practices, policies, and/or procedures, and conforms to CFPB regulations and industry standards.

Notice to Tribe and BIA—Borrower default § 1005.741. This proposed section compliments HUD's current practice and policy to notify the BIA when a Borrower defaults on a Section 184 Guaranteed Loan, in accordance with applicable requirements under 25 CFR part 162. This section also includes a new requirement for Servicers. When given consent by the Borrower, Servicers must notify the Borrower's Tribe when a Borrower defaults on Section 184 Guaranteed Loan. This proposed section addresses a request made during Tribal consultation in which Tribal representatives expressed a desire to be notified when a member has defaulted on their Section 184 Guaranteed Loan, so that the Tribe may provide financial assistance, if available.

Relief for Borrower in military service § 1005.743. This proposed section outlines the options for Borrowers who are in military service, in addition to benefits afforded under other applicable laws, including postponement of principal payments, forbearance, and postponement of foreclosure. This section is being proposed to provide accommodations for Borrowers that are persons in ''military service,'' as such term is defined in the Servicemembers Civil Relief Act (50 U.S.C. 3901, *et seq.*). This proposed section is consistent with current program policy, practice, and/or procedure, and aligns with industry standards.

Forbearance plans § 1005.745. This section proposes forbearance options a Servicer may offer to defaulting Borrowers. This section sets out the requirements for informal forbearance, formal forbearance, unemployment forbearance, and servicemember forbearance. Each type has its own agreement requirements, duration period requirements, property condition requirements, and required documents. HUD is proposing this regulation to ensure that several options are available for defaulting Borrowers. This proposed section is consistent with current program policy, practice, and/or procedure, and aligns with industry standards.

Assumption § 1005.747. This section would require Servicers to explore loan assumption as a Loss Mitigation option. HUD is proposing this regulation to provide another Loss Mitigation option for a Borrower that has defaulted on their guaranteed loan. This proposed section is consistent with current program policy, practice, and/or procedure, and aligns with industry standards.

Loan modification § 1005.749. This section proposes loan modifications as a Loss Mitigation option and sets forth the eligibility and qualifications necessary for a Servicer to approve a Borrower's application and the required property conditions. This section also discusses

the use of trial payment plans, the execution of loan modification documents that conform to all applicable Tribal, Federal, and State laws, and when the Servicer must provide modified loan guarantee documents to HUD. HUD is proposing this regulation to provide another Loss Mitigation option for Borrowers in default. This proposed section is consistent with current program policy, practice, and/or procedure.

Pre-foreclosure sale § 1005.751. This section would provide authority for pre-foreclosure sale as a Loss Mitigation option. The requirements specified for this review include: surchargeable calculation of the Borrower's cash reserve contribution, condition of title for both fee simple and Trust Land Properties, verification of discharge of all junior liens, and listing the property at no less than the value determined in the required appraisal. The Servicer would be required to send all required pre-foreclosure documentation to HUD and send an approval to participate agreement and required addendum notice to the Borrower.

This section also would provide Tribal notification of the option to assume the Section 184 Guaranteed Loan or purchase the either the Note or the property. The section sets out the requirements for the Borrower in securing a real estate broker and required clauses in the contract between the Servicer and broker, as well as the time period for the Borrower to market the property in listings. For all pre-foreclosure sale Properties, the Servicer is required to conduct property inspections and maintenance, and the Borrower is required to disclose any damage that has occurred immediately. If damage has occurred, the Servicer is required to work with the Borrower to file hazard insurance claims. The section sets out the responsibilities for the seller in receiving sufficient bids, reviewing the sales contract, as well as closing and post-closing responsibilities. The section details early termination initiated by both the Borrower and the Servicer, and how to proceed in the event the Borrower fails to complete the pre-foreclosure sale. HUD is proposing this regulation to provide an additional option for defaulted Borrowers. This is a new loss mitigation option for the Section 184 Program. HUD is proposing this section to give Native American Borrowers comparable loss mitigation options to Borrowers in other loan guarantee programs.

Deed-in-lieu/lease-in-lieu of foreclosure § 1005.753. This section would require the use of deed-in-lieu/lease-in-lieu of foreclosure as a Loss Mitigation option. This section also sets out the required documents to effectuate the transfer and, upon Conveyance to HUD, the Servicer must file for record the required documents within two days and report to HUD. The Servicer must also comply with all applicable Federal, State, Tribal, and local reporting requirements. HUD is proposing this regulation in order to provide an additional option for Borrowers in default. This proposed section is consistent with current program policy, practice, and/or procedure and aligns with industry standards.

Incentive payments to Borrower § 1005.755. This section proposes that HUD may authorize incentive payments to the Borrower when Borrowers complete certain loss mitigation options and when Borrowers agree to vacate the property after foreclosure to avoid an eviction. This section also proposes that HUD may authorize incentive payments to Lender and Servicer for their completion of certain Loss Mitigation options and incentive payments to Tribes and TDHEs when they assist HUD in the loss mitigation, sale or transfer of the Trust Land property. HUD plans to provide further guidance on the incentives in Section 184 Program Guidance. HUD is proposing this new authority to encourage Borrowers' and Servicers' participation in Loss Mitigation, to avoid the time and expense of foreclosing on the property and evicting the Borrower after foreclosure.

Property on Trust Land—Tribal first right of refusal; foreclosure or assignment § 1005.757. This section proposes the timeframe in which a Servicer must contact a Tribe or TDHE and offer an option to assume or purchase the property or the Note under § 1005.757(a) when a defaulted loan pertains to property that is located on Trust Land, as well as the TDHE or Tribe's acceptance of the offer. This section also allows for the Servicer to choose between foreclosure or assignment to HUD for a defaulted Section 184 Guaranteed Loan located on Trust Lands. HUD is proposing this regulation to clarify options available to the Servicer but also to ensure timely action. This proposed section is consistent with current program policy, practice, and/or procedure.

Fee simple properties—foreclosure or assignment with HUD approval § 1005.759. This section proposes the requirement for Servicers to initiate foreclosures or request the ability to assign a defaulted property to HUD. HUD may approve assignments under limited circumstances. HUD is proposing this regulation in order to ensure that Servicers timely initiate foreclosure proceedings and is consistent with current policy, practice and/or procedure.

First Legal Action deadline and automatic extensions § 1005.761. This section proposes to provide a timeline for the initiation of foreclosure by the Servicer on defaulted Section 184 Guaranteed Loans. This proposed section is consistent with current program policy, practice, and/or procedure and aligns with industry standards.

Assignment of the Section 184 Guaranteed Loan § 1005.763. This section presents the requirements for assigning a defaulted Section 184 Guaranteed Loan to HUD. This proposed section is consistent with current program policy, practice, and/or procedure and aligns with industry standards.

Inspection and preservation of Properties § 1005.765. This section proposes that the Servicer comply with inspection requirements under § 1005.737 when the Servicer knows or should know the property is vacant or abandoned. The section also proposes to require that the Servicer take action to preserve and protect the property until Conveyance to HUD. HUD is proposing this section in order to ensure the Servicer continues to inspect and preserve the property. This proposed section is consistent with current program policy, practice, and procedure and aligns with industry standards.

Property condition § 1005.767. This section would mandate the condition of the property and the Servicer's responsibilities at the time a property is transferred to HUD through Conveyance or assignment. This proposed section is consistent with current program policy, practice, and/or procedure.

Conveyance of property to HUD at or after foreclosure; time of Conveyance § 1005.769. This section proposes the methods and timeframe in which a Servicer may convey a property to HUD after foreclosure, including HUD notification of the Conveyance. HUD is proposing this section in order to ensure the Servicer timely conveys the property to HUD. This proposed section is consistent with current program policy, practice, and/or procedure and aligns with industry standards.

Acceptance of property by HUD § 1005.771. This section would establish the date which HUD is deemed to have accepted an assignment of a Section 184 Guaranteed Loan, or title to and possession of a property. HUD is proposing this section to clarify when HUD has accepted title to a conveyed

property. This proposed section is consistent with current program policy, practice, and/or procedure and aligns with industry standards.

H. Claims (Subpart H)

This subpart includes the requirements for Servicers to submit claims to HUD. The subpart is organized into five sections: claims application, submission categories, and types; submission of claims; property title transfers and title waivers; condition of the property; and payment of guarantee benefits.

Purpose § 1005.801. This section proposes the purpose of this subpart which is to set forth the requirements applicable to a submission of an application for loan guarantee benefits (Claim submission). It explains that Servicers must comply with regulations presented in subpart H and process details included in Section 184 Program Guidance. This subpart also sets forth requirements processing and payment of Claim. This proposed section is consistent with current program policy, practice, and/or procedure.

Claim case binder; HUD authority to review records § 1005.803. This section would require Servicers to maintain a Claim case binder for a minimum of five years after the final Claim has been paid and allow HUD access to the case binder. Section 1005.803(b) allows HUD access to the Claim case binder at any time and would provide that Servicer denial of HUD access to any of the files may subject the Servicer to sanctions under §§ 1005.905 and 1005.907. Section 1005.803(c) would provide that the Servicer must make available to HUD any request for Claim files within three business days of the request. This proposed section is consistent with current practices and establishes new timeframes for Servicers to respond to HUD's request for a Claim case binder. These policies are necessary to ensure HUD has appropriate oversight of the program.

Effect of noncompliance § 1005.805. This section proposes to establish the actions HUD may take if a Claim case binder does not comply with the requirements of subpart D, including: rejecting the claim, paying the claim but demanding reimbursement from the Originating Direct Guarantee Lender, reconveying the property or reassigning the deed of trust or mortgage in accordance with § 1005.849 and sanctions in accordance with §§ 1005.905 and 1005.907. Further, it would establish actions HUD may take if it finds the Servicer failed to service the Section 184 Guaranteed Loan in accordance with subpart G, committed fraud, known or should have known of fraud or material misrepresentation in violation of this part. These include holding the claim to remedy the deficiency, rejecting expenses under § 1005.807(b), reconveying the property or reassigning the deed of trust or mortgage in accordance with § 1005.849, administrative offset, sanctions in accordance with §§ 1005.905 and 1005.907, and other remedies as determined by HUD. This section also limits the expenses that can be changed when a reconveying the property or reassigning the deed of trust or mortgage. This proposed section is consistent with current program policy, practice, and/or procedure.

Claim submission categories § 1005.807. This section lists the three Claim submission categories. The three Claim categories are: payment of the unpaid principal balance; reimbursement of eligible reasonable expenses up to assignment, Conveyance or transfer of the property; and supplemental claims for eligible expenses incurred that were omitted from the Servicer's prior submission or for a calculation error made by the Servicer or HUD. This proposed section is consistent with current program policy, practice, and/or procedure.

Claim types § 1005.809. This section would establish five Claim types, which are submitted based on property disposition, timeframes for Claim submission, and the documentation required for each Claim type. The five Claim types are: Conveyance; assignment of the loan; post-foreclosure claims without Conveyance of title; pre-foreclosure sale; and supplemental claims.

Paragraph (a) would provide for a Claim when the Servicer conveys the property to HUD after foreclosure or execution of a deed-in-lieu or lease-in-lieu. The Servicer has 45 days from date the deed to HUD is executed to submit the Conveyance Claim. For fee simple properties, the section would require final title policy. For Trust Land Properties, a Title Status Report from the Bureau of Indian Affairs evidencing ownership vested to HUD is required. Where Servicer is unable to obtain a Title Status Report from the Bureau of Indian Affairs, the Servicer may submit a Claim on the 45th day in accordance with Claim processing instructions that HUD will provide. Lenders must submit claims related to reimbursable eligible expenses no later than the 60th day of the date the deed is executed to HUD, unless extension of time is given by HUD.

Paragraph (b) describes the assignment of the Section 184 Guaranteed Loan and would require the Servicer to submit a Claim no later than 45 days from the date of the assignment of the Section 184 Guaranteed Loan to HUD is executed. The section would require the Servicer provide a final title policy or, where applicable, a certified Title Status Report evidencing the assignment of the mortgage to HUD. Where the Servicer is unable to comply with the documentation from title policy or Title Status Report, the Servicer may submit a Claim on the 45th day in accordance with processing instructions from HUD. For assignment of a Section 184 Guaranteed Loan, the Servicer must submit a Claim for reimbursable expenses, if any, within 45 days of the date the loan assignment is executed. This section would require the Servicer to certify that the Section 185 Guaranteed Loan is in first lien position and prior to all mechanics' and materialmen's liens filed for record, the amount due and owing under the loan, there are no offsets or counterclaims, the Servicer has good right to assign, and has met the property inspection and property preservation requirements of this part.

Paragraph (c) explains the post-foreclosure claims without Conveyance of title requirements and addresses when a third-party purchases fee simple Properties at foreclosure. The Servicer must submit a Claim to HUD no later than 180 days from the date the deed to the third-party is executed. Paragraph (d) is the pre-foreclosure sale Claim. It authorizes claims when a property is sold prior to foreclosure in accordance with HUD's pre-foreclosure sale requirements at § 1005.751 or § 1005.753. The Servicer must submit a Claim no later than 45 days from the date the deed or assignment of the lease to the third-party is executed.

Paragraph (e) discusses supplemental claims, and limits Servicers to one supplemental Claim for each Claim related to the payment of unpaid principal balance and reimbursement of eligible reasonable expenses. Paragraph (e) limits supplemental claims to reasonable eligible expenses incurred on the date of Conveyance of the property or assignment of the Section 184 Guaranteed Loan, when invoices are received after payment of the Claim or when there is a calculation error made by the Servicer or HUD. Supplemental claims must be submitted within six months of when the Servicer files a Claim for reimbursement of eligible reasonable expenses. Any supplemental claims received after the six-month period will not be reviewed or paid by HUD. This section makes clear any supplemental Claim paid by HUD shall

be considered final satisfaction of the loan guarantee.

Proposed paragraphs (a) through (d) are consistent with HUD's existing policies, practices, and procedures with the exception of paragraph (b)(4), which proposes to implement a new Servicer certification requirement. Proposed paragraph (e) is consistent, in part, with HUD's existing policies, practices, and procedures, but proposes to add a new requirement that supplemental claims are time limited to a 6-month window. These policies are proposed to ensure HUD maintains its fiduciary duty to protect the Fund and reduce its risk against Claim payments that do not meet Section 184 requirements.

Claims supporting documentation § 1005.811. This section proposes to require Servicers to submit supporting documentation required for each Claim to the satisfaction of HUD. Such documentation will be provided for in Section 184 Program Guidance. This proposed section is consistent with current program policy, practice, and/or procedure.

Upfront and Annual Loan Guarantee Fee reconciliation § 1005.813. This section proposes to require Lenders to submit, as part of a Claim submission under § 1005.807(b), a reconciliation evidencing the payment of the Annual Loan Guarantee Fee to HUD. This section proposes a new process to ensure Lenders can verify they have paid all Loan Guarantee Fees prior to HUD payment of any claims.

Conditions for withdrawal of claim § 1005.815. This section provides the conditions under which a Servicer can withdraw a Claim submission after there has been a Conveyance. HUD will permit withdrawal of the application when a Servicer accepts a reconveyance of the property under a deed which warrants against the acts of HUD and all claiming by, through or under HUD, promptly files a reconveyance for record; accepts without continuation the title evidence it furnished to HUD; and reimburses HUD for property expenditures HUD incurred after Conveyance to HUD. This proposed section is consistent with HUD's current practice, policy, and/or procedure.

Conveyance of Good and Marketable Title § 1005.817. This section proposes to mandate that a property have Good and Marketable Title when conveyed to HUD from a Lender. This proposed section is consistent with current program, policy and/or practice. Within this section, HUD is proposing a new timeframe in which a Servicer must correct any title defects. HUD is proposing that the Servicer make this correction in 60 days, or the Servicer must reimburse HUD for the cost of holding the property until any defect is corrected or until HUD reconveys the property to the Servicer. This proposed time frame is intended to help ensure timely action by the Servicer to correct title defects.

Types of satisfactory title evidence § 1005.819. This section would provide six types of title evidence that may be submitted with a Claim submission. The permissible types of title evidence include: fee or owner's title policy; Lender's policy of title insurance; abstract and legal opinion; torrens or similar certificate; title standard of U.S., Tribal, or State government; and Title Status Report issued by the Bureau of Indian Affairs. This proposed section is consistent with current program policy, practice, and/or procedure.

Coverage of title evidence § 1005.821. This section would establish that evidence of title or Title Status Report shall be executed subsequent to the filing for record of the deed or assignment to HUD. The title evidence must show that, according to public records, there are not, as of the date of the recordation of the deed or assignment to HUD, any outstanding prior liens, including any past due and unpaid ground rents, general taxes, or special assessments, if applicable. This proposed section is consistent with current program policy, practice, and/or procedure.

Waived title objections for properties on fee simple land § 1005.823. This section would provide that reasonable title objections for fee simple properties shall be waived by HUD. Reasonable title objections will be prescribed in Section 184 Program Guidance. This proposed section is consistent with current program policy, practice, and/or procedure.

Waived title objections for properties on Trust Land § 1005.825. This section proposes that HUD shall not object to title restrictions placed on Trust Land by a Tribe or the Bureau of Indian Affairs, so long as those restrictions do not adversely impact the property or marketability. This proposed section is consistent with current program policy, practice, and/or procedure.

Damage or neglect § 1005.827. This section would provide a Lender's responsibilities when a property has suffered damage or neglect and HUD's remedy when a damaged property is conveyed to HUD without prior notice or approval. Section 1005.827(a) would provide that if a property has been damaged by fire, flood, earthquake, tornado, or due to Lender's failure to take action to protect and preserve the property, the Servicer must submit a Claim to the hazard insurance policy, and the damage must be repaired before Conveyance of the property or assignment of the loan to HUD.

Paragraph (b) would provide that if the property damage is not covered by a hazard insurance policy, the Servicer must notify HUD of the damage. Servicer may not convey until directed to do so by HUD. If HUD requires the Servicer to repair the damage before Conveyance, HUD may reimburse Servicer for reasonable payments not in excess of HUD's estimate of the cost of repair, less any insurance recovery or require the Lender to repair the damage before Conveyance at the Servicer's own expense.

Paragraph (c) would provide that in the event the Servicer conveys property to HUD without repair to the damage or without notice to HUD of the damage, HUD may, after notice, reconvey the property to the Servicer and seek reimbursement for expenses HUD incurred in connection with the Conveyance. This proposed section is consistent with current program policy, practice, and/or procedure.

Certificate of property condition § 1005.829. This section would require a Servicer to submit a certification of property condition as part of the Claim submission. This section would provide that, as part of the Claim submission, the Servicer certifies the property was undamaged by fire, flood, earthquake, or tornado, was undamaged due to failure of the Servicer to act, and undamaged while the property was in possession of the Borrower. Alternatively, if the property was damaged, the Servicer includes a copy of the HUD approval to convey the property in damaged condition.

Paragraph (b) would provide that, in the absence of evidence to the contrary, the Servicer's certificate or description of the damage shall be accepted by HUD as establishing the condition of the property, as of the date of the filing of the deed or assignment of the loan. This proposed section is consistent with current program policy, practice, and/or procedure, and to ensure Servicers confirm the property is conveyed to HUD undamaged.

Cancellation of hazard insurance § 1005.831. This section proposes to provide that Servicers shall cancel any hazard insurance policy as of the date of the filing for record of the deed to HUD, subject to certain conditions. The conditions include: (1) the amount of the return premium, due to the Servicer because of such cancellation, may be calculated on a ''short-rate'' basis and reported on fiscal data, and the amount shall be deducted from the total amount

claimed; (2) If the Servicer's calculation of the return premium is less than the actual return, the amount of the difference between the actual refund and the calculated amount shall be remitted to HUD, accompanied by the carrier's or agent's statement; (3) If the Servicer's calculation of the return premium is more than the actual return, the Servicer may include in its Claim submission, the statement of the amount of the refund from the insurance carrier or agent, and include the amount of the difference as an eligible cost in accordance with § 1005.843(a)(3). This proposed section is consistent with current program policy, practice, and/or procedure.

Method of payment § 1005.833. This section would establish that HUD will make payment of guarantee benefits by electronic transfer of funds for all approved claim submissions. This proposed section is consistent with current program policy, practice, and/or procedure.

Claim payment not conclusive evidence of claim meeting all HUD requirements § 1005.835. This section proposes to provide that any payment of claim by HUD is not conclusive evidence of a Servicer's compliance with Section 184 Program requirements. HUD reserves the right to conduct post-claim payment review of any claim file within 5 years from the date of last claim payment. This section states when non-compliance with any requirements of this part is identified, HUD may take appropriate post-claim action against the Servicer. This section is a codification of existing policy, practice, and procedure with the exception of the five-year period. The proposed five-year period is necessary to ensure uniformity in the time frame for HUD to conduct post-claim reviews of the loan file.

Payment of claim: unpaid principal balance § 1005.837. This section would state that HUD will pay claims for unpaid principal balance submitted under § 1005.807(a), minus any receipts for the sale or transfer of the property. This proposed section is consistent with current program policy, practice, and/or procedure.

Payment of claim: interest on unpaid principal balance § 1005.839. This section would establish the payment timeframe for interest payments on the unpaid principal balance. HUD shall pay interest on the unpaid principal balance from the date of default to the earlier of the following: the execution of the deed to the Lender, HUD, or third-party; execution of Conveyance of deed to either Lender, HUD, or third-party; execution of the assignment of the loan to HUD; or expiration of the reasonable diligence timeframes as prescribed by Section 184 Program Guidance. This proposed section is consistent with current program policy, practice, and/or procedure and aligns with industry standards.

Payment of claim: reimbursement of eligible and reasonable costs § 1005.841. This section proposes to provide that reimbursement of eligible and reasonable costs under § 1005.807(b) shall be paid as part of the guarantee benefits. HUD will prescribe reasonable costs that are eligible for reimbursement in Section 184 Program Guidance. This proposed section is consistent with current program policy, practice, and/or procedure and aligns with industry standards.

Reductions to the Claim submission amount § 1005.843. This section proposes the circumstances under which Lenders should reduce their Claim amount. The Servicer shall reduce its Claim when the following amounts are received by the Lender: amounts received by the Servicer instituting foreclosure or acquisition of the property by direct Conveyance or otherwise after default; amounts received by the Servicer from any source relating to the property on the account of rent or other income after deducting reasonable expenses incurred in handling the property; and all cash retained by the Lender, including amounts held or deposited for the account of the Borrower or to which is entitled under the loan transaction that have not been applied in reduction of the principal loan indebtedness. This proposed section is consistent with current program policy, practice, and/or procedure and aligns with industry standards.

Rights and liabilities under the Indian Housing Loan Guarantee Fund § 1005.845. This section would state that Borrowers and Lenders shall not have any vested right in the Fund nor be subject to any liability arising under such Fund. In addition, that the Indian Housing Loan Guarantee Fund will be credited and debited in accordance with 12 U.S.C. 1715z–13a(i)(2). This proposed section is consistent with current program policy, practice, and/or procedure and aligns with industry standards.

Final payment § 1005.847. This section would establish the conditions for final payment from HUD to the Lender. Paragraph (a) would provide that payment of the Claim shall be deemed as final payment to the Servicer and that the Servicer would have no further claims against the Borrower or HUD. The provision further states final payment to the Servicer does not preclude HUD from seeking reimbursement of costs and return of amounts from the Servicer when there is a reconveyance to the Lender.

Paragraph (b) would provide that when there is a reconveyance to the Servicer, and the Servicer reimburses HUD for all expenses and returns all Claim amounts paid, the final payment to the Servicer restriction under § 1005.849(a) will not apply. The section makes clear that in the event the Servicer resubmits a Claim after reconveyance to the Servicer, then the Servicer shall not be reimbursed for any expenses incurred after the date of the HUD Conveyance. This proposed section is consistent with current program policy, practice, and/or procedure.

Reconveyance and reassignment § 1005.849. This section proposes actions HUD may take when there is a reconveyance of a property or a reassignment of the deed of trust or mortgage back to the Holder. Paragraph (a) would provide that HUD may reconvey the property to the Holder due to an Originating Direct Guarantee Lender or Servicer's noncompliance with the requirements of this part or if there is a withdrawal of a Claim for benefits in accordance with § 1005.815. Paragraph (b) proposes to provide that HUD may take action against the Holder, including, but not limited to, seeking reimbursement of all Claim costs paid. Paragraph (c) proposes to provide that where HUD has conveyed the property or reassigned the deed of trust or mortgage back to the Holder, and a Claim is subsequently resubmitted, the Holder will not be reimbursed for any expenses incurred after the date of the HUD Conveyance or assignment. This proposed section is consistent with current program policy, practice, and/or procedure and aligns with industry standards.

Reimbursement of expenses to HUD § 1005.851. This section would establish a Holder or the Originating Direct Guarantee Lender reimbursement responsibilities when HUD determines it will reconvey of a property previously conveyed to HUD under the claims process. This section proposes that when there is a reconveyance or reassignment by HUD, to the Holder or the Originating Direct Guarantee Lender, or when HUD determines noncompliance, the Holder or the Originating Direct Guarantee Lender shall reimburse HUD for all Claim costs paid, HUD's cost of holding the property, and reimbursement plus interest on the loan guarantee benefits from the date the loan guarantee benefits were paid to the date HUD

receives the refund from the Holder. The interest rate shall be in conformity with the Treasury Fiscal Requirements Manual. This proposed section is consistent with current program policy, practice, and/or procedure and aligns with industry standards.

I. Lender Program Performance, Reporting, Sanctions, and Appeals (Subpart I)

Direct Guarantee Lender, Holder, or Servicer *performance reviews § 1005.901.* This section would establish HUD's authority to conduct periodic performance reviews of Direct Guarantee Lenders, Non-Direct Guarantee Lenders, Holders, and Servicers. These reviews will include, but are not limited to, an evaluation of compliance with this regulation. Monitoring reviews ensure that Direct Guarantee Lenders, Non-Direct Guarantee Lenders, Holders, and Servicers are complying with the requirements of the program and reduces risk to the Fund. This proposed section is consistent with current program policy, practice, and procedure and aligns with industry standards.

Direct Guarantee Lender, Holder, or Servicer r*eporting and certifications § 1005.903.* This section proposes to mandate Direct Guarantee Lenders, Non-Direct Guarantee Lenders, or Servicers provide timely and accurate reports and certifications to HUD and provides HUD the authority to subject the Lender to sanctions for failure to submit such documents. This proposed section is consistent with current program policy, practice, and/or procedure.

Direct Guarantee Lender, Holder, or Servicer n*otice of sanctions § 1005.905.* This section would state that HUD will provide notice to the Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer of the specific-noncompliance and, where applicable, allow for a reasonable time to return to compliance, prior to any sanctions or civil money penalties If the Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer fails to return to compliance, HUD shall provide written notice of the sanction or civil money penalties to be imposed and the basis for the action. This proposed section is consistent with current program policy, practice, and/or procedure and aligns with industry standards.

Direct Guarantee Lender, Holder, or Servicer *sanctions and civil money penalties § 1005.907.* This section proposes that sanctions and civil money penalties may be imposed by HUD when a Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer fails to comply with this part. Such compliance may include complying with Section 184 Program Guidance when it specifically provides reasonable times, processes, and procedures for complying with part 1005 requirements. This includes: termination from the program; bar the Direct Guarantee Lender, or Holder from acquiring additional loans guaranteed under this section; require that the Direct Guarantee Lender assume not less than 10 percent of any loss on further loans made by the Direct Guarantee Lender; require that the Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer comply with a corrective action plan or amend Direct Guarantee Lender, Non-Direct Guarantee Lender, or Servicer's quality control plan; or impose a civil money penalty on the Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer in the manner and amount provided pursuant to Section 184 of the Native American Assistance and Self-Determination Act of 1996 (12 U.S.C. 1715z-13a) and 24 CFR part 30. This proposed section is statutorily authorized and is intended to protect the Fund and Section 184 Program integrity by allowing HUD to sanction poorly performing Direct Guarantee Lenders, Non-Direct Guarantee Lenders, Holders, or Servicers.

Direct Guarantee Lender, Holder, or Servicer a*ppeals process § 1005.909.* This section would establish an appeal process for Non-Direct Guarantee Lenders, Direct Guarantee Lenders, and Servicers to appeal a denial of participation in the Section 184 Program and to appeal sanctions or civil money penalties imposed pursuant to § 1005.907. This proposed section is intended to provide Lenders the opportunity to appeal a decision to HUD for HUD's reconsideration.

HUD's Part 58 Regulations

Currently Tribes may elect to assume environmental responsibility for Section 184 Guaranteed Loans pursuant to 24 CFR part 58, requiring Tribes to ensure applicable environmental requirements are met. HUD proposes to not have Tribes assume environmental responsibility for the Section 184 Program for fee simple Properties that are located outside of a reservation in order to streamline the environmental review process and relieve the burden upon Tribes. It is impractical to have a Tribe assume environmental responsibilities for Section 184 Guaranteed Loans on fee simple Properties outside of a reservation, which may be located far from the reservation of the Borrower's Tribe. Forgoing Tribal involvement and responsibility for Federal environmental review on such properties will increase the efficiency in providing HUD assistance, as well as relieve the Tribes of a burden. Accordingly, the proposed rule would revise § 58.1(b), which lists the programs that are subject to part 58, to indicate that Indian Housing Loan Guarantees under Section 184 are subject to part 58 for Properties on trust land and on fee land within a reservation. Thus, Properties not on trust land not on fee land within a reservation shall be subject to § 50.19(b)(17).

For loan guarantees that are subject to part 58, part 58 indicates which activities are categorically excluded from environmental assessment under the National Environmental Policy Act (42 U.S.C. 4321, *et seq.*) (NEPA) and which categorically excluded activities remain subject to related Federal environmental laws and authorities listed in § 58.5. HUD's existing regulation at § 58.35(b) lists a number of programs that are categorically excluded from assessment under NEPA and not subject to such related authorities, and this proposed rule would add to the list HUD's guarantee of loans for one- to four-family dwellings under the Direct Guarantee procedure for the Section 184 Program where there is no review or approval of the application for the loan guarantee by HUD or the responsible entity, or approval of the loan guarantee by HUD, before the execution of the contract for construction or rehabilitation and the loan closing.[1] The proposed rule would update HUD's categorical exclusions and increase efficiency in providing HUD assistance, as well as reducing reduce costs associated with HUD's environmental review process to eliminate unnecessary regulatory burdens that impede affordable housing development.

Specific Question for Comment—Environmental Regulations

HUD invites comments on the proposal to shift environmental responsibility from Tribes to HUD for

[1] A comparable categorical exclusion for loan guarantees under the Section 184 Direct Guarantee procedure is already contained in 24 CFR part 50, which applies when a Tribe declines to assume environmental review responsibilities and HUD performs any required environmental review. See 24 CFR 50.19(b)(17). The proposed exclusion under part 58 would adapt the existing exclusion to apply when a Tribe assumes environmental responsibilities, where there is no HUD review or approval of the application for the loan guarantee by HUD or the responsible entity, or approval of the loan guarantee by HUD before the completion of construction or rehabilitation and the loan closing.

fee simple Properties that are located outside of a reservation.

III. Tribal Consultation

HUD's policy is to consult with Indian Tribes early in the rulemaking process on matters that have Tribal implications. Accordingly, HUD began consulting with Indian Tribes in February 2018. HUD held eleven in-person Tribal consultation sessions before the regulations in this proposed rule were drafted. As draft subparts of the regulation were completed, HUD held three additional in-person consultations to solicit Tribal feedback on each subpart. On April 4, 2019, HUD sent out a copy of the full draft proposed rule to all Tribal leaders and directors of TDHEs for review and comment. The Tribal comment period was originally from April 4, 2019, to June 4, 2019, but it was extended to June 30, 2019, after Tribal leaders requested more time to review the draft proposed rule. During this time, HUD also held two in-person Tribal consultations and two national teleconferences to review the draft proposed rule.

Tribal feedback has been an integral part of the process to develop this proposed rule. Throughout the consultation process, HUD used Tribal feedback to refine and improve this proposed rule. Tribal comments included areas such as Lender relationships and qualifications, loan limits, rate and fees, loan processing, Borrower qualifications, eligible units, Section 184 Approved Program Area, Tribal courts, and Tribal involvement. HUD considered all written comments submitted to HUD, as well as recorded comments received from in-person Tribal consultation sessions, and revised the proposed rule as appropriate.

IV. Findings and Certifications

Regulatory Review—Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both the costs and benefits of reducing costs, of harmonizing rules, and of promoting flexibility.

Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. This proposed rule, as discussed above, would introduce changes to make the program sustainable, protect Borrowers, address recommendations by the OIG in areas such as Lender underwriting and the claims process, and provide clarity for new and existing Lenders who participate in the Section 184 Program. These changes would allow for Lenders to serve the growing demand for the program and introduce stronger governing regulations to reduce the increased risk to the Fund.

Many current and potential Section 184 Lenders and Servicers participate in the FHA single family mortgage program. Where appropriate, aligning the new Section 184 regulations with the FHA single family mortgage program regulations should also minimize costs to new and existing Lenders. Additionally, clarifying servicing requirements will protect the Borrowers by requiring Servicers to consider Loss Mitigation options for Borrowers. Moreover, the added requirements and protections will help to reduce losses to the Fund and thereby allow the Section 184 Program to provide additional loans and decrease the cost of the loans to eligible Borrowers.

This rule was determined to be a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and therefore was reviewed by OMB. However, this rule was not deemed to be economically significant. Because program participants have long followed the substantive standards that this rule would establish, HUD anticipates that this rule will have little to no economic effect.

The docket file is available for public inspection in the Regulations Division, Office of General Counsel, Room 10276, 451 7th Street SW, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, please schedule an appointment to review the docket file by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

Paperwork Reduction Act

Currently, the Section 184 Program has an existing information collection requirement previously approved by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and assigned OMB control number 2577–0200. The proposed rule would modify some of the documents in this information collection and would create new documents to bring additional efficiency and accountability to the program. In accordance with the Paperwork Reduction Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid OMB control number.

The proposed rule would amend the existing Lender and Direct Guarantee Lender application process. Under § 1005.207, HUD would require all Lenders to select a level of participation in the Section 184 Program on a form prescribed by HUD. This form requests detailed information about the Lender, in addition to the participation level. This proposed revision of the Lender application process would allow HUD to more closely track how many, and the type of, Lenders participating in the program. The proposed rule would request information that would give HUD further assurances that the Lenders participating in the Section 184 Program have the experience, staffing, and financial resources to follow program guidelines.

Currently the Section 184 Program uses FHA forms as part of securing a loan on a manufactured home, assumptions, and pre-foreclosure sale process. This has led to confusion by Lenders over which information to submit, since the Section 184 Program may require the same information collected on the FHA form. As part of the proposed rule, under §§ 1005.429(a)(3)(iv), 1005.711(c), and 1005.751(h)(1), (s)(2), and (t)(1), HUD would develop and gain approval, when required, of forms similar to the FHA documents, but specific to the Section 184 Program, which would reduce the paperwork burden on the Lenders.

The proposed rule would establish new requirements in the areas of annual Lender and Tribal Recertification §§ 1005.223(a) and 1005.307 to provide additional accountability when changes occur that might impact a Lender or Tribe's eligibility for the program. The proposed rule would establish new requirements for Tribal application under § 1005.303 to clarify the information a Tribe needs to submit when seeking HUD approval of eligibility to guarantee loans on a its Tribal Land.

Based on comments received during Tribal consultation, the proposed rule at § 1005.501(j), would establish a new loan closing document, signed by the

Borrower, in which the Borrower may elect to authorize the Lender to notify the Borrower's Tribe in the event of default. Tribes requested this notification so they may assist the Borrower with default if such assistance was available.

Under § 1005.769(b), HUD has new requirement for Lenders conveying a property to HUD at or after foreclosure, to submit a notification of Conveyance advising HUD of the filing of such Conveyance.

The total annual estimated paperwork burden for the proposed rule is 520.41 hours. The overall new paperwork burden for the proposed rule, as compared to the burden under the previous rule, is 303.7 hours. The bulk of this time is related to the new loan closing document required in § 1005.501(j), which would allow the Borrower to elect Tribal notification in the event of default. This form would be required for each loan guaranteed by the program. The estimated burden for this form is 5 minutes, and the program's total loan volume is 3,750 loans for a total of 187.5 hours of estimated annual burden.

The burden of the information collections in this rule is estimated as follows:

REPORTING AND RECORDKEEPING BURDEN

Section reference	Number of respondents	Number of responses per respondent	Estimated average time for requirement (in hours)	Estimated annual burden (in hours)
1005.207	32	1	0.08	2.56
1005.223(a)	150	1	0.25	37.5
1005.303	6	1	0.33	1.98
1005.307	226	1	0.17	38.42
1005.429(a)(3)(iv)	350	1	0.03	10.5
1005.501(b)	3750	1	0.05	187.5
1005.501(j)	3750	1	0.05	187.5
1005.711(c)	5	1	0.05	0.25
1005.751(h)(1)	25	1	0.15	3.75
1005.751(s)(2)	25	1	0.25	6.25
1005.751(t)(1)	25	1	0.25	6.25
1005.769(b)	115	1	0.33	37.95
Total Paperwork Burden for the New Rule	.....	.....	.....	520.41

In accordance with 5 CFR 1320.8(d)(1), HUD is soliciting comments from members of the public and affected agencies concerning this collection of information to:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Interested persons are invited to submit comments regarding the information collection requirements in this rule. Comments must refer to the proposal by name and docket number (FR–5593–P–01) and must be sent to:

HUD Desk Officer: Office of Management and Budget, New Executive Office Building, Washington, DC 20503, Fax: (202) 395–6947, and Reports Liaison Officer, Office of Public and Indian Housing, Department of Housing and Urban Development, Room, 451 7th Street SW, Washington, DC 20410.

Interested persons may submit comments regarding the information collection requirements electronically through the Federal eRulemaking Portal at *https://www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *https://www.regulations.gov* website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601, *et seq.*), generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. As discussed above, this rule would provide clarity for new and existing Lenders who participate in the Section 184 Program. Participation in the Section 184 Program is voluntary. HUD does not believe the additional requirements will have a significant impact on small entities.

Notwithstanding HUD's determination that this rule will not have a significant economic impact on a substantial number of small entities, HUD specifically invites comments regarding less burdensome alternatives to this rule that will meet HUD's objectives, as described in this preamble.

Executive Order 13132, Federalism

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

Environmental Impact

A Finding of No Significant Impact (FONSI) with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement Section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The FONSI is available for public inspection at *https://www.hud.gov/codetalk* and between 8 a.m. and 5 p.m. weekdays in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, an advance appointment to review the docket file must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Hearing or speech-impaired individuals may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4; approved March 22, 1995) (UMRA) proposes to establish requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments, and on the private sector. This proposed rule does not impose any Federal mandates on any State, local, or Tribal government, or on the private sector, within the meaning of the UMRA.

List of Subjects

24 CFR Part 58

Community development block grants, Environmental impact statements, Grant programs-housing and community development, Reporting and recordkeeping requirements.

24 CFR Part 1005

Indians, Loan programs-Indians, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, HUD proposes to amend 24 CFR parts 58 and 1005 as follows:

PART 58—ENVIRONMENTAL REVIEW PROCEDURES FOR ENTITIES ASSUMING HUD ENVIRONMENTAL RESPONSIBILITIES

■ 1. The authority citation for part 58 continues to read as follows:

Authority: 12 U.S.C. 1707 note, 1715z–13a(k); 25 U.S.C. 4115 and 4226; 42 U.S.C. 1437x, 3535(d), 3547, 4321–4335, 4852, 5304(g), 12838, and 12905(h); title II of Pub. L. 105–276; E.O. 11514 as amended by E.O. 11991, 3 CFR, 1977, Comp., p. 123.

■ 2. In § 58.1, revise paragraph (b)(11) to read as follows:

§ 58.1 Purpose and applicability.

* * * * *

(b) * * *

(11) Indian Housing Loan Guarantees authorized by section 184 of the Housing and Community Development Act of 1992 on trust land and on fee land within a reservation, in accordance with section 184(k) (12 U.S.C. 1715z–13a(k)); and

* * * * *

■ 3. In § 58.35, add paragraph (b)(8) to read as follows:

§ 58.35 Categorical exclusions.

* * * * *

(b) * * *

(8) HUD's guarantee of loans for one-to-four family dwellings on trust land and on fee land within a reservation under the Direct Guarantee procedure for the Section 184 Indian Housing loan guarantee program without any review or approval of the application for the loan guarantee by HUD or the responsible entity or approval of the loan guarantee by HUD before the execution of the contract for construction or rehabilitation and the loan closing.

* * * * *

■ 4. Revise part 1005 to read as follows:

PART 1005—LOAN GUARANTEES FOR INDIAN HOUSING

Subpart A—General Program Requirements

Sec.

Subpart B—Lender Eligibility & Requirements

Subpart C—Lending on Trust Land

Subpart D—Underwriting

Eligible Borrowers

Eligible Properties

Eligible Loans

Underwriting

Subpart E—Closing and Endorsement

Closing

Authority: 12 U.S.C. 1715z–13a; 15 U.S.C. 1639c; 42 U.S.C. 3535(d).

Subpart A—General Program Requirements

§ 1005.101 Purpose.

This part implements the Section 184 Indian Home Loan Guarantee Program (''Section 184 Program'') authorized under Section 184 of the Housing and Community Development Act of 1992, as amended, codified at 12 U.S.C. 1715z–13a. Section 184 authorizes the U.S. Department of Housing and Urban Development (HUD) to establish a loan guarantee program for American Indian and Alaskan Native families, Tribes and Tribally Designated Housing Entities (TDHE). The loans guaranteed under the Section 184 Program are used to construct, acquire, refinance, or rehabilitate one- to four-family standard housing located on Trust Land, land located in an Indian or Alaska Native area, and Section 184 Approved Program Area. These regulations apply to Lenders, Servicers and Tribes seeking to or currently participating in the Section 184 Program.

§ 1005.103 Definitions.

The following definitions apply throughout this part:

Acquisition Cost means the sum of the sales price or construction cost for a property and the cost of allowable repairs or improvements for the same property, less any unallowable sales concession(s). For the purposes of this definition, the term ''sales concession'' means an inducement to purchase a property paid by the seller to consummate a sales transaction.

Amortization means the calculated schedule of repayment of a Section 184 Guaranteed Loan in full, through structured, regular payments of principal and interest within a certain time frame.

Amortization Schedule means the document generated at the time of loan approval outlining the Borrower's schedule of payments of principal and interest for the life of the loan and the unpaid principal balance with and without financed Upfront Loan Guarantee Fee, where applicable.

Annual Loan Guarantee Fee means a fee calculated on an annual basis and paid in monthly installments by the Borrower, which is collected by the Servicer and remitted to HUD for the purposes of financing the Indian Housing Loan Guarantee Fund.

BIA means the United States Department of Interior, Bureau of Indian Affairs.

Borrower means each and every individual on the mortgage application. For the purposes of servicing the loan, Borrower refers to each and every original Borrower who signed the note and their heirs, executors, administrators, assigns, and approved substitute Borrowers. Borrower includes Tribes and TDHEs.

Claim means the Servicer's application to HUD for payment of benefits under the Loan Guarantee Certificate for a Section 184 Guaranteed Loan.

Conflict of Interest means any party to the transaction who has a direct or indirect personal business or financial relationship sufficient to appear that it may cause partiality or influence the transaction, or both.

Date of default means the day after the Borrower's obligation to make a loan payment or perform an obligation under the terms of the loan, Loss Mitigation plan, or any other agreement with the Direct Guarantee Lender was due.

Day means calendar day, except where the term ''business day'' is used.

Default means when the Borrower has failed to make a loan payment or perform an obligation under the terms of the Section 184 Guaranteed Loan, Loss Mitigation plan, lease, or any other agreement with the Direct Guarantee Lender.

Direct Guarantee Lender means a Lender approved by HUD under § 1005.211 to originate, underwrite, close, service, purchase, hold, or sell Section 184 Guaranteed Loans.

Eligible Nonprofit Organization means a nonprofit organization established under Tribal law or organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 as an organization exempt from taxation under section 501(a) of the Code, which has:

(1) Two years' experience as a provider of low- or moderate-income housing;

(2) A voluntary board; and

(3) No part of its net earnings inuring to the benefit of any member, founder, contributor or individual.

Financial Statements means audited financial statements or other financial records as required by HUD.

Firm Commitment means a commitment by HUD to reserve funds, for a specified period of time, to guarantee a Loan under the Section 184 program, when a Loan for a specific Borrower and property meets standards as set forth in subpart D of this part.

First Legal Action means the first public action required by Tribal or State law to foreclose, such as filing a complaint or petition, recording a notice of default, or publication of a notice of sale.

Good and Marketable Title means title that contains exceptions or restrictions, if any, which are permissible under subpart D of this part; and any objections to title that have been waived by HUD or otherwise cleared; and any discrepancies have been resolved to ensure the Section 184 Guaranteed Loan is in first lien position. In the case of Section 184 Guaranteed Loans on Trust Land, Good and Marketable Title includes the ownership rights of the improvements as reported in the Title Status Report issued by the BIA.

Holder means an entity that holds title to a Section 184 Guaranteed Loan and has the right to enforce the mortgage agreement.

Identity of Interest means a sales transaction between family members, business partners, or other business affiliates.

Indian means a person who is recognized as being an Indian or Alaska Native Federally by a recognized Indian Tribe, a regional or village corporation as defined in the Alaska Native Claims Settlement Act, or a State recognized Tribe eligible to receive assistance under Title I of the Native American Housing Assistance and Self-Determination Act of 1996 (NAHASDA).

Indian Family means one or more persons maintaining a household where at least one Borrower is an Indian.

Indian Housing Loan Guarantee Fund or *Fund* means a fund established at the U.S. Department of Treasury for the purpose of providing loan guarantees under the Section 184 Program.

Lease or leasehold interest means a written contract between a Borrower and a Tribe, entity, or individual, whereby the Borrower, as lessee, is granted a right of possession of Trust Land for a specific purpose and duration, according to applicable Tribal, Federal, or State law.

Lender means a financial institution engaging in mortgage lending that is eligible to participate in the Section 184 Program under § 1005.203 or § 1005.205, but has not yet had a program participation level approved under § 1005.207.

Loan means a loan application or mortgage loan that has not received a Loan Guarantee Certificate.

Loan Guarantee Certificate means evidence of endorsement by HUD of a Loan for guarantee issued under § 1005.525.

Loss Mitigation means an alternative to foreclosure offered by the Holder of a Section 184 Guaranteed Loan that is made available through the Servicer to the Borrower.

Non-Direct Guarantee Lender means a Lender approved by HUD under § 1005.207 who has selected a level of program participation limited to originating Section 184 Guaranteed Loans.

Month or *monthly* means thirty days in a month, regardless of the actual number of days.

Origination or *originate* means the process by which the Lender accepts a new loan application along with all required supporting documentation. Origination does not include underwriting the loan.

Owner of Record means, for fee simple properties, the owner of property as shown on the records of the recorder in the county where the property is located. For properties held in trust by the United States, the current lessee or owner of property, as shown on the Title Status Report provided by the BIA.

Partial Payment means a Borrower payment of any amount less than the full amount due under the terms of the Section 184 Guaranteed Loan at the time the payment is tendered.

Property means a one to four-family dwelling that meets the requirements for standard housing under § 1005.419 and located on Trust Land, land located in an Indian or Alaska Native area, or Section 184 Approved Program Area.

Section 184 Approved Program Area means the Indian Housing Block Grant (IHBG) Formula Area as defined in 24 CFR 1000.302 or any other area approved by HUD, in which HUD may guarantee Loans.

Section 184 Guaranteed Loan is a Loan that has received a Loan Guarantee Certificate.

Section 184 Program Guidance means administrative guidance documents that may be issued by HUD, including but not limited to **Federal Register** Notices, Dear Lender Letters, handbooks, guidebooks, manuals, and user guides.

Security means any collateral authorized under existing Tribal, Federal, or State law.

Servicer means a Direct Guarantee Lender that chooses to services Section 184 Guaranteed Loans or a Non-Direct Guarantee Lender or a financial institution approved by HUD under § 1005.705 to service Section 184 Guaranteed Loans.

Sponsor means an approved Direct Guarantee Lender that enters into a relationship with a Non-Direct Guarantee Lender or another Direct Guarantee Lender (Sponsored Entity), whereby the Sponsor provides underwriting, closing, purchasing, and holding of Section 184 Guaranteed Loans and may provide servicing.

Sponsored Entity means a Non-Direct Guarantee or Direct Guarantee Lender operating under an agreement with a Sponsor to originate Section 184 Guaranteed Loans in accordance with § 1005.213.

Tax-exempt bond financing means financing which is funded in whole or in part by the proceeds of qualified mortgage bonds described in section 143 of the Internal Revenue Code of 1986 on which the interest is exempt from Federal income tax. The term does not include financing by qualified veterans' mortgage bonds as defined in section 143(b) of the Code.

Title Status Report is defined in 25 CFR 150.2, as may be amended.

Tribe means any Indian Tribe, band, nation, or other organized group or community of Indians, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. 1601, *et seq.*), that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians pursuant to the Indian Self Determination and Education Assistance Act of 1975.

Tribally Designated Housing Entity (TDHE) means any entity as defined in the Indian Housing Block Grant Program under the Native American Housing Assistance and Self Determination Act at 25 U.S.C. 4103(22).

Trust Land means land title which is held by the United States for the benefit of an Indian or Tribe or title which is held by a Tribe subject to a restriction against alienation imposed by the United States or Tribe. This definition shall include but is not limited to allotted, restricted fee, or assigned trust lands.

Upfront Loan Guarantee Fee means a fee, paid by the Borrower at closing, collected by the Direct Guarantee Lender and remitted to HUD for the purposes of financing the Indian Housing Loan Guarantee Fund.

Subpart B—Lender Eligibility & Requirements

§ 1005.201 Lender approval and participation.

(a) *Approval types.* The Section 184 Program has two types of Lender approval:

(1) Lenders deemed approved by statute, as described in § 1005.203; or

(2) Lenders required to obtain secretarial approval under § 1005.205.

(b) *Lender participation.* In accordance with § 1005.207, approved Lenders must select a level of program participation and submit a completed application package, as prescribed by Section 184 Program Guidance, to participate in the Section 184 program.

§ 1005.203 Lenders deemed approved by statute.

(a) The following Lenders are deemed approved by statute:

(1) Any mortgagee approved by HUD for participation in the single-family mortgage insurance program under Title II of the National Housing Act;

(2) Any Lender whose housing loans under the U.S. Department of Veterans Affairs, 38 U.S.C. chapter 37, are automatically guaranteed pursuant to 38 U.S.C. 3702(d);

(3) Any Lender approved by the U.S. Department of Agriculture to make Guaranteed Loans for single family housing under the Housing Act of 1949; and

(4) Any other Lender that is supervised, approved, regulated, or insured by any other Federal agency of the United States, including but not limited to Community Development Financial Institutions.

(b) [Reserved]

§ 1005.205 Lenders required to obtain Secretarial approval.

(a) *Lender application process.* Lenders not meeting the requirements of § 1005.203 must apply to HUD for approval to participate in the Section 184 Program by submitting to HUD a completed application package, as prescribed by Section 184 Program Guidance. The application must establish that the Lender meets the following qualifications:

(1) *Business form.* The Lender shall be a corporation or other chartered institution, a permanent organization having succession, or a partnership, organized under Tribal or State law.

(i) *Partnership requirements.* A partnership must meet the following requirements:

(A) Each general partner must be a corporation or other chartered institution consisting of two or more partners.

(B) One general partner must be designated as the managing general partner. The managing general partner shall also comply with the requirements specified in § 1005.205(a)(1)(i)(C) and (D). The managing general partner must have as its principal activity the management of one or more partnerships, all of which are mortgage lending institutions or property improvement or manufactured home lending institutions, and must have exclusive authority to deal directly with HUD on behalf of each partnership. Newly admitted partners must agree to the management of the partnership by the designated managing general partner. If the managing general partner withdraws or is removed from the partnership for any reason, a new managing general partner shall be substituted, and HUD must be notified in writing within 15 days of the substitution.

(C) The partnership agreement shall specify that the partnership shall exist for a minimum term of ten years, as required by HUD. All Section 184 Guaranteed Loans held by the partnership shall be transferred to a Lender approved under this part prior to the termination of the partnership. The partnership shall be specifically authorized to continue its existence if a partner withdraws.

(D) HUD must be notified in writing within 15 days of any amendments to the partnership agreement that would affect the partnership's actions under the Section 184 Program.

(ii) *Use of business name.* The Lender must use its HUD-registered business name in all advertisements and promotional materials related to the Guaranteed Loan. HUD-registered business names include any alias or ''doing business as'' (DBA) on file with HUD. The Lender must keep copies of all print and electronic advertisements and promotional materials for a period of 2 years from the date that the materials are circulated or used to advertise.

(2) *Identification and certification of employees.* The Lender shall identify personnel and certify that they are trained and competent to perform their assigned responsibilities in mortgage lending, including origination, servicing, collection, and Conveyance activities, and shall maintain adequate staff and facilities to originate or service mortgages, or both, in accordance with applicable Tribal, Federal, or State requirements, to the extent it engages in such activities.

(3) *Identification and certification of officers.* The Lender shall identify officers and certify that all employees who will sign applications for Guaranteed Loans on behalf of the Lender shall be corporate officers or shall otherwise be authorized to bind the Lender in the Origination transaction. The Lender shall certify that only authorized person(s) report on guarantees, purchases, and sales of Guaranteed Loans to HUD for the purpose of obtaining or transferring guarantee coverage.

(4) *Financial statements.* The Lender shall:

(i) Furnish to HUD a copy of its most current annual audited financial statement.

(ii) Furnish such other information as HUD may request; and

(iii) Submit to examination of the portion of its records that relates to its activities under the Section 184 Program.

(5) *Quality control plan.* The Lender shall submit a written quality control plan in accordance with § 1005.217.

(6) *Identification of branch offices.* A Lender may maintain branch offices. A financial institution's branch office must be registered with HUD to originate or submit applications for Guaranteed Loans. The financial institution shall remain responsible to HUD for the actions of its branch offices.

(7) *Certification of conflict of interest policy.* The Lender must certify that the lender shall not pay anything of value, directly or indirectly, in connection with any Guaranteed Loan to any person or entity if such person or entity has received any other consideration from the seller, builder, or any other person for services related to such transactions or related to the purchase or sale of the property, except that consideration, approved by HUD, may be paid for services actually performed. The Lender shall not pay a referral fee to any person or organization.

(8) *Licensing certification.* A Lender shall certify that it has not been refused a license and has not been sanctioned by any Tribal, Federal, or State, or authority in which it will originate Section 184 Guaranteed Loans.

(9) *Minimum net worth.* Irrespective of size, a Lender shall have a net worth of not less an amount as established by Section 184 Program Guidance.

(10) *Identification of operating area.* The Lender must submit a list of states in which they wish to participate in the Section 184 Program and evidence of Lender's license to operate in those states, as may be prescribed by Section 184 Program Guidance.

(11) *Other.* Other qualifications by notice for comment.

(b) *HUD approval.* HUD shall review applications under § 1005.203(a) and any other publicly available information related to the Lender, its officers, and employees. If HUD determines the Lender meets the requirements for participation in this subpart, HUD shall provide written notification of the approval to be a Section 184 Lender.

(c) *Limitations on approval.* A Lender may only operate in the Section 184 Approved Program Area where they are licensed.

(d) *Denial of participation.* A Lender may be denied approval to become a Section 184 Lender if HUD determines the Lender does not meet the qualification requirements of this subpart. HUD will provide written notification of denial and that decision may be appealed in accordance with the procedures set forth in § 1005.909.

§ 1005.207 Lender participation options.

(a) *Levels of participation.* Lenders must choose one of two levels of program participation, a Non-Direct Guarantee Lender or a Direct Guarantee Lender and submit an application to participate on a form prescribed by Section 184 Program Guidance. A participation level must be selected by the Lender and approved by HUD before initiating any Section 184 Program activities.

(b) *Non-Direct Guarantee Lender.* (1) A Non-Direct Guarantee Lender originates Loans.

(2) A Non-Direct Guarantee Lender must be a Sponsored Entity under § 1005.213.

(3) A Non-Direct Guarantee Lender must submit documentation supporting their eligibility as a Lender under § 1005.203 or approved by HUD under § 1005.205 and other documentation as prescribed by Section 184 Program Guidance to HUD through their Sponsor.

(c) *Direct Guarantee Lender.* (1) A Direct Guarantee Lender may originate, underwrite, close, service, purchase, hold, and sell Section 184 Guaranteed Loans.

(2) A Direct Guarantee Lender may sponsor Non-Direct Guarantee Lenders or other Direct Guarantee Lenders in accordance with § 1005.213.

(3) To become a Direct Guarantee Lender, Lenders must submit additional documentation as provided in § 1005.209 and obtain HUD approval under § 1005.211.

§ 1005.209 Direct Guarantee Lender application process.

(a) Lenders must apply to HUD for approval to participate in the Section 184 Program as a Direct Guarantee Lender. Lenders must submit a completed application package in accordance with Section 184 Program Guidance.

(b) To be approved as a Direct Guarantee Lender, a Lender must establish in its application that it meets the following qualifications:

(1) Eligibility under § 1005.203 or HUD approval under § 1005.205, as evidenced by approval documents and most recent recertification documents.

(2) Has a principal officer with a minimum of five years' experience in the origination of Loans guaranteed or insured by an agency of the Federal Government. HUD may approve a Lender with less than five years of experience, if a principal officer has had a minimum of five years of managerial experience in the origination of loans guaranteed or insured by an agency of the Federal Government.

(3) Has on its permanent staff an underwriter(s) that meets the following criteria:

(i) Two years' experience underwriting loans guaranteed or insured by an agency of the Federal Government;

(ii) Is an exclusive employee of the Lender;

(iii) Authorized by the Lender to obligate the Lender on matters involving the origination of Loans;

(iv) Is registered with HUD as an underwriter and continues to maintain such registration; and

(v) Other qualifications by notice for comment.

(c) The Lender must submit a list of states or geographic regions in which it is licensed to operate, evidenced by submitting the active approvals for each State or region, and declare its interest in participating in the Section 184 Program.

(d) The Lender must submit the quality control plan as required by its approving agency, modified for the Section 184 Program.

(e) If a Lender wants to service Section 184 Guaranteed Loans as Direct Guarantee Lender, they must meet qualifications and submit an application in accordance with § 1005.703.

§ 1005.211 Direct Guarantee Lender approval.

HUD shall review all documents submitted by a Lender under § 1005.209 and make a determination of conditional approval or denial.

(a) *Conditional approval.* Conditional approval is signified by written notification from HUD that the Lender is a conditionally approved Direct Guarantee Lender under the Section 184 Program subject to the following conditions:

(1) The Lender signs an agreement to comply with requirements of this part, and any applicable Tribal, Federal, or State law.

(2) If applicable, the Lender submits a list of entities it currently sponsors under another Federal loan program and intends to sponsor in the Section 184 Program. This list shall include the following for each Sponsored Entity:

(i) Contact information, including mailing address, phone number, and email address for corporate officers.

(ii) The Federal tax identification number (TIN) for the Sponsored Entity, and

(iii) Names and Nationwide Multistate Licensing System and Registry numbers for all loan originators and processors.

(3) The Lender certifies it monitors and provides oversight of Sponsored Entities to ensure compliance with this part, and any applicable Tribal, Federal, or State law.

(4) The Lender must, for each underwriter, submit a number, prescribed by Section 184 Program Guidance, of test endorsement case binders, which meet the requirements of subparts D and E of this part. Unsatisfactory performance by an underwriter during HUD's test case review may constitute grounds for denial of approval to participate as a Direct Guarantee Lender. If participation is denied, such denial is effective immediately and may be appealed in accordance with the procedures set forth in § 1005.909.

(5) The Lender will operate only in accordance with the Lender's licensing in Section 184 Approved Program Areas.

(b) *Final approval.* Final approval is signified by written notification from HUD that the Lender is an approved Direct Guarantee Lender under the Section 184 Program without further submission of test case endorsement case binders to HUD. HUD retains the right to request additional test cases as determined necessary.

(c) *Limitations on approval.* (1) A Lender may only operate as a Direct Guarantee Lender in accordance with the Lender's Tribal or State licensing and within Section 184 Approved Program Areas.

(2) The Lender must employ and retain an underwriter with the qualifications as provided in § 1005.209(b)(3). Failure to comply with this provision may subject the Lender to sanctions under § 1005.907.

(d) *Denial of participation.* A Lender may be denied approval to become a Direct Guarantee Lender if HUD determines the Lender does not meet the qualification requirements of this subpart. HUD will provide written notification of denial and that decision may be appealed in accordance with the procedures set forth in § 1005.909.

§ 1005.213 Non-Direct Guarantee Lender application, approval, and Direct Guarantee Lender sponsorship.

(a) *Sponsorship.* A Sponsorship is a contractual relationship between a Sponsor and a Sponsored Entity.

(b) *General responsibility requirements of a Sponsor.* (1) The Sponsor must determine the eligibility of a Lender and submit to HUD, as prescribed in Section 184 Program Guidance, a recommendation for approval under § 1005.207(b) or evidence of HUD approval under § 1005.205(b) or § 1005.211(b).

(2) Upon HUD approval of eligibility under § 1005.207(b), or HUD acknowledgement of the evidence of HUD approval under § 1005.205(b) or § 1005.211(b), the Sponsor may enter into a Sponsorship with the Sponsored Entity.

(3) The Sponsor must notify HUD of changes in a Sponsorship within 10 days.

(4) The Sponsor must provide HUD-approved training to the Sponsored Entity on the requirements of the Section 184 Program before the Sponsored Entity may originate Section 184 Guaranteed Loans for the Sponsor.

(5) Each Sponsor shall be responsible to HUD for the actions of its Sponsored Entity in originating Loans. If Tribal or State law requires specific knowledge by the Sponsor or the Sponsored Entity, HUD shall presume the Sponsor had such knowledge and shall remain liable.

(6) The Sponsor is responsible for conducting quality control reviews of the Sponsored Entity's origination case binders and Loan performance to ensure compliance with this part and any other Tribal, Federal, State, or law requirements.

(7) The Sponsor is responsible for maintaining all records for loans originated by a Sponsored Entity in accordance with this part.

(8) A Sponsor must notify HUD of any changes in a sponsorship within 15 days.

(c) *Responsibilities of the Sponsored Entity.* A Sponsor must ensure that a Sponsored Entity complies with this part and any other Tribal, Federal, State, or law requirements.

§ 1005.215 Annual reporting requirements.

Direct Guarantee Lenders must submit an annual report on Loan performance, including that of all Sponsored Entities, where applicable, along with any other required reporting under § 1005.903 and other such reports as prescribed by Section 184 Program Guidance.

§ 1005.217 Quality control plan.

(a) A quality control plan sets forth a Lender's procedures for ensuring the quality of the Lender's Section 184 Guaranteed Loan origination, underwriting, closing, and/or servicing. The purpose of the quality control plan is to ensure Lender's compliance with Section 184 Program requirements and protect HUD and Lender from unacceptable or unreasonable risks. A Lender must adopt and implement a quality control plan.

(b) A quality control plan must:

(1) Be maintained and updated, as needed, to comply with all applicable Section 184 Program requirements.

(2) Cover all policies and procedures, whether performed by the Lender or an agent, to ensure full compliance with all Section 184 Program requirements.

(3) Provide the Lender with information sufficient to adequately monitor and oversee the Lender's compliance and measure performance, as it relates to the Lender's Section 184 Guaranteed Loan activity.

(4) Require the Lender to retain all quality control plan related documentation, including selection criteria, review documentation, findings, and actions to mitigate findings, for a period of three years from initial quality control review, or from the last action taken to mitigate findings, whichever is later.

(5) Allow the Lender to use employees or agents to perform the quality control functions, so long as they do not directly participate in any loan administration processes as outlined in Section 184 Program Guidance.

(6) Ensure the Lender assumes full responsibility for any agent's conduct of quality control reviews.

(7) Require the Lender to train all staff, agents working with the Section 184 Program on Loan administration and quality control processes and provide staff access to all current Section 184 legal authorities and policy guidance. The Lender must retain copies of training documentation for all staff working on the Section 184 Program in accordance with § 1005.219(d)(3). Failure to comply with the training and documentation requirements may subject the Lender to sanctions in accordance with § 1005.907.

(8) Ensure that the Lender's employees, agents, are eligible to participate in the Section 184 Program. Any designated employees, agents, deemed ineligible shall be restricted from participating in the program in the Section 184 Program.

(9) Ensure the Borrower's information maintained related to the Section 184 Guaranteed Loan are used only for the purpose for which they were received and follow all applicable Federal, State, and Tribal requirements.

(10) Require the Lender to refer any suspected fraud or material misrepresentation by any party whatsoever directly to HUD's Office of

Inspector General (OIG) and the Office of Native American Programs.

(11) Require the Lender to report all material deficiencies and submit a corrective action plan to HUD within a timeframe as prescribed by Section 184 Program Guidance.

(12) Require the Lender to conduct appropriate Loan level quality control procedures, in accordance with requirements as prescribed by Section 184 Program Guidance.

(13) Require that the Lender maintain complete and accurate records of the Section 184 Guaranteed Loans which are selected for the quality control sample for a timeframe as prescribed by Section 184 Program Guidance.

(14) Require the Lender to review a random statistical sample of rejected loan applications within 90 days from the end of the month in which the decision was made. The reviews must be conducted no less frequently than monthly and with the goal to ensure that the reasons given for the rejection were valid and each rejection received concurrence of an appropriate staff person with sufficient approval authority. The Lender must submit a report of this review in form and timeframe as prescribed in Section 184 Program Guidance.

(c) Lenders to applying be a Direct Guarantee Lender under § 1005.209, must submit a quality control plan in accordance with paragraph (b) of this section and include the following additional requirements:

(1) Require the Lender to collect and forward all Loan Guarantee Fees in accordance with the Section 184 Program requirements, with sufficient documentation evidencing the timely collection and payment of the fees to HUD.

(2) Require the Lender to verify that the endorsement case binder is submitted to HUD for guarantee within required time frames.

(3) Require the Lender to review a random statistical sample of its endorsement case binders for potential fraud, material misrepresentations, or other findings on a quarterly basis. The Lender must investigate and determine if fraud, material misrepresentation or other findings occurred.

(4) Require the Lender to perform quality control review of its Sponsored Entities in the same manner and under the same conditions as required for the Lender's own operation.

(5) Where applicable, require the Sponsor to apply paragraphs (b)(7) through (8) of this section to its Sponsored Entities.

(d) All Sponsored Entities shall comply with paragraph (b) of this section and provide a quality control plan directly to their Sponsor in accordance with their sponsorship agreement.

§ 1005.219 Other requirements.

(a) *Federal law.* All Direct Guarantee Lenders, Non-Director Guarantee Lenders, and Servicers must comply with all applicable Federal laws which impact mortgage-related activities.

(b) *Dual employment.* All Non-Direct Guarantee Lenders and Direct Guarantee Lenders must require its employees to be exclusive employees, unless the Lender has determined that the employee's other employment, including any self-employment, does not create a Conflict of Interest.

(c) *Reporting requirements.* All Direct Guarantee Lenders must submit reports in accordance with § 1005.903. Unless requested directly by HUD, Non-Direct Guarantee Lenders must submit required reports to their Sponsor, under this part or any requirements as prescribed by Section 184 Program Guidance, or any special request for information within the time frames prescribed in the request.

(d) *Records retention.* Records retention requirements are as follows:

(1) Direct Guarantee Lenders must maintain an endorsement case binder for a period of three years beyond the date of satisfaction or maturity date of the Loan, whichever is sooner. However, where there is a payment of claim, the endorsement case binder must be retained for a period of at least five years after the final claim has been paid. Section 184 Program Guidance shall prescribe additional records retention time depending on the circumstances of the claim.

(2) All Direct Guarantee Lender and Non-Direct Guarantee Lenders must retain personnel files of employees for one year beyond the employee's separation.

(3) All Direct Guarantee Lenders and Non-Direct Guarantee Lenders must follow the applicable records retention requirements imposed by applicable Tribal, Federal, and State laws and regulations.

(4) Direct Guarantee Lenders and Non-Direct Guarantee Lenders must maintain the quality control plan records for a period prescribed in § 1005.217(b)(4).

(e) *Minimum level of lending on Trust Land.* (1) Direct Guarantee Lenders must actively market, originate, underwrite, and close Loans on Trust Land. A Sponsor must ensure its Sponsored Entities actively market and originate loans on Trust Land. HUD may impose a minimum level of lending on Tribal Trust Land, which may be adjusted periodically, through publication in the **Federal Register**.

(2) Failure to meet the minimum level of lending on Trust Land may result in sanctions in accordance with §§ 1005.905 and 1005.907.

(3) HUD may grant exceptions for Direct Guarantee Lenders and Non-Direct Guarantee Lenders licensed and doing business in a State or States with limited Trust Lands. The process for Lenders to request the exception will be prescribed by Section 184 Program Guidance.

§ 1005.221 Business change reporting.

(a) Within a timeframe as prescribed by Section 184 Program Guidance, Direct Guarantee Lenders shall provide written notification to HUD, in such a form as prescribed by Section 184 Program Guidance of:

(1) All changes in the Direct Guarantee Lender or Sponsored Entity's legal structure, including, but not limited to, mergers, acquisitions, terminations, name, location, control of ownership, and character of business;

(2) Staffing changes with senior leadership and Loan underwriters for Direct Guarantee Lenders and Sponsored Entities; and

(3) Any sanctions by another supervising entity.

(b) Failure to report changes within a reasonable timeframe prescribed in Section 184 Program Guidance may result in sanctions in accordance with §§ 1005.905 and 1005.907.

§ 1005.223 Annual recertification.

(a) All Direct Guarantee Lenders are subject to annual recertification on a date and form as prescribed by Section 184 Program Guidance.

(b) With each annual recertification, Direct Guarantee Lenders must submit updated contact information, continued eligibility documentation and other pertinent materials as prescribed by Section 184 Program Guidance, including but not limited to:

(1) A certification that it has not been refused a license by any Tribe, State, or Federal entity;

(2) A certification that the Direct Guarantee Lender is in good standing with any Tribe, State, or Federal entity in which it will perform Direct Guarantee Lender activities; and

(3) Renewal documents and certification of continued eligibility from an authorizing entity listed in § 1005.203.

(4) Lenders approved under § 1005.205 must submit documentation supporting continued eligibility as prescribed by Section 184 Program Guidance.

(c) All Sponsored Entities shall comply with this requirement and provide the annual recertification documentation directly to their Sponsor in accordance with their sponsorship agreement.

(d) Direct Guarantee Lenders must also submit the following in accordance with Section 184 Program Guidance:

(1) a certification that the Direct Guarantee Lender continues to meet the direct guarantee program eligibility requirements in accordance with § 1005.209;

(2) A list of all Sponsored Entities with which the Direct Guarantee Lender has a sponsorship relationship, and a certification of their continued eligibility; and

(3) Any reports required in accordance with Section 184 Program Guidance.

(e) Direct Guarantee Lenders must retain documentation related to the continued eligibility of their Sponsored Entities for a period as prescribed by Section 184 Program Guidance.

(f) Direct Guarantee Lenders may request an extension of the recertification deadline, but such request must be presented at least 45 days before the recertification deadline.

(g) HUD will review the annual recertification submission and may request any further information required to determine recertification.

(h) HUD will provide written notification of approval to continue participation in the Section 184 Program or denial. A denial may be appealed pursuant to § 1005.909.

(i) If an annual recertification is not submitted by a reasonable deadline prescribed in Section 184 Program Guidance, HUD may subject the Direct Guarantee Lender to sanctions under § 1005.907.

§ 1005.225 Program ineligibility.

(a) *Ineligibility.* A Direct Guarantee Lender or Non-Direct Guarantee Lender may be deemed ineligible for Section 184 Program participation when HUD becomes aware that the entity or any officer, partner, director, principal, manager or supervisor, loan processor, loan underwriter, or loan originator of the entity was:

(1) Suspended, debarred, under a limited denial of participation (LDP), or otherwise restricted under 2 CFR part 2424, or under similar procedures of any other Federal agency;

(2) Indicted for, or have been convicted of, an offense that reflects adversely upon the integrity, competency, or fitness to meet the responsibilities of the Direct Guarantee Lender or Non-Direct Guarantee Lender to participate in the Title I or Title II programs of the National Housing Act, or Section 184 Program;

(3) Found to have unresolved findings as a result of HUD or other governmental audit, investigation, or review;

(4) Engaged in business practices that do not conform to generally accepted practices of prudent Lenders or that demonstrate irresponsibility;

(5) Convicted of, or have pled guilty or nolo contendere to, a felony related to participation in the real estate or mortgage loan industry during the 7-year period preceding the date of the application for licensing and registration, or at any time preceding such date of application, if such felony involved an act of fraud, dishonesty, or a breach of trust or money laundering;

(6) In violation of provisions of the Secure and Fair Enforcement Mortgage Licensing Act of 2008 (12 U.S.C. 5101, *et seq.*) or any applicable provision of Tribal or State law; or

(7) In violation of 12 U.S.C. 1715z–13a.

(b) [Reserved]

Subpart C—Lending on Trust Land

§ 1005.301 Tribal legal and administrative framework.

(a) *Tribal requirements.* (1) A Tribe seeking to allow eligible Borrowers to place a mortgage lien on Trust Land under the Section 184 Program must apply to HUD for approval to participate in the program.

(2) Tribes electing to make Trust Land or restricted fee land available under the Section 184 Program must provide to HUD a legal and administrative framework for leasing, foreclosure and eviction on Trust Land to protect the interests of the Borrower, Tribe, Direct Guarantee Lender, and HUD.

(3) Approved Tribes shall assist in facilitating Loss Mitigation efforts and assist in the disposition of defaulted properties on Trust Land.

(b) *Legal and administrative framework.* A Tribe may enact legal procedures through Tribal council resolution or any other recognized legislative action. These procedures must be legally enforceable and include the following requirements:

(1) *Foreclosure and assignment.* When a Borrower is in default, and is unwilling or unable to successfully complete Loss Mitigation in accordance with subpart G of this part; and Servicer either initiates First Legal Action against the Borrower, or assigns the Loan to HUD after offering the Tribe the option to assume the Section 184 Guaranteed Loan or purchase the property under § 1005.757(a):

(i) The Tribe must demonstrate that a foreclosure will be processed through the legal systems having jurisdiction over the Section 184 Guaranteed Loan. Jurisdiction must include Federal Court jurisdiction when HUD forecloses on the property.

(ii) Foreclosure ordinances must allow for the legal systems with jurisdiction to reassign the lease to HUD or provide for a new lease to be issued to HUD in the event the lease is vacated.

(iii) If the Holder assigns the Loan to HUD without initiating or completing the foreclosure process, or the property becomes vacant during the Loss Mitigation or foreclosure process, the Tribe may assign the lease to HUD to facilitate disposition of the property.

(2) *Property disposition.* Once a lease is vacated or reassigned, the Tribe or the TDHE shall work with HUD to sell the property to an eligible party.

(3) *Eviction.* The Tribe must have a legal and administrative framework implementing eviction procedures, allowing for the expedited removal of the borrower in default, all household residents, and any unauthorized occupants of the property. Eviction procedures must enable the Servicer or the Tribe to secure possession of the property. Eviction may be required upon:

(i) The completion of a foreclosure;

(ii) The involuntary termination of the lease;

(iii) The reassignment of the lease; or

(iv) The sale of the property.

(4) *Lien priority.* Section 184 Guaranteed Loans must be in a first lien position securing the property.

(i) To ensure that each Section 184 Guaranteed Loan holds a first lien position, the Tribe must enact an ordinance that either:

(A) Provides for the satisfaction of the Section 184 Guaranteed Loan before any and all other obligations; or

(B) Follows State law to determine the priority of liens against the property. If a Tribal jurisdiction spans two or more states, the State in which the property is located is the applicable State law.

(ii) For a lien to be considered valid on Trust Land, the lien must be:

(A) Approved by the Tribe and BIA, as applicable; and

(B) Recorded by the BIA.

(5) *Lease provisions for Trust Land.* The lease provisions for Trust Land must meet the following requirements:

(i) Tribes may use a model lease available from HUD for Section 184 Guaranteed Loan lending on Trust Land. The Tribe may use a rider to make modifications to the model lease, with the approval of HUD and BIA.

(ii) Tribes may draft their own lease in compliance with 25 CFR part 162 and

contain mandatory lease terms and language as prescribed in Section 184 Program Guidance, with approval of HUD and BIA.

(A) Identify lessor.

(B) Identify the lessee (Tribe, TDHE, enrolled member of the Tribe or HUD).

(C) Legal description of the land and property address covered by the lease.

(D) The lease must have a minimum term of 50 years. For refinances the lease must have a remaining term which exceeds the maturity date of the loan by a minimum of ten years.

(E) In the event of lessee default under the lease, the lease shall allow the servicer to accelerate the Section 184 Guaranteed Loan and foreclose or assign the Section 184 Guaranteed Loan to HUD, with HUD approval.

(F) The lease must be executed by all interested parties to be enforceable.

(G) Lender and HUD consent shall be required for any lease termination when the Section 184 Guaranteed Loan is secured by the property.

(H) The Tribal lease must contain the following provision: ''If lessee default(s) on a Section 184 Guaranteed Loan, under which the lease and improvements on the leased premises are pledged as security, the lessee or lessor may assign the lease and deliver possession of the leased premises, including any improvements thereon, to HUD. HUD may transfer this lease and the leased premises to a successor lessee; provided, however, that the lease may only be transferred to another member of the Tribe or Tribal entity, as approved by the Tribe.''

(I) lease language as prescribed by Section 184 Program Guidance.

(J) The lease must also provide that in the event of foreclosure, the lease will not be subject to any forfeiture or reversion and will not be otherwise subject to termination.

§ 1005.303 Tribal application.

A Tribe shall submit an application on a form prescribed by HUD. The application must include a copy of the Tribe's foreclosure, eviction, lease, priority lien ordinances, all cross-referenced ordinances in those sections, and any other documents in accordance with Section 184 Program Guidance.

§ 1005.305 Approval of Tribal application.

HUD shall review applications under § 1005.303 and where all requirements of § 1005.301 are met, HUD shall provide written notification of the approval of the Tribe to participate in the Section 184 Program. If HUD determines the application is incomplete, or the documents submitted do not comply with the requirements of this subpart or any process prescribed in Section 184 Program Guidance, HUD will work with the Tribe to cure the deficiencies before there is a denial of the application.

§ 1005.307 Tribal recertification.

A Tribe shall recertify annually to HUD whether it continues to meet the requirements of this subpart, on a form and by a deadline prescribed by Section 184 Program Guidance. Recertification shall include Tribal certification of no changes to the Tribe's foreclosure, eviction, lease, and lien priority ordinances. The Tribe shall provide any updated contact information and similar information that may be required under Section 184 Program Guidance.

§ 1005.309 Duty to report changes.

Based on the timeframe as prescribed by Section 184 Program Guidance, the Tribe must notify HUD of any proposed changes in the Tribe's foreclosure, eviction, lease, and lien priority ordinances or contact information. HUD shall require approval of the changes in the foreclosure, eviction, lease, and lien priority ordinances. HUD will provide written notification of the review of the changes and determine whether the updated documents meet the requirements of this subpart.

§ 1005.311 HUD notification of any lease default.

In cases where the lessee is in default under the lease for any reason, the lessor shall provide written notification to HUD within 30 days of the lease default.

§ 1005.313 Tribal reporting requirements.

The Tribe shall provide timely and accurate reports and certifications to HUD, as may be prescribed by Section 184 Program Guidance.

Subpart D—Underwriting

Eligible Borrowers

§ 1005.401 Eligible Borrowers.

(a) Eligible Borrowers are Indian Families, Tribes, or TDHEs. Indian Family Borrowers are limited to one Section 184 Guaranteed Loan at a time.

(b) Indian Family Borrowers must document their status as American Indian or Alaska Native through evidence as prescribed by Section 184 Program Guidance.

§ 1005.403 Principal Residence.

(a) *Principal Residence.* Means the dwelling where the Borrower maintains as a permanent place of abode. A Borrower may have only one Principal Residence at any one time.

(b) *Occupancy requirement.* Borrowers who are an Indian Family must occupy the property as a Principal Residence. Borrowers who are a TDHE or Tribe do not need to occupy the property as a Principal Residence.

(c) *Non-occupant Co-Borrower.* A co-Borrower who does not occupy the property as a principal resident is permitted. A Non-occupant Co-Borrower must be related by blood (*e.g.,* parent-child, siblings, aunts-uncles/nieces-nephews), or an unrelated individual who can document evidence of a family-type, longstanding, and substantial relationship not arising out of the loan transaction.

§ 1005.405 Borrower residency status.

(a) An eligible Borrower who is an Indian must be:

(1) A U.S. citizen;

(2) A lawful permanent resident alien; or

(3) A non-permanent resident alien.

(b) Documentation must be provided to the Direct Guarantee Lender to support lawful residency status as defined in the Immigration and Nationality Act, codified at 8 U.S.C. 1101, *et seq.*

§ 1005.407 Relationship of income to loan payments.

(a) *Adequacy of Borrower gross income.* (1) All Borrowers must establish, in accordance with Section 184 Program Guidance, that their gross income is and will be adequate to meet:

(i) The periodic payments required by the Loan to be guaranteed by the Section 184 Program; and

(ii) Other long-term obligations.

(2) In cases where there is a Non-occupant Co-Borrower, the occupying Borrower must meet a minimum qualifying threshold, in accordance with Section 184 Program Guidance.

(b) *Non-discrimination.* Determinations of adequacy of Borrower income under this section shall be made in a uniform manner without regard to race, color, national origin, religion, sex (including gender identity and sexual orientation), familial status, disability, marital status, source of income of the Borrower, or location of the property.

§ 1005.409 Credit standing.

(a) A Borrower must have a general credit standing satisfactory to HUD. A Direct Guarantee Lender must not use a Borrower's credit score when evaluating the Borrower's credit worthiness. The Direct Guarantee Lender must analyze the Borrower's credit history and payment pattern to determine credit worthiness.

(b) If a Borrower had a previous default on a Section 184 Guaranteed

Loan which resulted in a claim payment by HUD, the Borrower shall be subject to a reasonable waiting period, as may be prescribed by Section 184 Program Guidance.

§ 1005.411 Disclosure and verification of Social Security and Employer Identification Numbers or Tax Identification Number.

All Borrowers must meet applicable requirements for the disclosure and verification of Social Security, Employer Identification Numbers, or Tax Identification Numbers.

Eligible Properties

§ 1005.413 Acceptable title.

To be considered acceptable title, a Section 184 Guaranteed Loan must be secured by an interest in real estate held in fee simple or a leasehold interest on Trust Land. Where title evidences a lease that is used in conjunction with the Section 184 Guaranteed Loan on Trust Land, the lease must comply with relevant provisions of § 1005.301.

§ 1005.415 Sale of property.

(a) *Owner of Record requirement.* The property must be or have been purchased from the Owner of Record and the transaction may not involve or had not involved any sale or assignment of the sales contract.

(b) *Supporting documentation.* The Direct Guarantee Lender shall obtain documentation verifying that the seller is the Owner of Record and must submit this documentation to HUD as part of the application for a Section 184 Guaranteed Loan. This documentation may include, but is not limited to, a property ownership history report from the Tribe, State, or local government, a copy of the recorded deed from the seller, or other documentation (such as a copy of a property tax bill, title commitment, or binder) demonstrating the seller's ownership.

(c) *Time restrictions on re-sales*—(1) *General.* The eligibility of a property for a Loan guaranteed by HUD is dependent on the time that has elapsed between the date the seller acquired the property (based upon the date of settlement) and the date of execution of the sales contract that will result in the HUD guarantee (the re-sale date). The Direct Guarantee Lender shall obtain documentation verifying compliance with the time restrictions described in this paragraph and must submit this documentation to HUD as part of the application for Section 184 Guaranteed Loan, in accordance with § 1005.501.

(2) *Re-sales occurring 90 days or less following acquisition.* If the re-sale date is 90 days or less following the date of acquisition by the seller, the property is not eligible for a Loan to be guaranteed by HUD.

(3) *Re-sales occurring between 91 days and 180 days following acquisition.* (i) If the re-sale date is between 91 days and 180 days following acquisition by the seller, the property is generally eligible for a Section 184 Guaranteed Loan.

(ii) However, HUD will require that the Direct Guarantee Lender obtain additional documentation if the re-sale price is 100 percent over the purchase price. Such documentation must include a second appraisal from another a different appraiser. The Direct Guarantee Lender may also document its Loan file to support the increased value by establishing that the increased value results from the rehabilitation of the property.

(iii) Additional documentation, as may prescribed by notice for comment.

(4) *Authority to address property flipping for re-sales occurring between 91 days and 12 months following acquisition.* (i) If the re-sale date is more than 90 days after the date of acquisition by the seller, but before the end of the twelfth month after the date of acquisition, the property is eligible for a Loan to be guaranteed by HUD.

(ii) However, HUD may require that the Direct Guarantee Lender provide additional documentation to support the re-sale value of the property if the re-sale price is 5 percent or greater than the lowest sales price of the property during the preceding 12 months (as evidenced by the contract of sale). At HUD's discretion, such documentation must include, but is not limited to, a second appraisal from a different appraiser. HUD may exclude re-sales of less than a specific dollar amount from the additional value documentation requirements.

(iii) If the additional value documentation supports a value of the property that is more than 5 percent lower than the value supported by the first appraisal, the lower value will be used to calculate the maximum principal loan amount under § 1005.443. Otherwise, the value supported by the first appraisal will be used to calculate the maximum principal loan amount.

(iv) Additional value documentation may be prescribed by notice for comment.

(5) *Re-sales occurring more than 12 months following acquisition.* If the re-sale date is more than 12 months following the date of acquisition by the seller, the property is eligible for a loan guaranteed by HUD.

(d) *Exceptions to the time restrictions on sales.* The time restrictions on sales described in paragraph (b) of this section do not apply to:

(1) Sales by HUD of real estate owned (REO) properties under 24 CFR part 291 and of single-family assets in revitalization areas pursuant to section 204 of the National Housing Act (12 U.S.C. 1710);

(2) Sales by an agency of the United States Government of REO single family properties pursuant to programs operated by such agencies;

(3) Sales of properties by Tribes, TDHEs, State, or local governments, or Eligible Nonprofit Organizations approved to purchase HUD REO single family properties at a discount with resale restrictions;

(4) Sales of properties that were acquired by the sellers by death, devise, or intestacy;

(5) Sales of properties purchased by an employer or relocation agency in connection with the relocation of an employee;

(6) Sales of properties by Tribes, TDHEs, State and local government agencies; and

(7) Only upon announcement by HUD through issuance of a notice, sales of properties located in areas designated by the President as Federal disaster areas. The notice will specify how long the exception will be in effect.

(8) HUD may approve other exceptions on a case-by-case basis.

§ 1005.417 Location of property.

At the time a loan is guaranteed, the property must be for residential use under Tribal, State, or local law and be located within a Section 184 Approved Program Area.

§ 1005.419 Requirements for standard housing.

(a) *General standards.* Every property guaranteed under the Section 184 Program must:

(1) Be decent, safe, sanitary, and modest in size and design.

(2) Conform with applicable general construction standards for the region.

(3) Contain a heating system that:

(i) Has the capacity to maintain a minimum temperature in the dwelling of 65 degrees Fahrenheit during the coldest weather in the area;

(ii) Is safe to operate and maintain;

(iii) Delivers a uniform distribution of heat; and

(iv) Conforms to any applicable Tribal heating code, or if there is no applicable Tribal code, an appropriate local, State, or national code.

(4) Contains a plumbing system that:

(i) Uses a properly installed system of piping;

(ii) Includes a kitchen sink and partitional bathroom with lavatory, toilet, and bath or shower; and

(iii) Uses water supply, plumbing, and sewage disposal systems that conform to any applicable Tribal code or, if there is no applicable Tribal code, the minimum standards established by the appropriate local, State, or national code.

(5) Contain an electrical system using wiring and equipment properly installed to safely supply electrical energy for adequate lighting and for operation of appliances that conforms to any applicable Tribal code or, if there is no applicable Tribal code, an appropriate local, State, or national code.

(6) Meets minimum square footage requirements and be not less than:

(i) 570 square feet in size, if designed for a family of not more than 4 persons;

(ii) 850 square feet in size, if designed for a family of not less than 5 and not more than 7 persons;

(iii) 1020 square feet in size, if designed for a family of not less than 8 persons; or

(iv) Current locally adopted standards for size of dwelling units, documented by the Direct Guarantee Lender.

(v) Upon the written request of a Tribe, or THDE, HUD may waive the minimum square footage requirements under paragraphs (a)(6)(i) through (iv) of this section for properties located on Trust Land.

(7) Conform with the energy performance requirements for new construction established by HUD under section 526(a) of the National Housing Act (12 U.S.C. 1735f–4(a)).

(b) *Additional requirements.* HUD may prescribe any additional requirements to permit the use of various designs and materials in housing acquired under this part.

(c) *Lead-based paint.* The relevant requirements of the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. 4821–4846), the Residential Lead-Based Paint Hazard Reduction Act of 1992 (42 U.S.C. 4851–4856), and implementing regulations at 24 CFR part 35, subparts A, B, H, J, K, M, and R, shall apply.

(d) *Environmental review procedures.* (1) The regulations in 24 CFR 1000.20 applies to an environmental review for Trust Land and for fee land within a reservation in connection with a Loan guaranteed under this part. That section permits a Tribe to choose to assume environmental review responsibility.

(2) Before HUD issues a commitment to guarantee any Loan, or before HUD guarantees a Loan if there is no commitment, the Tribe or HUD must comply with environmental review procedures to the extent applicable under part 58 or part 50 of this title, as appropriate.

(3) If the Loan involves proposed or new construction, HUD will require the Lender to submit a signed Builder's Certification of Plans, Specifications and Site (Builder's Certification). The Builder's Certification must be in a form prescribed by Section 184 Program Guidance and must cover:

(i) Flood hazards;

(ii) Noise;

(iii) Explosive and flammable materials storage hazards;

(iv) Runway clear zones/clear zones;

(v) Toxic waste hazards; and

(vi) Other foreseeable hazards or adverse conditions (*i.e.,* rock formations, unstable soils or slopes, high ground water levels, inadequate surface drainage, springs, etc.) that may affect the health and safety of the occupants or the structural soundness of the improvements.

(4) The Builder's Certification must be provided to the appraiser for reference before the performance of an appraisal on the property.

(e) *Special Flood Hazard Areas and Coastal Barrier Resource System.* A property is not eligible for a Section 184 loan guarantee if a residential building and related improvements to the property are located within a Special Flood Hazard Area (SFHA) designated by a FEMA Flood Insurance Rate Map and insurance under the National Flood Insurance Program (NFIP) is not available in the community; or the improvements are, or are proposed to be, located within the Coastal Barrier Resources System.

(1) *Eligibility for new construction in SFHAs.* If any portion of the dwelling, related structures, or equipment essential to the value of the property and subject to flood damage is located within an SFHA, the property is not eligible for a Section 184 loan guarantee unless the Direct Guarantee Lender obtains from FEMA a final Letter of Map Amendment (LOMA) or final Letter of Map Revision (LOMR) that removes the property from the SFHA; or obtains a FEMA National Flood Insurance Program Elevation Certificate (FEMA Form 086–0–33) prepared by a licensed engineer or surveyor. The elevation certificate must document that the lowest floor including the basement of the residential building, and all related improvements/equipment essential to the value of the property, is built at or above the 100-year flood elevation in compliance with the NFIP criteria, and flood insurance must be obtained.

(2) *Eligibility for existing construction in SFHAs.* When any portion of the residential improvements is determined to be located within an SFHA, flood insurance must be obtained and maintained.

(3) *Required flood insurance amount for properties located within an SFHA.* Flood insurance must be maintained for the life of the Section 184 Guaranteed Loan in an amount that at a minimum equals the project cost less the estimated land cost; the outstanding principal balance of the loan; or the maximum amount of NFIP insurance available with respect to the property improvements, whichever is the least.

(4) *Required documentation.* The Direct Guarantee Lender must obtain a Life of Loan Flood Certification for all Properties. If applicable, the Direct Guarantee Lender must also obtain a FEMA Letter of Map Amendment; FEMA Letter of Map Revision; or FEMA National Flood Insurance Program Elevation Certificate (FEMA Form 086–0–33).

(5) *Restrictions on property within Coastal Barrier Resources System.* In accordance with the Coastal Barrier Resources Act, a property is not eligible for a Section 184 loan guarantee if the improvements are or are proposed to be located within the Coastal Barrier Resources System.

(f) *Airport hazards*—(1) *Existing construction.* If a property is existing construction and is located within a Runway Clear Zone (also known as a Runway Protection Zone) at a civil airport or within a Clear Zone at a military airfield, the Direct Guarantee Lender must obtain a Borrower's acknowledgement of the hazard.

(2) *New construction.* If a new construction property is located within a Runway Clear Zone (also known as a Runway Protection Zone) at a civil airport or within a Clear Zone at a military airfield, the Direct Guarantee Lender must reject the property for loan guarantee. Properties located in Accident Potential Zone 1 (APZ 1) at a military airfield may be eligible for a Section 184 loan guarantee provided that the Direct Guarantee Lender determines that the property complies with Department of Defense guidelines.

§ 1005.421 Certification of appraisal amount.

A Section 184 Guaranteed Loan must be accompanied by a sales contract satisfactory to HUD, executed by the seller, whereby the seller agrees that before any sale of the property, the seller will deliver to the purchaser of the property a certification of the appraisal, in a form satisfactory to HUD, setting forth the amount of the appraised value of the property.

§ 1005.423 Legal restrictions on Conveyance.

(a) Legal Restrictions on Conveyance means any provision in any legal instrument, law or regulation applicable to the Borrower or the mortgaged property, including but not limited to a lease, deed, sales contract, declaration of covenants, declaration of condominium, option, right of first refusal, will, or trust agreement, that attempts to cause a Conveyance (including a lease) made by the Borrower to:

(1) Be void or voidable by a third party;

(2) Be the basis of contractual liability of the Borrower for breach of an agreement not to convey, including rights of first refusal, pre-emptive rights or options related to Borrower efforts to convey;

(3) Terminate or subject to termination all or a part of the interest held by the Borrower in the property if a Conveyance is attempted;

(4) Be subject to the consent of a third party;

(5) Be subject to limits on the amount of sales proceeds retainable by the seller; or

(6) Be grounds for acceleration of the Guaranteed Loan or increase in the interest rate.

(b) Section 184 Guaranteed Loans shall not be subject to any Legal Restrictions on Conveyance, except for restrictions in this paragraph (b):

(1) A lease or any other legal document that restricts the assignment of interest in properties held in trust or otherwise restricted to an eligible Indian Family.

(2) A mortgage funded through tax-exempt Bond F and includes a due-on-sale provision in a form approved by HUD that permits the Direct Guarantee Lender to accelerate a mortgage that no longer meets Federal requirements for tax-exempt bond financing or for other reasons acceptable to HUD. A mortgage funded through tax-exempt bond financing shall comply with all form requirements prescribed under this subpart and shall contain no other provisions designed to enforce compliance with Federal or State requirements for tax-exempt bond financing.

(3) A mortgaged property subject to protective covenants which restrict occupancy by, or transfer to, persons of a defined population if:

(i) The restrictions do not have an undue effect on marketability as determined in the original plan.

(ii) The restrictions do not constitute illegal discrimination and are consistent with the Fair Housing Act and all other applicable nondiscrimination laws under Tribal, State, or local law, where applicable.

(4) HUD shall require that the previously approved restrictions automatically terminate if the lease or title to the mortgaged property is transferred by foreclosure, deed-in-lieu/lease-in-lieu of foreclosure, or if the loan is assigned to HUD.

§ 1005.425 Rental properties.

(a) *When a Borrower is an Indian Family.* A Section 184 Guaranteed Loan may be used to purchase, construct, rehabilitate, or refinance an up to four-unit property. The Borrower must occupy one unit as a Principal Residence and may rent the additional units.

(b) *When the Borrower is a Tribe or TDHE.* There is no limit to the number of one- to four-unit properties a Tribe or TDHE may purchase or own with a Section 184 Guaranteed Loan(s) on or off Trust Land. However, the Tribe or TDHE must meet all Borrower program requirements.

§ 1005.427 Refinancing.

(a) *Refinance eligibility.* HUD may permit a Borrower to refinance any qualified mortgage, including an existing Section 184 Guaranteed Loan, so long as the Borrower and property meet all Section 184 Program requirements.

(b) *Types of refinances.* HUD may guarantee a Rate and Term refinance, a Streamline refinance, or a Cash-Out refinance, consistent with paragraphs (d) through (f) of this section.

(c) *General requirements.* All types of refinances are subject to the following requirements:

(1) The term of the refinancing Loan may not exceed a term of 30 years.

(2) The Borrower must have a payment history on the existing mortgage that is acceptable to HUD.

(3) The Direct Guarantee Lender may not require a minimum principal amount to be outstanding on the loan secured by the existing mortgage.

(4) If an Upfront Loan Guarantee Fee was financed as part of the existing mortgage, no refund will be given. However, the maximum amount of the refinancing Loan computed in accordance with § 1005.443 may be increased by the amount of the Upfront Loan Guarantee Fee associated with the new refinancing Loan and exceed the applicable Section 184 Guaranteed Loan limit as established by HUD for an area pursuant to § 1005.441.

(d) *Rate and term refinance.* (1) Rate and term refinance is the refinancing of an existing mortgage loan for the purpose of changing the interest rate or term, or both, of a loan without advancing new funds on the loan, with the exception of allowable closing costs.

(2) A Rate and Term Refinance Loan must meet the following requirements:

(i) The Loan must be in an amount that does not exceed the lesser of the original principal amount of the existing mortgage; or the sum of the unpaid principal balance of the existing mortgage plus loan closing charges and allowable fees approved by HUD.

(ii) The Loan must result in a reduction in regular monthly payments by the Borrower, except when refinancing a mortgage for a shorter term will result in an increase in the Borrower's regular monthly payments.

(e) *Streamline Refinance.* Streamline Refinance refers to the refinance of an existing Section 184 Guaranteed Loan requiring limited Borrower credit documentation and underwriting.

(1) A Streamline Refinance Loan must be in an amount that does not exceed the unpaid principal balance of the existing Section 184 Guaranteed Loan and meet all other applicable Section 184 Program requirements.

(2) A Streamline Refinance with an appraisal may be in the amount equal to the unpaid principal balance of the existing mortgage plus Loan closing charges and allowable fees approved by HUD. The refinanced Loan must be subject to an appraisal and meet all other applicable Section 184 Program requirements.

(f) *Cash-Out refinance.* (1) A Cash-Out refinance is when a Section 184 Guaranteed Loan is made for a Loan amount larger than the existing unpaid principal balance, utilizing the property's equity.

(2) A Cash-Out refinance Loan amount cannot exceed a maximum loan to value ratio, as established by HUD.

(3) A Borrower may elect to receive a portion of equity in the form of cash in an amount up to a reasonable maximum allowed amount, as prescribed by Section 184 Program Guidance.

(4) All cash advances, except cash amounts to the Borrower, must be used for approved purposes in accordance with HUD and BIA requirements, and must be supported by verified documentation.

(5) The Cash-Out refinance must meet all other applicable Section 184 Program requirements.

§ 1005.429 Eligibility of Loans covering manufactured homes.

A Loan covering a manufactured home (as defined in 24 CFR part 3280), shall be eligible for a Section 184 Guaranteed Loan when the following requirements have been met:

(a) *For manufactured homes located on a fee simple site.* (1) The manufactured home, as erected on site, must be installed in accordance with 24 CFR part 3286; conform with property standards under § 1005.419; and shall have been constructed in accordance with 24 CFR part 3280, as evidenced by the certification label.

(2) The Loan shall cover the manufactured home and site, shall constitute a Loan on a property classified and taxed as real estate.

(3) In the case of a manufactured home which has not been permanently erected on a site for more than one year prior to the date of the application for the Loan Guarantee Certificate:

(i) The manufactured home shall be erected on a site-built permanent foundation that meets or exceeds applicable requirements of the Minimum Property Standards (MPS) for one- and two-family property, in accordance with 24 CFR 200.929(b)(1) and shall be permanently attached thereto by anchoring devices adequate for all loads identified in the MPS. The towing hitch or running gear, which includes axles, brakes, wheels, and other parts of the chassis that operate only during transportation, shall have been removed. The finished grade level beneath the manufactured home shall be at least two feet above the 100-year return frequency flood elevation. The site, site improvements, and all other features of the mortgaged property not addressed by the Manufactured Home Construction and Safety Standards shall meet or exceed applicable requirements of the MPS.

(ii) The space beneath the manufactured home shall be enclosed by continuous foundation-type construction designed to resist all forces to which it is subject without transmitting forces to the building superstructure. The enclosure shall be adequately secured to the perimeter of the manufactured home and be constructed of materials that conform to MPS requirements for foundations.

(iii) The manufactured home shall be braced and stiffened before it leaves the factory to resist racking and potential damage during transportation.

(iv) Section 1005.431 is modified to the extent provided in this paragraph (a). Applications relating to the guarantee of Loans under this paragraph (a) must be accompanied by an agreement in a form satisfactory to HUD executed by the seller or manufacturer or such other person as HUD may require, agreeing that in the event of any sale or Conveyance of the property within a period of one year beginning with the date of initial occupancy, the seller, manufacturer, or such other person will, at the time of such sale or Conveyance, deliver to the purchaser or owner of such property the manufacturer's warranty on a form prescribed by HUD. This warranty shall provide that the manufacturer's warranty is in addition to and not in derogation of all other rights and remedies the purchaser or owner may have, and a warranty in form satisfactory to HUD warranting that the manufactured home, the foundation, positioning, and anchoring of the manufactured home to its permanent foundation, and all site improvements are constructed in substantial conformity with the plans and specifications (including amendments thereof or changes and variations therein which have been approved in writing by HUD) on which HUD has based its valuation of the property. The warranty shall also expressly state that the manufactured home sustained no hidden damage during transportation, and if the manufactured home is a double-wide, that the sections were properly joined and sealed. The warranty must provide that upon the sale or Conveyance of the property and delivery of the warranty, the seller, builder, or such other person will promptly furnish HUD with a conformed copy of the warranty establishing by the purchaser's receipt thereon that the original warranty has been delivered to the purchaser in accordance with this section.

(4) In the case of a manufactured home which has been permanently erected on a site for more than one year prior to the date of the application for the Section 184 Guaranteed Loan:

(i) The manufactured home shall be permanently anchored to and supported by permanent footings and shall have permanently installed utilities that are protected from freezing. The space beneath the manufactured home shall be a properly enclosed crawl space.

(ii) The site, site improvements, and all other features of the mortgaged property not addressed by 24 CFR parts 3280 and 3286 shall meet or exceed HUD requirements. The finished grade level beneath the manufactured home shall be at or above the 100-year return frequency flood elevation.

(b) *For manufactured homes located on Trust Land.* Manufactured homes built and installed on Trust Land, shall meet manufactured home installation standards pursuant to Tribal laws, if any. In the absence of Tribal laws, the requirements in paragraph (a) of this section shall apply.

§ 1005.431 Acceptance of individual residential water purification.

If a property does not have access to a continuing supply of safe and potable water as part of its plumbing system without the use of a water purification system, the requirements of this section apply. The Direct Guarantee Lender must provide appropriate documentation with the submission for a Section 184 Guaranteed Loan to address each of the requirements of this section.

(a) *Equipment.* Water purification equipment must be approved by a nationally recognized testing laboratory acceptable to Tribal, State, or local health authority.

(b) *Certification by Tribal, State, or local health authority.* A Tribal, State, or local health authority certification must be submitted to HUD, which certifies that a point-of entry or point-of-use water purification system is used for the water supply, the treatment equipment meets the requirements of the Tribal, State, or local health authority, and has been determined to meet Tribal, State, or local health authority quality standards for drinking water. If neither Tribal, State, nor local health authority standards are applicable, then quality shall be determined in accordance with standards set by the Environmental Protection Agency (EPA) pursuant to the Safe Drinking Water Act. (EPA standards are prescribed in the National Primary Drinking Water requirements, 40 CFR parts 141 and 142.)

(c) *Borrower notices and certification.* (1) The prospective Borrower must have received written notification, when the Borrower signs a sales contract, that the property does not have access to a continuing supply of safe and potable water without the use of a water purification system to remain safe and acceptable for human consumption.

(2) Prior to final ratification of the sales contract, the Borrower must have received:

(i) A water safety report identifying specific contaminants in the water supply serving the property, and the related health hazard arising from the presence of those contaminants.

(ii) A written good faith estimate of the maintenance and replacement costs of the equipment necessary to assure continuing safe drinking water.

(3) The prospective Borrower must sign a certification, acknowledging the required notices have been received by the Borrower, in the form prescribed by Section 184 Program Guidance, at the time the application for mortgage credit approval is signed by the Direct Guarantee Lender. The required certification must be submitted to HUD

with the request for the Loan Guarantee Certificate.

§ 1005.433 Builder warranty.

(a) Applications relating to proposed construction must be accompanied by an agreement in a form satisfactory to HUD, executed by the seller or builder or such other person as HUD may require, and agreeing that in the event of any sale or Conveyance of the property, within a period of one year beginning with the date of initial occupancy, the seller, builder, or such other person will, at the time of such sale or Conveyance, deliver to the purchaser or owner of such property a warranty in a form satisfactory to HUD, warranting that the property is constructed in substantial conformity with the plans and specifications (including amendments thereof or changes and variations therein which have been approved in writing by HUD) on which HUD has based on the valuation of the property.

(b) Such agreement must provide that upon the sale or Conveyance of the property and delivery of the warranty, the seller, builder, or such other person will promptly furnish HUD with a confirmed copy of the warranty, establishing by the purchaser's receipt thereon that the original warranty has been delivered to the purchaser in accordance with this section.

Eligible Loans

§ 1005.435 Eligible collateral.

A Section 184 Loan Guarantee may be secured by any collateral authorized under existing Federal law or applicable State or Tribal law. The collateral must be sufficient to cover the amount of the loan, as determined by the Direct Guarantee Lender and approved by HUD. Improvements on Trust Lands may be considered as eligible collateral. Trust Land cannot be considered as part of the eligible collateral.

§ 1005.437 Loan provisions.

(a) *Loan form.* (1) The Loan shall be in a form meeting the requirements of HUD. HUD may prescribe loan closing documents. For each case in which HUD does not prescribe loan closing documents, HUD shall require specific language in the Loan which shall be uniform for every Loan. HUD may also prescribe the language or substance of additional provisions for all Loans, as well as the language or substance of additional provisions for use only in particular jurisdictions.

(2) Each Loan shall also contain any provisions necessary to create a valid and enforceable Security interest under Tribal law or the laws of the jurisdiction in which the property is located.

(b) *Loan multiples.* A Loan, in whole dollars, shall be in an amount not to exceed the maximum principal loan amount (as calculated under § 1005.443) for the area where the property is located.

(c) *Payments.* The Loan payments shall:

(1) Be due on the first of the month;

(2) Contain complete Amortization provisions in accordance with § 1005.453 and an Amortization period not in excess of the term of the Loan; and

(3) Provide for payments to principal and interest to begin no later than the first day of the month, 60 days after the date the Loan is executed. For closings taking place within the first seven days of the month, interest credit is acceptable.

(d) *Maturity.* The Loan shall have a repayment term of not more than the maximum period as approved by HUD and fully amortizing.

(e) *Property standards.* The Loan must be a first lien upon the property that conforms with the requirements for standard housing under § 1005.419.

(f) *Disbursement.* The entire principal amount of the Loan must have been disbursed to the Borrower or to the Borrower's creditors for the Borrower's account and with the Borrower's consent.

(g) *Disbursement for construction advances.* (1) HUD may guarantee Loans from which advances will be made during construction. HUD will provide guarantees for advances made by the Direct Guarantee Lender during construction when all the following conditions are satisfied:

(i) The Direct Guarantee Lender and Borrower execute a building Loan agreement, approved by HUD, setting forth the terms and conditions under which advances will be made.

(ii) The advances may be made only as provided in the building agreement.

(iii) The principal amount of the Loan is held by the Direct Guarantee Lender in an interest-bearing account, trust, or escrow for the benefit of the Borrower, pending advancement to the Borrower or Borrower's creditors as provided in the loan agreement.

(iv) The Loan shall bear interest on the amount advanced to the Borrower or the Borrower's creditors and on the amount held in an account or trust for the benefit of the Borrower.

(2) Notwithstanding the requirements in paragraph (g)(1) of this section, upon request of the Lender, HUD may provide for the approval of advances prior to construction.

(h) *Prepayment privilege.* The Loan must contain a provision permitting the Borrower to prepay the Loan in whole or in part at any time and in any amount. The Loan may not provide for the payment of any fee on account of such prepayment.

§ 1005.439 Loan lien.

(a) *First lien.* A Borrower must establish that, after the Loan offered for guarantee has been recorded, the property will be free and clear of all liens other than such Loan, and that there will not be outstanding any other unpaid obligations contracted in connection with the loan transaction or the purchase of the property, except obligations that are secured by property or collateral owned by the Borrower independently of the property.

(b) *Junior lien.* With prior approval of HUD, the property may be subject to a junior lien held by a Direct Guarantee Lender or a Tribe or instrumentality, TDHE, Federal, State, local government, or an Eligible Nonprofit Organization. Unless the junior lien is for the purpose described in paragraph (c) of this section, it shall meet the following requirements:

(1) Periodic payments shall be collected monthly and be substantially the same;

(2) The monthly Loan payments for the Section 184 Guaranteed Loan and the junior lien shall not exceed the Borrower's reasonable ability to pay, as determined by HUD;

(3) The sum of the principal amount of the Section 184 Guaranteed Loan and the junior lien shall not exceed the loan-to-value limitation applicable to the Section 184 Program, and shall not exceed the loan limit for the area, except as otherwise permitted by HUD;

(4) The repayment terms shall not provide for a balloon payment before ten years unless approved by HUD;

(5) The junior lien must become due and payable on sale or refinancing of the secured property covered by the Section 184 Guaranteed Loan, unless otherwise approved by HUD; and

(6) The junior lien shall contain a provision permitting the Borrower to prepay the junior lien in whole or in part at any time and shall not require a prepayment penalty.

(c) *Junior liens to reduce Borrower monthly payments.* With the prior approval of HUD, the property may be subject to a junior lien advanced to reduce the Borrower's monthly payments on the Section 184 Guaranteed Loan following the date it is guaranteed, if the junior lien meets the following requirements:

(1) The junior lien shall not provide for any payment of principal or interest until the property securing the junior lien is sold or the Section 184 Guaranteed Loan is refinanced, at which time the junior lien shall become due and payable.

(2) The junior lien shall not provide for any payment of principal or interest so long as the occupancy requirements are met; and, where applicable, shall provide for forgiveness of the junior lien amount at the end of the term of the junior lien.

(d) *Junior liens related to tax-exempt bond financing and low-income housing tax credits.* HUD approval shall be required when Borrower seeks to encumber property with a junior lien pursuant to § 1005.423(b).

§ 1005.441 Section 184 Guaranteed Loan limit.

The Section 184 Guaranteed Loan limit is the level set by HUD for the Section 184 Approved Program Area and is based upon the location of the property. The limit that is in effect on the date the Section 184 case number is issued in accordance with § 1005.445 shall apply, regardless of the closing date. The limit shall be revised periodically by HUD and published in Section 184 Program Guidance.

§ 1005.443 Loan amount.

(a) *Minimum required investment.* The Borrower is required to make a minimum investment in the property. This investment must come from the Borrower's own funds, gifts, or Tribal, State, or local funds awarded to the Borrower. The minimum investment in the property is the difference between the sales price and the base loan amount.

(b) *Calculating base loan amount.* (1) The base loan amount is determined by calculating:

(i) 97.75 percent of the appraised value of the property or the Acquisition Cost, whichever is less; or

(ii) 98.75 percent of the lessor of the appraised value or sales price when the appraised value or sales price is $50,000 or less.

(2) The base loan amount cannot exceed the Section 184 Guaranteed Loan limits established under § 1005.441.

(c) *Maximum principal loan amount.* The maximum principal loan amount is the base loan amount and the Upfront Loan Guarantee Fee. The Section 184 Guaranteed Loan limit may only be exceeded by the amount of the Upfront Loan Guarantee Fee.

(d) *Minimum principal loan amount.* A Direct Guarantee Lender may not require a minimum loan amount for a Section 184 Guaranteed Loan.

§ 1005.445 Case numbers.

(a) Section 184 case numbers may only be obtained by a Direct Guarantee Lender when the Direct Guarantee Lender or its Sponsored Entity has an active loan application from a Borrower(s) and a property is identified.

(b) To obtain a case number, the Direct Guarantee Lender must:

(1) Provide evidence of Tribal enrollment or Alaska Native status;

(2) Verify that the property is located in a Section 184 Approved Program Area;

(3) Confirm that the Loan does not exceed the Section 184 Loan limit; and

(4) Submit Loan specific information as prescribed in Section 184 Program Guidance.

(c) Case numbers are automatically cancelled after a limited period is identified in Section 184 Program Guidance, unless a Firm Commitment is issued, or an extension is granted by HUD in accordance with Section 184 Program Guidance prior to the expiration of the case number.

§ 1005.447 Maximum age of Loan documents.

Documents reviewed at underwriting may not be older than 60 days and may not be more than 120 days old at the Loan closing date. Documents whose validity for underwriting purposes is not affected by the passage of time, such as divorce decrees or tax returns, are not subject to the 60- and 120-day limitations.

§ 1005.449 Qualified mortgage.

A Section 184 Guaranteed Loan, except for mortgage transactions exempted under 15 U.S.C. 1639c(b)(3)(ii), is afforded safe harbor as a qualified mortgage that meets the ability-to-repay requirements in 15 U.S.C. 1639c(a).

§ 1005.451 Agreed interest rate.

The Loan shall bear interest at the rate agreed upon by the Direct Guarantee Lender and the Borrower and determined by HUD to be reasonable. The agreed upon interest rate may not exceed the rate generally charged in the area for mortgage loans not guaranteed or insured by any agency or instrumentality of the Federal Government, or a rate determined by HUD, whichever is lower. The agreed upon interest rate must not take into consideration a Borrower's credit score in accordance with § 1005.409 and must not be based on risk-based pricing.

§ 1005.453 Amortization provisions.

The Loan must contain complete Amortization provisions satisfactory to HUD, requiring payments due on the first day of each month by the Borrower. The sum of the principal and interest payments in each month shall be substantially the same.

Underwriting

§ 1005.455 Direct guarantee underwriting.

(a) *Underwriter due diligence.* A Direct Guarantee Lender shall exercise the same level of care which it would exercise in obtaining and verifying information for a Loan in which the Direct Guarantee Lender would be entirely dependent on the property as Security to protect its investment. Direct Guarantee Lender procedures that evidence such due diligence shall be incorporated as part of the quality control plan required under § 1005.219. Compliance with HUD-prescribed underwriting guidelines shall be the minimum standard of due diligence in underwriting the Loans. Failure to comply with HUD-prescribed underwriting guidelines may result in sanctions in accordance with §§ 1005.905 and 1005.907.

(b) *Evaluating the Borrower(s) qualifications.* The Direct Guarantee Lender shall evaluate the Borrower's credit characteristics, adequacy, and stability of income to meet the periodic payments under the Loan and all other obligations, the adequacy of the Borrower's available assets to close the transaction, the Borrower's management capacity and grant performance, if applicable, and render an underwriting decision in accordance with applicable regulations, policies, and procedures.

(c) *Assumption.* Applications for the assumption of an existing Section 184 Guaranteed Loan shall be underwritten using the same Borrower eligibility and underwriting standards in accordance with this subpart.

§ 1005.457 Appraisal.

(a) A Direct Guarantee Lender shall have the property appraised in accordance with the Uniform Standards of Professional Appraisal Practice and the Fair Housing Act (42 U.S.C. 3601–19). HUD may establish alternative requirements to Uniform Standards of Professional Appraisal Practice and publish such alternative requirements in Section 184 Program Guidance.

(b) A Direct Guarantee Lender must select an appraiser identified on the Federal Housing Administration Appraiser Roster, compiled in accordance with 24 CFR part 200, subpart G. The Direct Guarantee Lender shall not discriminate on the basis of race, color, religion, sex, disability, familial status national origin, or age in the selection of an appraiser.

(c) The appraiser must be knowledgeable in the market where the property is located.

(d) A Direct Guarantee Lender and an appraiser must ensure that an appraisal and related documentation satisfy Federal Housing Administration, Fannie Mae, or Freddie Mac appraisal requirements, and both bear responsibility for the quality of the appraisal in satisfying such requirements.

(e) A Direct Guarantee Lender that submits, or causes to be submitted, an appraisal or related documentation that does not satisfy requirements under paragraphs (a) through (d) of this section may be subject to sanctions by HUD pursuant to §§ 1005.905 and 1005.907.

(f) The validity period of appraisals is 120 days:

(1) The validity period for an appraisal may be extended for 30 days at the option of the Direct Guarantee Lender if the Direct Guarantee Lender has obtained a Firm Commitment.

(2) If the transaction will not close within 120 days or 150 days with an approved extension, then the Direct Guarantee Lender must update the appraisal. The appraisal must be updated before the 120th-day validity period, or 150th day if extended, has expired. The updated appraisal is valid for an additional 120 days after the effective date of the initial appraisal report that is being updated.

(g) The Direct Guarantee Lender may request an extension of the 120-day validity period for up to two additional 120-day extensions requests. HUD may request an updated appraisal during the extension periods.

§ 1005.459 Loan submission to HUD for Direct Guarantee.

(a) *Deadline for submission.* Within 60 days after the date of closing the loan, a Direct Guarantee Lender must submit an endorsement case binder to HUD, in accordance with § 1005.503.

(b) *Late submission.* If the endorsement case binder is submitted past 60 days, the Direct Guarantee Lender must include, as part of the case binder, a late endorsement request with supporting documentation, affirming:

(1) The Loan is not currently in default;

(2) All escrow accounts for taxes, hazard insurance, and monthly Loan Guarantee Fees are current;

(3) Neither the Direct Guarantee Lender nor Servicer provided the funds to bring or keep the loan current or to bring about the appearance of acceptable payment history; and

(4) Notwithstanding paragraph (b)(3) of this section, with prior approval from HUD, Lender or Servicer may provide funds to bring or keep the loan current.

§ 1005.461 HUD issuance of Firm Commitment.

HUD may underwrite and issue a Firm Commitment when it is in the interest of HUD.

Subpart E—Closing and Endorsement

Closing

§ 1005.501 Direct Guarantee Lender closing requirements.

The Direct Guarantee Lender shall close the Loan in accordance with the following:

(a) *Chain of title/interest.* (1) For fee simple properties, the Direct Guarantee Lender must obtain evidence of all prior ownership within 12 months of the case number assignment date. The Direct Guarantee Lender must review the evidence of prior ownership to determine any undisclosed Identity of Interest transactions.

(i) If an Identity of Interest is discovered, the Direct Guarantee Lender must review for any possible Conflict of Interest.

(ii) As a requirement of closing, all Borrowers must execute a Section 184 Borrower's Certification, addressing any Identity of Interest and Conflict of Interest.

(2) For Trust Land transactions, the requirements for the determination of ownership title interest shall be prescribed by HUD in Section 184 Program Guidance.

(b) *Title/Title Status Report.* The Direct Guarantee Lender must ensure that all objections to title binder/initial certified Title Status Report have been cleared, and any discrepancies have been resolved, to ensure that the Section 184 Guaranteed Loan will be in first Security interest position.

(c) *Closing in compliance with Direct Guarantee Lender approval.* The Direct Guarantee Lender must instruct the settlement agent to close the Section 184 Guaranteed Loan on the same terms or on the same assumptions in which it was underwritten and approved.

(d) *Closing in the Direct Guarantee Lender's name.* A Section 184 Guaranteed Loan must close in the name of the Direct Guarantee Lender issuing the underwriting approval.

(e) *Required HUD documents at closing.* The Direct Guarantee Lender must use the forms and language as may be prescribed in Section 184 Program Guidance.

(f) *Projected escrow.* The Direct Guarantee Lender must establish an escrow account in accordance with § 1005.713 and the Real Estate Settlement Procedures Act and any other escrow requirements as prescribed under applicable Tribal and Federal laws and regulations.

(g) *Closing costs and fees.* The Direct Guarantee Lender may charge the Borrower reasonable and customary fees in accordance with § 1005.515.

(h) *Closing date.* The closing date must occur before the expiration of the Firm Commitment.

(i) *Per diem interest and interest credits.* The Direct Guarantee Lender may collect per diem interest from the closing date to the date Amortization begins. Alternatively, the Direct Guarantee Lender may begin Amortization up to 7 days prior to the closing date and provide a per diem interest credit. Any per diem interest credit may not be used to meet Borrower's minimum required investment. Per diem interest must be computed using a factor of 1/365th of the annual rate.

(j) *Authorization of Tribal notification in the event of default.* At closing, the Borrower must, on a form provided by HUD, elect whether to authorize the Direct Guarantee Lender and HUD to notify the Tribe in the event of a default.

(k) *Signatures.* Direct Guarantee Lender must ensure that the note, Security instrument, and all closing documents are signed by the required parties.

(l) *Other requirements.* Direct Guarantee Lender shall close the Loan in accordance with any applicable Tribal, State, or Federal requirements. Direct Guarantee Lenders must execute any other documents as may be required by applicable Tribal, Federal, or State law.

§ 1005.503 Contents of endorsement case binder.

The Direct Guarantee Lender's endorsement case binder shall be submitted in a format as prescribed by HUD and contain the documents meeting the requirements of § 1005.501 and any other documents supporting the Direct Guarantee Lender's underwriting determination.

§ 1005.505 Payment of Upfront Loan Guarantee Fee.

The Direct Guarantee Lender, shall provide evidence of the remittance of the Upfront Loan Guarantee Fee, as required under § 1005.607, in accordance with a process provided by HUD in Section 184 Program Guidance.

§ 1005.507 Borrower's payments to include other charges and escrow payments.

(a) The Direct Guarantee Lender must include in the Section 184 Guaranteed

Loan monthly payment the following charges and escrow payments:

(1) The ground rents, if any;

(2) Annual Loan Guarantee Fee, as prescribed in § 1005.607, if any;

(3) The estimated amount of all taxes;

(4) Special assessments, if any;

(5) Flood insurance premiums, if flood insurance is required; and

(6) Fire and other hazard insurance premiums, except master policy premiums payable to a condominium association or a Tribe and paid directly by the Borrower.

(b) The Section 184 Guaranteed Loan shall further provide that such payments shall be held by the Direct Guarantee Lender in a manner satisfactory to HUD for the purpose of paying such ground rents, taxes, assessments, and insurance premiums before the same become delinquent, for the benefit and account of the Borrower. The Section 184 Guaranteed Loan must also make provisions for adjustments in case the estimated amount of such taxes, assessments, and insurance premiums shall prove to be more, or less, than the actual amount thereof so paid by the Borrower. Such payments shall be held in an escrow subject to § 1005.717.

(c) The Borrower shall not be required to pay premiums for fire or other hazard insurance which protects only the interests of the Direct Guarantee Lender, or for life or disability income insurance, or fees charged for obtaining information necessary for the payment of property taxes. The foregoing does not apply to charges made or penalties exacted by the taxing authority, except that a penalty assessed, or interest charged, by a taxing authority for failure to timely pay taxes or assessments shall not be charged by the Direct Guarantee Lender to the Borrower if the Direct Guarantee Lender had sufficient funds in escrow for the account of the Borrower to pay such taxes or assessments prior to the date on which penalty or interest charges are imposed.

§ 1005.509 Application of payments.

All monthly payments to be made by the Borrower to the Servicer shall be added together, and the aggregate amount shall be paid by the Borrower each month in a single payment by the Borrower, in accordance with the Loan documents. The Servicer shall apply the Borrower's funds in accordance with § 1005.715.

§ 1005.511 Late fee.

When the monthly Section 184 Guaranteed Loan payment is 15 or more days in arrears, the Servicer may collect from Borrower a late fee, not to exceed four percent of the overdue payment of principal and interest, or any other limit as established by HUD through public notice with an opportunity for comment. The late fee provision must appear on the note executed at closing.

§ 1005.513 Borrower's payments when Section 184 Guaranteed Loan is executed.

The Borrower must pay to the Direct Guarantee Lender, upon execution of the Section 184 Guaranteed Loan, where applicable, the:

(a) One-time Upfront Loan Guarantee Fee or any portion payable pursuant to § 1005.603; and

(b) All other applicable monthly charges pursuant to § 1005.507, including the Annual Loan Guarantee Fee pursuant to § 1005.607 covering the period from the closing date to the due date of the first installment payment under the Section 184 Guaranteed Loan.

§ 1005.515 Charges, fees, or discounts.

(a) The Direct Guarantee Lender must ensure that all fees charged and disclosure requirements at closing to the Borrower comply with all applicable Tribal, Federal, State, and local laws.

(b) The Direct Guarantee Lender may collect from the Borrower the following charges, fees, or discounts at closing:

(1) A charge to compensate the Direct Guarantee Lender for expenses incurred in originating and closing the Loan. HUD may establish limitations on the amount of any such charge in Section 184 Program Guidance.

(2) Reasonable and customary amounts, but not more than the amount actually paid by the Direct Guarantee Lender, for any of the following items:

(i) Recording fees and recording taxes or other charges incident to recordation;

(ii) Credit report;

(iii) Survey, if required by Direct Guarantee Lender or Borrower;

(iv) Title examination;

(v) Title insurance, if any;

(vi) Fees paid to an appraiser or inspector approved by HUD for the appraisal and inspection, if required, of the property. The Direct Guarantee Lender may collect from the Borrower the reasonable and customary amounts for such appraisals and inspections;

(vii) Such other reasonable and customary charges as may be authorized by HUD;

(viii) Reasonable and customary charges in the nature of discounts; and

(ix) Interest calculations in accordance with § 1005.501(i).

(c) All charges, fees, or discounts are subject to review by HUD after endorsement.

§ 1005.517 Certificate of nondiscrimination by the Direct Guarantee Lender.

(a) Where applicable, a Direct Guarantee Lender shall certify to HUD as to each of the following:

(1) That neither the Direct Guarantee Lender, nor anyone authorized to act for the Direct Guarantee Lender, will refuse to sell, after the making of a bona fide offer, or refuse to negotiate for the sale otherwise make unavailable or deny the property covered by the Section 184 Guaranteed Loan to any eligible purchaser or discriminate in making a loan or engaging in a residential real estate-related transaction (as defined in 42 U.S.C. 3605) because of race, color, religion, sex, disability, familiar status, or national origin, except as provided by law.

(2) That any restrictive covenant, other than permissible restrictions on Trust Land, on such property relating to race, color, religion, sex, disability, familial status, or national origin is hereby illegal, unenforceable, or void.

(b) That civil action for preventative relief may be brought by the Attorney General in any appropriate U.S. District Court against any person responsible for a violation of this certification.

Endorsement and Post-Closing

§ 1005.519 Creation of the contract.

The Loan shall be a Section 184 Guaranteed Loan from the date of the issuance of a Loan Guarantee Certificate, from the date of the endorsement of the credit instrument, or from the date of HUD's electronic acknowledgement to the Direct Guarantee Lender that the Loan is guaranteed, as applicable. HUD and the Direct Guarantee Lender are thereafter bound by the regulations in this subpart with the same force and to the same extent as if a separate contract had been executed relating to the Section 184 Guaranteed Loan, including the provisions of the regulations in this subpart and 12 U.S.C. 1715z-13a.

§ 1005.521 Lender pre-endorsement review and requirements.

Direct Guarantee Lender must complete a pre-endorsement review of the endorsement case binder. This review must be conducted by staff not involved in the originating, processing, or underwriting of the Loan. This review must also confirm that the Loan was underwritten by an approved Direct Guarantee Lender. The endorsement case binder must contain all documentation relied upon by the Direct Guarantee Lender to justify its decision to approve the Loan in accordance with subpart D of this part. Upon finalizing the pre-endorsement review, the Direct Guarantee Lender

must certify that all required documents are submitted and meet the requirements of § 1005.503.

§ 1005.523 HUD pre-endorsement review.

(a) Direct Guarantee Lender shall submit to HUD within 60 days after the date of the closing of the Loan, or such additional time as permitted by HUD, the endorsement case binder;

(b) Upon submission by a Direct Guarantee Lender of the endorsement case binder containing those documents required by § 1005.503, HUD will review the documents to ensure that the Loan meets all statutory, regulatory, and administrative requirements, including but not limited to:

(1) There is no fee, late charge, or interest due to HUD;

(2) The Loan was not in default when submitted for the Loan Guarantee Certificate or if submitted for guarantee more than 60 days after the date of closing, the Loan shows an acceptable payment history; and

(3) The Loan was underwritten by an approved Direct Guarantee Lender.

(c) Upon review, if HUD determines the loan to meet program requirements, HUD will issue a Loan Guarantee Certificate. If HUD determines the Loan it be ineligible, HUD will provide the Direct Guarantee Lender a written determination and specify any available corrective actions that may be available. If there is information indicating that any certification or required document is false, misleading, or constitutes fraud or misrepresentation on the part of any party, or that the loan fails to meet a statutory or regulatory requirement, HUD will conduct a complete audit of the endorsement case binder. Repeated submission of deficient endorsement case binders may subject the Direct Guarantee Lender to sanctions or civil money penalties pursuant to §§ 1005.905 and 1005.907.

§ 1005.525 Loan Guarantee Certificate.

(a) HUD shall issue a Loan Guarantee Certificate as evidence of the guarantee when HUD completes a review of the Direct Guarantee Lender's endorsement case binder and determines the Loan complies with all applicable Section 184 Program requirements in this part.

(b) HUD may issue a Loan Guarantee Certificate for a Loan involving a Security interest in Trust Land before HUD receives the required trailing documents from BIA, if the Direct Guarantee Lender agrees to indemnify HUD. The indemnification agreement between HUD and the Direct Guarantee Lender will terminate only upon receipt of the Trailing Documents in a form and manner acceptable to HUD. Trailing Documents may include the following documents:

(1) A final certified Title Status Report (TSR) that identifies that the BIA approved and recorded the mortgage instrument and residential lease related to the Section 184 Loan, if applicable;

(2) A certified true copy of the recorded mortgage instrument;

(3) A certified true copy of the recorded lease, if applicable;

(4) A certified true copy of the recorded executed mortgage release documents for all prior mortgages identified on the initial certified TSR, if applicable; and

(5) A certified true copy of any BIA approved and executed subordination agreements.

(c) The Loan Guarantee Certificate is conclusive evidence of the eligibility of the Loan for guarantee under this part. Such evidence will be incontestable in the hands of the bearer and the full faith and credit of the United States is pledged to the payment of amounts agreed to be paid by HUD as Security for such obligations.

(d) This section may not be construed to preclude HUD from conducting a post-endorsement review. With respect to the original Direct Guarantee Lender, HUD may establish defenses against the original Direct Guarantee Lender based on fraud or material misrepresentation. This section may not be construed to bar HUD from establishing partial defenses to the amount payable on the Section 184 Guaranteed Loan.

§ 1005.527 Post-endorsement review.

(a) HUD may review an endorsement case binder at any time, including but not limited to a quality control review of all documents in § 1005.503.

(b) Within three business days of a request by HUD, the Direct Guarantee Lender must make available for review, or forward to HUD, copies of the identified endorsement case binder(s).

(c) A Direct Guarantee Lender's failure to provide HUD access to any files may be grounds for sanctions in accordance with §§ 1005.905 and 1005.907.

(d) Based on HUD's review under paragraph (a) of this section, if HUD determines that:

(1) The Loan does not satisfy the requirements of subpart F of this part;

(2) The Direct Guarantee Lender or Sponsored Entity committed fraud or a material misrepresentation; or

(3) The Direct Guarantee Lender or Sponsored Entity had known or should have known of fraud or a material misrepresentation in violation of this part, such that the Loan should not have been approved by the Direct Guarantee Lender.

(e) HUD may request indemnification from the originating Direct Guarantee Lender and impose sanctions on the Direct Guarantee Lender and Sponsored Entity pursuant to §§ 1005.905 and 1005.907.

§ 1005.529 Indemnification.

(a) When HUD conducts a pre- or post-endorsement review and HUD determines there is an underwriting deficiency where the Loan should not have been approved, HUD may request the originating Direct Guarantee to indemnify HUD.

(b) Underwriting deficiencies with respect to the Section 184 Guaranteed Loan may include but is not limited to fraud or misrepresentation by the originating Direct Guarantee Lender.

(c) HUD will notify the originating Direct Guarantee Lender in writing when an indemnification is required.

(d) Under an indemnification, the originating Direct Guarantee Lender must reimburse HUD when a subsequent Holder files a claim and HUD suffers a financial loss.

(e) If the originating Direct Guarantee Lender fails to indemnify HUD, HUD may impose sanctions pursuant to §§ 1005.905 and 1005.907.

Subpart F—Section 184 Guaranteed Loan Fees

§ 1005.601 Scope and method of payment.

HUD shall charge a one-time Section 184 Upfront Loan Guarantee Fee and a recurring Annual Loan Guarantee Fee, which will be collected by a Direct Guarantee Lender or Servicer as required by §§ 1005.603 and 1005.607 and remitted to HUD as required by §§ 1005.605 and 1005.609. The fees collected by the Direct Guarantee Lender or Servicer on behalf of HUD shall be payable to HUD in cash, in the manner prescribed by Section 184 Program Guidance.

§ 1005.603 Upfront Loan Guarantee Fee.

At settlement, the Direct Guarantee Lender will collect from the Borrower a one-time Upfront Loan Guarantee Fee in an amount, not exceeding three percent of the principal obligation of the Section 184 Guaranteed Loan. The amount will be set by HUD through a notice in the **Federal Register.**

§ 1005.605 Remittance of Upfront Loan Guarantee Fee.

The Direct Guarantee Lender shall remit the Upfront Loan Guarantee Fee to HUD within 15 days after settlement, using the payment system as prescribed by Section 184 Program Guidance. The Direct Guarantee Lender shall provide an account reconciliation of the Upfront

Loan Guarantee Fee in the time and manner as may be prescribed in Section 184 Program Guidance.

§ 1005.607 Annual Loan Guarantee Fee.

(a) *Percentage of Annual Loan Guarantee Fee.* Where applicable the Servicer must collect a monthly installment for the Annual Loan Guarantee Fee from the Borrower in an amount, not exceeding one percent of the principal obligation of the loan. The percentage used to calculate the Annual Loan Guarantee Fee amount will be prescribed by notice in the **Federal Register**.

(b) *Payment of Annual Loan Guarantee Fee.* Where applicable, the Section 184 Guaranteed Loan shall require monthly payments by the Borrower to the Servicer in an amount equal to one-twelfth of the Annual Loan Guarantee Fee, payable by the Servicer to HUD in accordance with the Amortization Schedule issued with the Loan approval.

(c) *Amortization Schedule.* The amount of the Borrower's monthly installment will be based on an Amortization Schedule as prescribed in Section 184 Program Guidance.

§ 1005.609 Remittance of Annual Loan Guarantee Fee.

(a) Monthly installment of the Annual Loan Guarantee Fee shall be due and payable to HUD no later than the 15th day of each month, beginning in the month in which the Borrower is required to make the first monthly loan payment. Monthly payments of the Annual Loan Guarantee Fee must be submitted using a HUD prescribed payment system, as prescribed by Section 184 Program Guidance.

(b) Subject to the exception in paragraph (d) of this section, the Servicer shall continue to collect from the Borrower and pay HUD the monthly installment of the Annual Loan Guarantee Fee, without taking into account Borrower's default, Loss Mitigation, prepayments, agreements to postpone payments, or agreements to recast the loan.

(c) The Servicer shall adjust the monthly installment of the Annual Loan Guarantee Fee in accordance the schedule provided in § 1005.607(b). Notwithstanding paragraph (a) of this section, the Servicer shall refund to the Borrower any overpayment of Annual Loan Guarantee Fees collected from the Borrower, due to a delayed adjustment of the Loan Guarantee Fee, within 30 days of the overpayment. Failure to refund the Borrower within this timeframe will result in a penalty in accordance with § 1005.611.

(d) The Servicer shall cease collecting the monthly installment of the Annual Loan Guarantee Fee when the amortized loan to value ratio equals an amount less than 78 percent, as established by a schedule provided in § 1005.607(b). Notwithstanding paragraph (a) of this section, the Servicer shall refund to the Borrower any overpayment of Annual Loan Guarantee Fees collected when the loan-to-value ratio is less than 78 percent, within 30 days of the overpayment. Failure to refund the Borrower within this timeframe will result in penalty in accordance with § 1005.611.

(e) Annual Loan Guarantee Fees paid in accordance with the schedule provided in § 1005.607(b) shall not be refundable to the Borrower.

(f) If the Servicer submits the monthly installment of the Annual Loan Guarantee Fee to HUD after the due date, the amount paid must include the required payment of penalties pursuant to § 1005.611(c).

(g)(1) When transfer of servicing occurs in accordance with § 1005.707:

(i) The schedule of monthly installment payments provided in § 1005.607(b) must be provided to the new Servicer; and

(ii) The account reconciliation of the Upfront Guarantee Fee and Annual Loan Guarantee Fee due and remitted to HUD must be provided to the new Servicer.

(2) The new Servicer is responsible for compliance with all requirements of this part, including, but not limited to, any outstanding Annual Loan Guarantee Fee payments and penalties owed to HUD, or any Annual Loan Guarantee Fee adjustments or refunds due to the Borrower.

(3) If a transfer results in missed monthly installment(s) of the Annual Loan Guarantee Fee, the new Servicer shall pay the overdue installment(s) in a lump sum to HUD within 30 days of acquisition of the loan and include any applicable penalties in accordance with § 1005.611.

(h) The Direct Guarantee Lender shall provide an account reconciliation of the Annual Loan Guarantee Fee in the time and manner as may be prescribed in Section 184 Program Guidance.

§ 1005.611 HUD imposed penalties.

(a) *Prohibited penalty pass through.* The Direct Guarantee Lender or Servicer shall not recover or attempt to recover from the Borrower any penalties HUD imposes upon the Direct Guarantee Lender or Servicer.

(b) *Failure of Direct Guarantee Lender to timely remit Upfront loan guarantee to HUD.* (1) The Direct Guarantee Lender shall include a late fee if the Upfront Loan Guarantee Fee to is not remitted to HUD within 15 days of settlement.

(2) Failure to remit the Upfront Loan Guarantee Fee, with a late fee where applicable, may result in HUD rejecting the endorsement or claim case binder.

(c) *Failure of Servicer to timely remit the monthly installment of the Annual Loan Guarantee Fee to HUD.* (1) The Servicer shall include a late fee for each monthly installment of the Annual Loan Guarantee Fee remitted to HUD after the 15th of each month.

(2) Failure to remit monthly installment of the Annual Loan Guarantee Fee to HUD, with late fee, may result in HUD rejecting the claim case binder, where applicable.

(d) *Failure of Servicer to adjust the amount of the Annual Loan Guarantee Fee.* (1) When a Servicer fails to make the annual adjustment to the amount of the monthly installment of the Annual Loan Guarantee Fee in accordance with § 1005.607(b), the Servicer shall, in addition to reimbursing the Borrower as required in § 1005.609(c), pay HUD a penalty for each month the Servicer collects an overpayment of the Annual Loan Guarantee Fee.

(2) The Servicer shall provide annual written notice, in the manner prescribed by Section 184 Program Guidance to the Borrower prior to the scheduled change in the monthly installment of the Annual Loan Guarantee Fee, with such advance notice as required by 12 CFR 1026.9, or other applicable Federal law.

(e) *Failure to cease collection of the Annual Loan Guarantee Fee.* When a Servicer fails to cease collection of the monthly installment of the Annual Loan Guarantee Fee after the loan to value ratio reaches the threshold described in § 1005.609(d), the Servicer shall, in addition to reimbursing the Borrower as required in § 1005.609(d), pay HUD a penalty for each month the Servicer collects an overpayment of the Annual Loan Guarantee Fee.

(f) *Late fee and penalty amounts.* All reasonable late fees and penalty amounts under this section shall be prescribed by HUD.

Subpart G—Servicing

Servicing Section 184 Guaranteed Loans Generally

§ 1005.701 Section 184 Guaranteed Loan servicing generally.

This subpart identifies the servicing requirements for Section 184 Guaranteed Loans. All Section 184 Guaranteed Loans must be serviced by Section 184 approved Servicers, including Section 184 Guaranteed Loans

owned by Holders. Holders are responsible for all servicing actions, including the acts of its Servicers. Servicers are responsible for their actions in servicing Section 184 Guaranteed Loans, including actions taken on behalf of, or at the direction of, the Holder. Failure to comply with this subpart may result in the reduction of the claims amount in accordance with subpart H of this part or may subject Servicer to sanctions pursuant to subpart I of this part. HUD requires Servicers to comply all applicable Tribal, Federal, and State requirements.

§ 1005.703 Servicer eligibility and application process.

(a) To be eligible to service Section 184 Guaranteed Loans, a Direct Guarantee Lender, Non-Direct Guarantee Lenders, or other financial institution must be an approved mortgage Servicer for the Federal Housing Authority (FHA) or another agency of the Federal Government.

(b) All eligible Direct Guarantee Lenders, Non-Direct Guarantee Lenders and other financial institutions must apply to become a Servicer in accordance with Section 184 Program Guidance.

(c) As of [EFFECTIVE DATE OF FINAL RULE], Direct Guarantee Lenders servicing Section 184 Guaranteed Loans may request a waiver of § 1005.703(a).

§ 1005.705 Servicer approval.

(a) *Final approval.* Approval is signified by:

(1) Written notification from HUD that the Direct Guarantee Lender, Non-Direct Guarantee Lender, or other financial institution is approved as a Servicer under the Section 184 Program; and

(2) Agreement by the Direct Guarantee Lender, Non-Direct Guarantee Lender, or other financial institution to comply with requirements of this part and any applicable Federal, State, or Tribal law requirement.

(b) *Limitations on approval.* The Direct Guarantee Lender, Non-Direct Guarantee Lender or other financial institution may only be approved to service Section 184 Guaranteed Loans in areas where the Direct Guarantee Lender, Non-Direct Guarantee Lender, or financial institution is licensed, as applicable.

(c) *Denial of participation.* A Direct Guarantee Lender, Non-Direct Guarantee Lender, or other financial institution may be denied approval to become a Servicer if HUD determines the Direct Guarantee Lender, Non-Direct Guarantee Lender, or other financial institution does not meet the qualification requirements of § 1005.703. HUD will provide written notification of denial and of the right to submit a written appeal in accordance with § 1005.909.

§ 1005.707 Responsibility for servicing.

(a) *Program compliance.* (1) The Servicer must participate in HUD training on the Section 184 program and comply with this part and all Tribal, State, and Federal requirements.

(2) A Servicer shall provide written notification to HUD of any changes that affect qualifications under this subpart within a timeframe prescribed by Section 184 Program Guidance.

(b) *Sub-Servicer.* (1) If a Servicer elects to use a sub-Servicer, the sub-Servicer must be an approved Servicer under § 1005.705.

(2) Servicers are responsible for the actions of their sub-Servicers. The Servicer shall remain fully responsible to HUD for Section 184 Guaranteed Loan servicing in accordance with this subpart, and the actions of a sub-Servicer shall be considered the actions of the Servicer.

(c) *Change in Servicer.* (1) When the responsibility of servicing a Section 184 Guaranteed Loan is transferred from one Servicer to another, the acquiring Servicer shall assume responsibility for compliance with this part, this includes addressing any noncompliance by the former Servicer.

(2) The former Servicer must notify HUD of the change in Servicer within a timeframe and format prescribed by Section 184 Program Guidance.

(3) The acquiring Servicer shall provide notice to the Borrower of the transfer of servicing in accordance with 12 CFR 1024.33, or other Federal laws that may require such notice.

(4) HUD will hold the acquiring Servicer responsible for errors, omissions, and unresolved HUD review findings on the part of the losing Servicer (or losing sub-Servicer), discovered after the transfer is reported even when the errors or omissions took place prior to the transfer.

(d) *Transfer of servicing rights.* The Servicer must submit written notification to HUD, in a timeframe prescribed by Section 184 Program Guidance, of the transfer of servicing rights through the of acquisition or sale of any Section 184 Guaranteed Loans.

(e) *Reporting requirements.* (1) On a date and manner established by Section 184 Program Guidance, the Servicer shall report to HUD the status of all Section 184 Guaranteed Loans in its servicing portfolio.

(2) Servicer shall provide an Annual Loan Guarantee Fee reconciliation to the Borrower and HUD, in a manner and timeframe as prescribed by Section 184 Program Guidance.

(3) Servicer must also comply with any other reporting requirements under § 1005.903.

(4) The Servicer's failure to submit required reports on time may subject the Servicer to sanctions and civil money penalties pursuant to §§ 1005.905 and 1005.907.

(f) *Business change reporting.* Within a timeframe and form as prescribed by Section 184 Program Guidance, the Servicer shall provide written notification to HUD of:

(1) All changes in the Servicer's legal structure, including, but not limited to, mergers, acquisitions, terminations, name, location, control of ownership, and character of business;

(2) Staffing changes related to servicing Section 184 Guaranteed Loans; and

(3) Any sanctions by another supervising entity.

(4) Failure to report changes within the timeframe prescribed in Section 184 Program Guidance may result in sanctions in accordance with §§ 1005.905 and 1005.907.

(g) *Annual recertification.* (1) All Servicers are subject to annual recertification on a date and manner as prescribed by Section 184 Program Guidance. With each annual recertification, Servicers must submit updated contact information, current FHA recertification status, and other pertinent documents as prescribed by Section 184 Program Guidance.

(2) Servicers may request an extension of the recertification deadline in accordance with Section 184 Program Guidance.

(3) HUD will review the annual recertification submission and may request any further information required to determine recertification. HUD will provide written notification of approval to continue participation in the Section 184 Program or denial. A denial may be appealed pursuant to § 1005.909.

(4) If an annual recertification is not submitted by the reasonable deadline as prescribed in Section 184 Program Guidance, HUD may subject the Servicer to sanctions under § 1005.907.

(h) *Program ineligibility.* Servicer may be deemed ineligible for Section 184 Program participation when HUD becomes aware that the entity or any officer, partner, director, principal, manager, or supervisor of the entity was:

(1) Suspended, debarred, under a limited denial of participation (LDP), or otherwise restricted under 2 CFR part 2424, or under similar procedures of any other Federal agency;

(2) Indicted for, or have been convicted of, an offense that reflects adversely upon the integrity, competency, or fitness to meet the responsibilities of the Servicer to participate in the Title I or Title II programs of the National Housing Act, or Section 184 Program;

(3) Found to have unresolved findings as a result of HUD or other governmental audit, investigation, or review;

(4) Engaged in business practices that do not conform to generally accepted practices of prudent Servicers or that demonstrate irresponsibility;

(5) Convicted of, or have pled guilty or nolo contendere to, a felony related to participation in the real estate or mortgage Loan industry during the 7-year period preceding the date of the application for licensing and registration, or at any time preceding such date of application, if such felony involved an act of fraud, dishonesty, or a breach of trust or money laundering;

(6) In violation of provisions of the Secure and Fair Enforcement Mortgage Licensing Act of 2008 (12 U.S.C. 5101, *et seq.*) or any applicable provision of Tribal or State law; or

(7) In violation of 12 U.S.C. 1715z–13a or any other requirement established by HUD.

(i) *Records retention.* Servicers must maintain the servicing case binder for a period of three years beyond the date of satisfaction or maturity date of the Loan, whichever is sooner. However, where there is a payment of claim, the claim case binder must be retained for a period of at least five years after the final claim has been paid. Section 184 Program Guidance shall prescribe additional records retention time depending on the circumstances of the claim.

§ 1005.709 Providing information to Borrower and HUD.

(a) Servicers shall provide Section 184 Guaranteed Loan information to Borrowers and arrange for individual loan consultation on request. The Servicer must establish written procedures and controls to assure prompt responses to inquiries. At a minimum, the Servicer must provide contact information to the Borrower in accordance with 12 CFR 1024.36 and 1026.41, including:

(1) A written address a Borrower can use to request and submit information; and

(2) A toll-free telephone number a Borrower can use to verbally ask questions and seek information.

(b) All Borrowers must be informed of the system available for obtaining answers to loan inquiries, the Servicer's office from which needed information may be obtained, and reminded of the system at least annually.

(c) Within 30 days after the end of each calendar year, the Servicer shall furnish to the Borrower a statement of the interest paid, and of the taxes disbursed from the escrow account during the preceding year.

(d) At the Borrower's request, the Servicer shall furnish a statement of the escrow account sufficient to enable the Borrower to reconcile the account.

(e) Each Servicer of a Section 184 Guaranteed Loan shall deliver to the Borrower a written notice of any transfer of the Servicing of the Section 184 Guaranteed Loan. The notice must be sent in accordance with 12 CFR 1024.33(b)(3) and shall contain the information required by 12 CFR 1024.33(b)(4). Servicers must respond to Borrower inquiries pertaining to the transfer of Servicing in accordance with 12 CFR 1024.33.

(f) Servicers must respond to HUD's written or electronic requests for information concerning individual accounts within a reasonable timeframe established by Section 184 Program Guidance, or the deadline placed by other applicable law, whichever is sooner.

§ 1005.711 Assumption and release of personal liability.

(a) *Assumption.* Section 184 Guaranteed Loans may be fully assumed by eligible substitute Borrowers, if such assumption is approved by HUD and other required parties, including but not limited to a Tribe, TDHE, or the BIA. HUD approval will be based on the following:

(1) *Creditworthiness.* At least one person acquiring ownership must be determined to be creditworthy under subpart D of this part. If the Servicer is approved as a Direct Guarantee Lender, the Servicer performs a creditworthiness determination under § 1005.409. If the Servicer is not approved as a Direct Guarantee Lender, then the Servicer shall request a creditworthiness determination in a manner prescribed by Section 184 Program Guidance.

(2) *Trust Lands.* (i) The lease document may require Tribal and BIA approval of the assignment of the lease to the new Borrower. Servicers shall not proceed to closing on the assumption until and unless the Tribe has assigned the leasehold to the new Borrower, and it has been approved by the BIA.

(ii) The lease may contain other Conveyance restrictions. Servicer must review the lease for Conveyance restrictions and ensure the lease complies with § 1005.303(b)(2).

(b) *Fees.* The Servicer may collect from the Borrower the following fees and costs:

(1) A charge to compensate the Direct Guarantee Lender for reasonable and necessary expenses incurred as part of the assumption review and processing. HUD may establish limitations on the amount of any such charge.

(2) Reasonable and customary costs, but not more than the amount actually paid by the Direct Guarantee Lender, for any of the following items: credit report, verification of employment and the execution of additional release of liability forms.

(3) Additional fees and costs over and above the assumption fee and reasonable and customary costs cannot be assessed.

(c) *Release of liability.* At closing, the Servicer must release the existing Borrower from any personal liability on a form approved by HUD; the eligible and approved substitute Borrower assumes personal liability of the Section 184 Guaranteed Loan when the release is executed.

(d) *Modification of Loan Guarantee Certificate.* Upon completion of an assumption, the Servicer shall submit copies of the documentation required in this section to HUD, in a manner and form prescribed by HUD. HUD will subsequently issue a revised Loan Guarantee Certificate.

§ 1005.713 Due-on-sale provision.

A Section 184 Guaranteed Loan shall contain a due-on-sale clause permitting acceleration, in a form prescribed by Section 184 Program Guidance. The Servicer shall promptly advise HUD of any sale or other transfer that occurs without the approval of the Direct Guarantee Lender. If acceleration is permitted by applicable Tribal, Federal, or State law, the Servicer shall certify as to the legal authority and seek HUD's approval, in a form and manner prescribed by Section 184 Program Guidance. Within 30 days of receipt of HUD approval to accelerate, the Servicer shall notify the Borrower of default and acceleration.

§ 1005.715 Application of Borrower payments.

(a) Servicer shall comply with § 1005.509 with respect to the application of Borrower payments. The Servicer shall apply the payments in the following order:

(1) Escrow items, including monthly payments of the Annual Loan Guarantee Fee, rents, taxes, special assessments, and if required, flood insurance, fire and other hazard insurance premiums;

(2) Interest accrued on the Section 184 Guaranteed Loan;

(3) Principal of the Section 184 Guaranteed Loan; and

(4) Late charges, if permitted under the terms of the Section 184 Guaranteed Loan and subject to such conditions as HUD may prescribe.

(b) Partial Payments shall be applied in accordance with § 1005.723.

§ 1005.717 Administering escrow accounts.

(a) The Servicer shall not use escrow funds for any purpose other than that for which they were received. It shall segregate escrow commitment deposits, work completion deposits, and all periodic payments received on account of leasehold rents, taxes, assessments, monthly payments of Annual Loan Guarantee Fee, and insurance charges or premiums, and shall deposit such funds with one or more financial institutions in a special account or accounts that are fully insured by the Federal Deposit Insurance Corporation or the National Credit Union Administration. Leasehold rents on Trust Lands may require additional escrow segregation by Servicer's which HUD will prescribe in Section 184 Program Guidance.

(b) It is the Servicer's responsibility to ensure timely escrow disbursements and their proper application. Servicers must establish controls to ensure that accounts payable from the escrow account or the information needed to pay such accounts payable is obtained on a timely basis. Penalties for late payments for accounts payable from the escrow account must not be charged to the Borrower or HUD unless the Servicer can show that the penalty was the direct result of the Borrower's error or omission. The Servicer shall further comply with all requirements set forth in 12 CFR 1024.17, including method of calculations related to escrow, the methods of collection and accounting, and the payment of the accounts payable for which the money has been escrowed.

(c) The Servicer shall not initiate foreclosure for escrow account shortfalls resulting from advances made pursuant to this section.

(d) When a Loan Guarantee Certificate is terminated voluntarily or due to Borrower's prepayment, in total satisfaction of the Section 184 Guaranteed Loan, amounts in the escrow account designated to pay any HUD required program fees shall be remitted to HUD in a form approved by HUD at the time of the required reporting related to the voluntary termination or prepayment. When a Section 184 Guaranteed Loan is prepaid in full, amounts held in escrow for taxes, hazard insurance, or rents, if applicable, that are not yet due or incurred, shall be released to the Borrower.

§ 1005.719 Fees and costs after endorsement.

(a) After endorsement, the Servicer may collect reasonable and customary fees and costs from the Borrower only as provided in paragraphs (a)(1) through (14) of this section. The Servicer may collect these fees or costs from the Borrower only to the extent that the Servicer is not reimbursed for such fees or costs by HUD. Permissible fees and costs include:

(1) Late fee in accordance with § 1005.511;

(2) Costs for processing or reprocessing a check returned as uncollectible (where bank policy permits, the Servicer must deposit a check for collection a second time before assessing an insufficient funds charge);

(3) Fees for processing a change of ownership of the property;

(4) Fees and costs for processing an assumption of the Section 184 Guaranteed Loan in connection with the sale or transfer of the property;

(5) Costs for processing a request for credit approval incurred in the course of processing an assumption or substitute Borrower;

(6) Costs for substitution of a hazard insurance policy at other than the expiration of term of the existing hazard insurance policy;

(7) Costs for modification of the Section 184 Guaranteed Loan requiring recordation of the agreement, including those for extension of term or re-Amortization;

(8) Fees and costs for processing a partial release of the property;

(9) Attorney's and trustee's fees and costs actually incurred (including the cost of appraisals and advertising) when a Section 184 Guaranteed Loan has been referred to foreclosure counsel and subsequently the Section 184 Guaranteed Loan is reinstated. No attorney's fee and cost that exceeds the reasonable limits prescribed by Section 184 Program Guidance may be collected from the Borrower, unless approved by HUD;

(10) A trustee's fee, if the Security instrument provides for payment of such a fee, for execution of a satisfactory release when the deed of trust is paid in full;

(11) Where permitted by the Security instrument, attorney's fees and costs actually incurred in the defense of any suit or legal proceeding wherein the Servicer shall be made a party thereto by reason of the Section 184 Guaranteed Loan. No attorney's fee may be charged for the services of the Servicer's staff attorney or other employee;

(12) Property preservation costs incurred, subject to reasonable limits prescribed by Section 184 Program Guidance, or otherwise approved by HUD;

(13) Fees permitted for providing a beneficiary notice under applicable Tribal or State law, if such a fee is not otherwise prohibited by applicable law, under 12 CFR 1024.36; and

(14) Such other reasonable and customary costs as may be authorized by HUD.

(b) Reasonable and customary fees must be based upon the actual cost of the work performed, including out-of-pocket expenses. HUD may establish maximum fees and costs which are reasonable and customary in different geographic areas. Except as provided in this part, no fee or costs shall be based on a percentage of either the face amount of the Section 184 Guaranteed Loan or the unpaid principal balance due.

§ 1005.721 Enforcement of late fees.

(a) A Servicer shall not commence foreclosure when the Borrower's only default is his or her failure to pay a late fee(s).

(b) A late fee that may be assessed under the Section 184 Guaranteed Loan shall not justify return of a payment submission. However, if the Servicer thereafter notifies the Borrower of his obligation to pay a late fee, such a fee may be deducted from any subsequent payment or payments submitted by the Borrower or on his behalf if this is not inconsistent with the terms of the Section 184 Guaranteed Loan. Partial Payments shall be treated as provided in § 1005.723.

(c) A payment submission may be returned because of failure to include a late fee only if the Servicer notifies the Borrower before imposition of the charge of the amount of the monthly payment, the date when the late fee will be imposed, and either the amount of the late charge or the total amount due when the late fee is included.

(d) During the 60-day period beginning on the effective date of transfer of the Servicing of a Section 184 Guaranteed Loan, a late fee shall not be assessed. If a payment is received by the prior Servicer on or before the due date (including any applicable grace period allowed by the Section 184 Guaranteed Loan), no late fees shall be assessed by the new Servicer.

(e) A Servicer shall not assess a late fee for failure to pay a late fee, as prohibited under 12 CFR 1026.36.

§ 1005.723 Partial payments.

(a) A Servicer must have a written policy on how it handles Partial Payments, in compliance with this section and that policy shall be readily available to the public.

(b) Upon receipt of a Partial Payment, a Servicer must provide to the Borrower a copy of the Servicer's written Partial Payment policy and a letter explaining how it will handle the received Partial Payment. The Servicer may:

(1) Accept a Partial Payment and either apply it to the Borrower's account;

(2) Identify it with the Borrower's account number and hold it in a trust account pending disposition; or

(3) Return the Partial Payment(s) to the Borrower.

§ 1005.725 Handling prepayments.

Notwithstanding the terms of the Section 184 Guaranteed Loan, the Servicer shall accept a prepayment at any time and in any amount. Monthly interest on the Section 184 Guaranteed Loan must be calculated on the actual unpaid principal balance of the Section 184 Guaranteed Loan as of the date the prepayment is received, and not as of the next payment due date.

§ 1005.727 Substitute Borrowers.

Where an original Borrower requests the substitution of an existing Borrower on the Section 184 Guaranteed Loan:

(a) A Servicer who is Non-Direct Guarantee Lender or financial institution must obtain HUD approval for the substitution. A remaining original Borrower must be maintained and continue to be personally liable for the Section 184 Guaranteed Loan, notwithstanding any discharge entered in accordance with applicable Tribal, Federal, or State law.

(b) A Servicer who is a Direct Guarantee Lender may, subject to limitations established by HUD, approve an eligible substitute Borrower that meets the requirements for Section 184 Guaranteed Loans which they own or service, and need not obtain further without specific approval from HUD. A remaining original Borrower must be maintained and continue to be personally liable for the Section 184 Guaranteed Loan, notwithstanding any discharge entered in accordance with applicable Tribal, Federal, or State law.

Servicing Default Section 184 Guaranteed Loans

§ 1005.729 Section 184 Guaranteed Loan collection action.

A Servicer shall take prompt action to collect amounts due from Borrowers to minimize the number of accounts in default status. The Servicer must exhaust all reasonable possibilities of collection, including assessing the Borrower's financial circumstances for Loss Mitigation options in accordance with § 1005.739.

§ 1005.731 Default notice to Borrower.

(a) *Live contact.* (1) The Servicer shall establish or make good faith efforts to establish live contact with a Borrower in default not later than the 36th day of the Borrower's default and, promptly after establishing live contact, inform such Borrower about the availability of Loss Mitigation options.

(2) A good faith effort to establish live contact consists of reasonable steps under the circumstances to reach a Borrower, including telephoning a Borrower on more than one occasion and, if unable to establish live contact, sending written or electronic communication encouraging a Borrower to establish live contact with the Servicer.

(b) *Written notice.* The Servicer shall give written notice of default to the Borrower, in a format approved by HUD, no later than the end of the 45th day of a Borrower default. The Servicer must contact the Borrower, whether the Borrower lives in the same or a different location. If an account is reinstated and again enters default, a new default notice shall be sent to the Borrower, except that the Servicer is not required to send a second default notice to the same Borrower more often than once during any 180-day period. The Servicer may give additional or more frequent notices of default, at its discretion.

(c) *Content of the written notice.* The notice required by paragraph (b) of this section shall include:

(1) A statement encouraging the Borrower to contact the Servicer;

(2) Servicer contact information, including but not limited to the telephone number to access Servicer personnel and the Servicer's mailing address;

(3) A statement providing a brief description of examples of Loss Mitigation options that may be available from the Servicer and a statement how a Borrower may obtain more information about Loss Mitigation options;

(4) An outline of all critical Servicing deadlines under this subpart, including but not limited to the Servicer timeframe for evaluating a complete Loss Mitigation application, deadline for Borrower to select a Loss Mitigation option, Tribal notice under § 1005.757(a), if applicable, and the process for filing First Legal Action;

(5) Disclosure to the Borrower that they may be eligible for additional protections under Consumer Financial Protection Bureau regulations in 12 CFR chapter X;

(6) A Loss Mitigation application and submission instructions, including a statement that delays in submission of the Loss Mitigation application or incomplete submissions shall reduce the availability of certain Loss Mitigation options to the Borrower;

(7) The manner in which a Borrower can access the HUD list of homeownership counselors or counseling organizations, including a website(s) or toll-free telephone(s); and

(8) A statement informing the Borrower that the Servicer may make information available to local credit bureaus and prospective creditors.

(d) *Conflicts with other law.* Nothing in this section shall require a Servicer to communicate with a Borrower in a manner otherwise prohibited by applicable Tribal, Federal, or State law.

§ 1005.733 Loss mitigation application, timelines, and appeals.

(a) *Servicer response to Loss Mitigation application.* Within five days after the Servicer receives the Borrower's Loss Mitigation application, the Servicer must, in writing:

(1) Acknowledge receipt of the application;

(2) Determine if the application is complete or incomplete; and

(3) If incomplete, notify the Borrower which documentation is required and missing, and that submission of the missing documents is required no later than fourteen days from the date of the response to provide missing documents to the Servicer. If Borrower does not timely submit the requested documents, the Servicer must initiate live contact with the Borrower.

(b) *Servicer timeframe for evaluating complete Loss Mitigation application.* Within fourteen days of receipt of a complete application from Borrower, the Servicer must evaluate the application.

(c) *Notification of Servicer determination.* The Servicer shall provide written notification: (1) Informing the Borrower of all available Loss Mitigation options;

(2) Encouraging the Borrower to review all available Loss Mitigation options and to contact the Servicer with any questions;

(3) Encouraging Borrowers, when feasible, to consider pursuing simultaneous Loss Mitigation options, to the extent it is offered by the Servicer;

(4) Informing the Borrower that if no Loss Mitigation option is elected or if all elected Loss Mitigation options fail, the Servicer may proceed with Tribal notice under § 1005.757(a) or First Legal Action at 180 days of default in accordance with § 1005.757 or § 1005.761; and

(5) Informing the Borrower that, upon First Legal Action or the assignment of the Section 184 Guaranteed Loan to HUD, the Servicer may no longer offer or authorize a pre-foreclosure sale as an alternative to foreclosure, and that the primary alternative to foreclosure shall be a deed-in-lieu/lease-in-lieu of foreclosure, subject to applicable Tribal, Federal, or State law or contractual requirements.

(d) *Appeal.* (1) If, after the Borrower receives the Servicer's Loss Mitigation options, the Borrower disagrees with Servicer's Loss Mitigation determination, the Borrower may appeal in writing and request that the Servicer re-evaluate the Borrower's Loss Mitigation application. The Borrower must submit its appeal no later than 14 days from the date of notification of the Servicer's Loss Mitigation determination. Upon receipt of the Borrower's appeal of the Servicer's Loss Mitigation determination, the Servicer shall re-evaluate the Borrower's Loss Mitigation application within thirty days but may not use the same staff that made the initial Loss Mitigation determination and shall notify the Borrower of its appeal decision in writing.

(2) If the Borrower submits a timely written appeal, the 180-day deadline for First Legal Action shall be suspended during the appeal process.

§ 1005.735 Occupancy inspection.

(a) *Occupancy inspection.* An occupancy inspection is a visual inspection of a Section 184 Guaranteed Loan property by the Servicer to determine if the property is vacant or abandoned and to confirm the identity of any occupants.

(b) *Occupancy follow-up.* An occupancy follow-up is an attempt to communicate with the Borrower via letter, telephone, or other method of communication, other than on-site inspection, to determine occupancy when the Section 184 Guaranteed Loan remains in default after the initial occupancy inspection that did not result in determination of the Borrower's occupancy status.

(c) *Initial occupancy inspection.* The Servicer must perform the initial occupancy inspection after the 45th day of default but no later than the 60th day of the default when:

(1) A payment has not been received within 45 days of the due date or for any other defaults under the Section 184 Guaranteed Loan; and

(2) Efforts to reach the Borrower or occupant have been unsuccessful.

(d) *Occupancy follow-ups and continued inspections.* If the Servicer is unable to determine the Borrower's occupancy status through the initial occupancy inspection, the Servicer must perform occupancy follow-ups and, if necessary, occupancy inspections every 25–35 days from the last inspection until the occupancy status is determined.

(e) *Occupancy inspections during bankruptcy.* When payments are not submitted and a Borrower is a debtor in bankruptcy, the Servicer must contact either the bankruptcy trustee or the Borrower's bankruptcy attorney, if the Borrower is represented, for information concerning the occupancy status of the property or if an occupancy inspection is necessary or requires authorization. If the Servicer cannot determine that the property is vacant or abandoned during the period of the automatic stay, the Servicer must document the servicing case binder with evidence that it timely contacted the attorney or trustee.

(f) *Conflicts with other law.* Nothing in this section shall require a Servicer to conduct an inspection when prohibited by applicable Tribal, Federal, State, or local law.

§ 1005.737 Vacant property procedures.

If the Servicer determines through an occupancy inspection or occupancy follow-up that the property is vacant or abandoned, the Servicer must send a letter, via certified mail or other method providing delivery confirmation, to all Borrowers at the property address, or other known address of Borrower, informing them of the Servicer's determination that the property is vacant or abandoned. This letter must include the Servicer's contact information.

(a) If occupancy is verified through the delivery confirmation, the Servicer shall continue pursuing collection efforts required by § 1005.729 until the Servicer has the authority to proceed to First Legal Action.

(b) If the Servicer verifies through the delivery confirmation process that the property is vacant or abandoned; then the Servicer shall:

(1) Commence first-time vacant property inspection;

(2) Take appropriate property preservation and protection actions to secure and maintain the property;

(3) For properties on Trust Land, initiate Tribal First Right of Refusal notice under § 1005.757(a) within seven days;

(4) For fee simple properties, initiate First Legal Action within seven days;

(5) Continue to perform vacant property inspections every 25–35 days until the default is cured, the property is disposed of, or the bankruptcy court has granted approval for the Servicer to contact the Borrower or to take any required property preservation actions; and

(6) Retain documentation in the servicing case binder providing evidence of activities required by HUD in this section or otherwise directed by HUD.

(c) *Conflicts with other law.* Nothing in this section shall require a Servicer to communicate with a Borrower in a manner prohibited by applicable Tribal, Federal, or State law.

Servicing Default Section 184 Guaranteed Loans Under the Loss Mitigation Program

§ 1005.739 Loss mitigation.

(a) The purpose of Loss Mitigation is to attempt to cure the Borrower's default and minimize financial loss to HUD. Servicer must also comply with 12 CFR 1024.41 and any applicable Tribal, Federal, and State requirements.

(b) The Servicer must offer a Loss Mitigation option, if applicable to the Borrower and if practical under the circumstances, within 180 days of the date of default.

(c) Loss mitigation options include:

(1) A forbearance plan;

(2) Assumption;

(3) A loan modification;

(4) Pre-foreclosure sale;

(5) A deed-in-lieu/lease-in-lieu of foreclosure; or

(6) Other options, as may be prescribed in Section 184 Program Guidance.

(d) A Loss Mitigation review shall, to the greatest extent possible, be based on a full financial assessment of the Borrower at time of default, and the collection technique(s) must take into account the circumstances particular to each Borrower.

(e) HUD may prescribe conditions and requirements for the eligibility and appropriate use of Loss Mitigation options.

(f) Within 180 days of default, if the Borrower is offered a Loss Mitigation option, other than loan modification, and subsequently fails to meet the Loss

Mitigation option requirements, the Servicer shall within the time period as may be established by Section 184 Program Guidance of the failure of the Loss Mitigation, determine whether Borrower should continue with the current Loss Mitigation option or reassess the Borrower for an alternate Loss Mitigation option.

(1) Upon competition of the Loss Mitigation assessment, the Servicer must notify the Borrower within two days of the Loss Mitigation option failure and any possible additional Loss Mitigation options.

(2) The Borrower shall respond to the Servicer within seven days and accept any offer of Loss Mitigation, or the Servicer will proceed with foreclosure or Tribal First Right of Refusal notice under § 1005.757(a).

(g) If the Borrower is satisfactorily performing under a Loss Mitigation option, other than a loan modification, at 180 days after default but subsequently fails to perform, the Servicer shall follow 12 CFR part 1024 (Regulation X) and, for Trust Land, initiate Tribal First Right of Refusal notice under § 1005.757(a) within five days of the Loss Mitigation option failure.

(h) Documentation must be maintained for the initial and all subsequent evaluations and resulting Loss Mitigation actions in the servicing case binder in accordance with § 1005.219(d)(2).

(i) A Servicer that is found to have failed to engage in and comply with Loss Mitigation as required under this subpart may be subject to enforcement action by HUD, including but not limited to sanctions under §§ 1005.905 and 1005.907.

§ 1005.741 Notice to Tribe and BIA—Borrower default.

(a) When two consecutive Section 184 Guaranteed Loan payments are in default or sixty days after other default under the Section 184 Guaranteed Loan, the Servicer shall provide notice of default to:

(1) The BIA, for Section 184 Guaranteed Loan property that is on Trust Land, in accordance with applicable requirements under 25 CFR part 162; and,

(2) The Tribe, for any Section 184 Guaranteed Loan property where a Borrower has provided consent of notification in accordance with § 1005.501(j).

(b) The Servicer shall continue exploring Loss Mitigation options, consistent with the requirements under this subpart, with the Borrower during the notification process to the Tribe or BIA.

§ 1005.743 Relief for Borrower in military service.

(a) *Postponement of principal payments.* If the Borrower is a person in ''military service,'' as such term is defined in the Servicemembers Civil Relief Act (50 U.S.C. 3901–4043), the Servicer may, by written agreement with the Borrower, postpone for the period of military service and three months thereafter any part of the monthly payment which represents the Amortization of principal. The agreement shall contain a provision for the resumption of monthly payments after such period in amounts which will completely amortize the Section 184 Guaranteed Loan within the maturity as provided in the original loan term.

(b) *Forbearance.* Forbearance plans may be available to Borrowers in military service pursuant to § 1005.745(e).

(c) *Postponement of foreclosure.* If at any time during default the Borrower is a person in ''military service,'' as such term is defined in the Servicemembers Civil Relief Act, the period during which the Borrower is in such military service shall be excluded in computing the period within which the Servicer shall commence First Legal Action to acquire the property or Tribal notice under § 1005.757(a). No postponement or delay in the prosecution of foreclosure proceedings during the period the Borrower is in such military service shall be construed as failure on the part of the Servicer to exercise reasonable diligence in prosecuting such proceedings to completion as required by this subpart.

§ 1005.745 Forbearance plans.

(a) *General.* Forbearance plans are arrangements between a Servicer and Borrower that may allow for a period of reduced or suspended payments and specific terms for the repayment plan.

(b) *Informal forbearance.* Informal forbearance plans are oral agreements, where permitted under Tribal or State law, between a Servicer and Borrower allowing for reduced or suspended payments and may provide specific terms for repayment.

(1) *Eligibility.* The Servicer may offer an informal forbearance plan to a Borrower with a delinquent Section 184 Guaranteed Loan who is not experiencing a loss of income or an increase in living expenses that can be verified.

(2) *Duration.* The period shall be three months or less.

(c) *Formal forbearance.* Formal forbearance plans are written agreements executed by the Servicer and Borrower, allowing for reduced or suspended payments and such plans may include specific terms for repayment.

(1) *Eligibility.* The Servicer may offer a formal forbearance plan when:

(i) The Borrower is not experiencing a loss of income or increase in living expenses that can be verified;

(ii) The Servicer determines that 85 percent of the Borrower's surplus income is sufficient to reinstate within six months; or

(iii) If the Servicer determines that the Borrower is otherwise ineligible for other Loss Mitigation options but has sufficient surplus income or other assets that could repay the indebtedness.

(2) *Agreement.* The Servicer shall execute a written agreement with the Borrower outlining the terms and conditions of the formal forbearance. The Servicer must include in the formal forbearance agreement a provision for the resumption of monthly payments on a date certain, with repayment in amounts which will completely reinstate the Section 184 Guaranteed Loan no later than the original maturity date. The Servicer must retain in the servicing case binder a copy of the written formal forbearance agreement postponing principal and interest payments.

(3) *Duration.* The repayment period shall be equal to or greater than three months but not to exceed six months, unless authorized by HUD.

(4) *Required documents.* The Servicer must obtain from the Borrower any necessary supporting documentation and retain this documentation in the servicing case binder.

(5) *Property condition.* The Servicer must conduct any review it deems necessary, including a property inspection, when the Servicer has reason to believe that the physical condition of the property adversely impacts the Borrower's use or ability to support the debt as follows:

(i) Financial information provided by the Borrower indicating large expenses for property maintenance;

(ii) The Servicer receives notice from local government or other third parties regarding property condition; or

(iii) The property may be affected by a disaster event.

(iv) If significant maintenance costs contributed to the default or are affecting the Borrower's ability to make payments under the loan or formal forbearance agreement, the Servicer may provide in the formal forbearance agreement a period of loan forbearance

during which repairs specified in the agreement will be completed at the Borrower's expense.

(d) *Special forbearance-unemployment.* The special forbearance-unemployment Loss Mitigation option is available when one or more of the Borrowers has become unemployed and the loss of employment has negatively affected the Borrower's ability to continue to make their monthly Section 184 Guaranteed Loan payment.

(1) *Eligibility.* The Servicer must ensure that the Borrower meets all the following eligibility requirements:

(i) The Section 184 Guaranteed Loan must be at least three months in default.

(ii) The Borrower is experiencing a verified loss of income or increase in living expenses due to loss of employment.

(iii) The Borrower must continue to occupy the property as a Principal Residence.

(iv) The Borrower must have a verified unemployment status and no Borrower is currently receiving continuous income; or an analysis of the Borrower's financial information indicates that special forbearance-unemployment is the best or only option available for the Borrower.

(2) *Agreement.* The Servicer shall execute a written special forbearance-unemployment agreement with the Borrower outlining the terms and conditions of the special forbearance—unemployment. The Servicer must include in the special forbearance-unemployment agreement a provision for the resumption of monthly payments on a date certain, with repayment in amounts which will completely reinstate the Section 184 Guarantee Loan no later than the original maturity. The Servicer must retain in the servicing case binder a copy of the written special forbearance-unemployment agreement postponing principal and interest payments.

(3) *Duration.* The repayment period shall not exceed six months. During this repayment period where Borrower is in compliance with the Special Forbearance-Unemployment Agreement, the Servicer shall not proceed to filing of First Legal Action or initiating Tribal First Right of Refusal notice under § 1005.757(a) until expiration or default of the Agreement.

(4) *Required documents.* The Servicer must obtain from the Borrower such supporting third party documentation, including receipts of unemployment benefits or an affidavit signed by the Borrower, stating the date that the Borrower became unemployed and stating that the Borrower is actively seeking, and is available, for employment. The Servicer must retain this documentation in the servicing case binder.

(5) *Property condition.* The Servicer must conduct any review it deems necessary, including a property inspection, when the Servicer has reason to believe that the physical condition of the property adversely impacts the Borrower's use or ability to support the debt as follows:

(i) Financial information provided by the Borrower indicating large expenses for property maintenance;

(ii) The Servicer receives notice from local government or other third parties regarding property condition; or

(iii) The property may be affected by a disaster event.

(iv) If significant maintenance costs contributed to the default or are affecting the Borrower's ability to make payments under the Section 184 Guaranteed Loan or special forbearance-unemployment agreement, the Servicer may provide in the special forbearance-unemployment agreement a period of forbearance during which repairs specified in the agreement will be completed at the Borrower's expense.

(e) *Special forbearance-servicemember.* The Servicer may, by written special forbearance-servicemember agreement with the Borrower, postpone any part of the monthly Section 184 Guaranteed Loan that represents amortization of principal, for the period permitted by HUD under § 1005.743.

(1) *Eligibility.* The servicemember must be in active-duty military service and meet the criteria established in 50 U.S.C. 3911. Dependents of servicemembers are entitled to protections in limited situations per the Servicemembers Civil Relief Act, as amended.

(2) *Duration.* The repayment period shall be for the period of military service and three months thereafter.

(3) *Required documents.* The Borrower shall provide Servicer with a copy of the servicemember's deployment orders.

(4) *Agreement.* (i) The Servicer shall execute a written special forbearance-servicemember agreement with the Borrower outlining the terms and conditions of the special forbearance-servicemember. The Servicer must include in the special forbearance-servicemember agreement a provision for the resumption of monthly payments on a date certain, with repayment in amounts which will completely reinstate the Section 184 Guaranteed Loan no later than the original maturity date. The Servicer must retain in the servicing case binder a copy of the written special forbearance-servicemember agreement postponing principal and interest payments.

(ii) The Servicer shall comply with all applicable requirements under the Servicemembers Civil Relief Act.

(f) *Continued review and re-evaluation.* The Servicer shall monitor the Borrower's compliance with an agreement under § 1005.743 every 30 days, until the end of the agreement.

§ 1005.747 Assumption.

The Servicer shall explore assumption as a Loss Mitigation option with the Borrower in accordance with § 1005.711.

§ 1005.749 Loan modification.

(a) *General.* A Section 184 Guaranteed Loan modification may include a change in one or more of the following: interest rate; capitalization of delinquent principal, interest or escrow items; or re-amortization of the balance due. A Section 184 Guaranteed Loan modification may not be used as a means to reinstate the Section 184 Guaranteed Loan prior to sale or assumption.

(b) *Eligibility.* The Servicer must ensure that the Borrower is able to support the monthly loan payment after the loan is modified.

(c) *Borrower qualifications.* The Servicer must ensure that the Borrower meets the following eligibility criteria:

(1) At least 12 months have elapsed since the closing date of the original Section 184 Guaranteed Loan.

(2) The Borrower has not executed a loan modification agreement in the past 24 months. The number of loan modification agreements may be limited as prescribed by Section 184 Program Guidance. The Servicer may approve the first loan modification agreement under the Loan, and HUD must approve any subsequent loan modifications.

(3) The Borrower's default is due to a verified loss of income or increase in living expenses.

(4) One or more Borrowers receives continuous income sufficient to support the monthly payment under the modified rate and term, although not sufficient to sustain the original Section 184 Guaranteed Loan and repay the arrearage.

(5) The Borrower's minimum surplus income and percentage of net income shall be prescribed by HUD.

(6) Eighty-five percent of the Borrower's surplus income is insufficient to cure arrears within six months.

(7) The Borrower's monthly payment, which consists of principal, interest,

taxes, insurance, and other escrow, can be reduced by the greater of 10 percent of the existing monthly Section 184 Guaranteed Loan payment amount or $100, using an agreed upon interested rate in accordance with § 1005.451 and amortizing for a term up to 30 years or any other period as may be prescribed by HUD.

(8) The Borrower has successfully completed a three-month trial payment plan based on the Section 184 Guaranteed Loan estimated modification monthly payment amount.

(d) *Property conditions.* The Servicer must conduct any review it deems necessary, including a property inspection, when the Servicer has reason to believe that the physical conditions of the property adversely impact the Borrower's use or ability to support the debt as follows:

(1) Financial information provided by the Borrower indicates large expenses for property maintenance;

(2) The Servicer receives notice from local government or other third parties regarding property condition; or

(3) The property is affected by a disaster event.

(e) *Trial payment plans.* A trial payment plan is a written agreement executed by all parties on the Section 184 Guaranteed Loan, for a minimum period of three months, during which the Borrower must make the agreed-upon consecutive monthly payments prior to execution of the final loan modification.

(1) *Trial payment plan terms.* The Servicer must ensure that the following apply to interest rates and monthly payment amounts under trial payment plan:

(i) The interest rate for the trial payment plan and the loan modification must in accordance with § 1005.451.

(ii) The interest rate is established when the trial payment plan is offered to the Borrower.

(iii) The established monthly loan modification payment must be the same or less than the established monthly trial payment.

(2) *Start of trial payments.* The Servicer must send the proposed trial payment plan agreement to the Borrower at least 30 days before the date the first trial payment is due.

(3) *Trial payment plan signatures.* (i) All parties on the Section 184 Guaranteed Loan and all parties that will be subject to the modified loan must execute the trial payment plan agreement unless:

(A) A Borrower or co-Borrower is deceased;

(B) A Borrower and a co-Borrower are divorced; or

(C) A Borrower or co-Borrower on the Section 184 Guaranteed Loan has been released from liability as the result of an approved substitute Borrower.

(ii) When a Borrower uses a non-Borrower household member's income to qualify for a loan modification, the non-Borrower household member must be on the modified note and Section 184 Guaranteed Loan and sign the trial payment plan agreement.

(4) *Application of trial payments.* The Servicer must treat payments made under the trial payment plan as Partial Payments, held in a suspense account and applied in accordance with procedures in the Section 184 Program Guidance and applicable Federal regulations.

(5) *End of trial payment plan period.* The Servicer must offer the Borrower a permanent loan modification after the Borrower's successful completion of a trial payment plan.

(6) *Trial payment plan failure.* The Borrower fails a trial payment plan when one of the following occurs:

(i) The Borrower does not return the executed trial payment plan agreement within the month the first trial payment is due;

(ii) The Borrower vacates or abandons the property; or

(iii) The Borrower does not make a scheduled trial payment plan payment by the last day of the month it was due.

(7) *Alternatives to foreclosure after trial payment plan failure.* If a Borrower fails to successfully complete a trial payment plan, the Servicer must:

(i) Provide notice to the Borrower of the failure to comply with the trial payment plan; and

(ii) Offer the Borrower the opportunity for a deed-in-lieu/lease-in-lieu of foreclosure, with seven days to respond to the offer.

(8) *Funds remaining at the end of trial payment period.* (i) At the end of a successful trial payment plan, any remaining funds that do not equal a full payment must be applied to any escrow shortage or be used to reduce the amount that would be capitalized onto the principal balance.

(ii) If the Borrower does not complete the trial payment plan, the Servicer must apply all funds held in suspense to the Borrower's account in the established order of priority.

(9) *Reporting of trial payment plans.* The Servicer must report the trial payment plans to HUD in the manner prescribed in Section 184 Program Guidance.

(f) *Loan modification documents.* HUD does not require a specific format for the loan modification documents; however, the Servicer must use documents that conform to all applicable Tribal, Federal, and State laws.

(g) *Post-modification review and modification of Loan Guarantee Certificate.* Upon completion of a successful trial payment plan and within 30 days of the execution of the loan modification documents, the Servicer shall provide copies of the loan modification documents to HUD. The Servicer shall comply with additional processing instructions as prescribed by Section 184 Program Guidance.

§ 1005.751 Pre-foreclosure sale.

(a) *General.* A pre-foreclosure sale, also known as a short sale, refers to the sale of real estate that generates proceeds that are less than the amount owed on the property and any junior lien holders have agreed to release their liens and forgive the deficiency balance on the real estate.

(b) *Eligibility.* To be eligible for a pre-foreclosure sale, a Servicer must ensure:

(1) The Section 184 Guaranteed Loan was originated at least 12 months prior to default;

(2) Default was due to an adverse and unavoidable financial situation impacting the Borrower;

(3) The property has a current fair market value that equal to or less than the unpaid principal balance;

(4) The Borrower elected the pre-foreclosure sale option within 120 days from default; and

(5) All other requirements of the pre-foreclosure sale Loss Mitigation option under this section are met.

(c) *Surchargeable damages.* Surchargeable damage is damage to the Section 184 Guaranteed Loan property caused by fire, flood, earthquake, tornado, boiler explosion (for condominiums only) or Servicer neglect. The Servicer is responsible for the cost of surchargeable damage. The Servicer must request HUD approval before approving the use of the pre-foreclosure sale Loss Mitigation option when the property has sustained surchargeable damage. If the damage is not surchargeable damage, the Servicer is not required to obtain HUD approval prior to approving the Approval to Participate Agreement with Borrower. The Servicer must comply with paragraph (l) of this section where a hazard insurance claim must be filed.

(d) *Cash reserves.* Before executing a pre-foreclosure sale agreement as described in paragraph (h) of this section, Servicer must calculate the Borrower's cash reserve contribution.

(1) The cash reserve contribution shall come from non-retirement liquid assets, which may be available for withdrawal

or liquidation from Borrower's financial institutions. Servicer shall calculate the total cash reserves using the highest ending balance of each cash reserve asset.

(2) The Servicer must require the Borrower with cash reserves greater than the contribution threshold to contribute 20 percent of the total amount exceeding the contribution threshold towards the Section 184 Guaranteed Loan debt. The Servicer must not require the Borrower to contribute more than the difference between the unpaid principal balance and the appraised value of the property. The Servicer must give written notice to the Borrower designating the amount of the Borrower's cash reserve contribution that is to be applied towards the transaction.

(3) If the cash reserve calculation returns an amount at or below the contribution threshold amount, or a negative amount, the Servicer is not required to obtain a contribution from the Borrower in connection with the transaction.

(e) *Condition of title or Title Status Report.* (1) For Section 184 Guaranteed Loans on fee simple lands, a Servicer must ensure the property has Good and Marketable Title. Before approving a pre-foreclosure sale Loss Mitigation option, the Servicer must obtain title evidence or a preliminary report verifying that the title is not impaired by unresolvable title defects or junior liens that cannot be discharged.

(2) For Section 184 Guaranteed Loans on Trust Land, the Servicer shall obtain a certified Title Status Report from the BIA. Before approving a pre-foreclosure sale Loss Mitigation option, the Servicer must verify that the property is not encumbered by unresolvable title defects or junior liens that cannot be discharged.

(f) *Discharge of junior liens.* The Servicer must contact all junior lienholders to verify the Borrower has secured a discharge of the junior liens.

(g) *Property list price and valuation*—(1) *List price.* The Servicer must ensure that the Borrower lists the property for sale at no less than the ''as-is'' value, as determined by an appraisal completed in accordance with the requirements in § 1005.457.

(2) *Appraisals.* The Servicer must obtain a standard electronically formatted appraisal performed by an FHA Appraiser Roster pursuant to the following requirements:

(i) The appraisal must contain an ''as-is'' fair market value for the subject property;

(ii) A copy of the appraisal must be provided to HUD. A copy of the appraisal must be provided to the Borrower or sales agent, upon request;

(iii) The ''as-is'' fair market value used for a pre-foreclosure sale transaction is valid for 120 days; and

(iv) A Servicer must present HUD with a request for a variance to approve a pre-foreclosure sale transaction if one of the following conditions exists:

(A) The current appraised value of the property is less than the unpaid principal balance by an amount of $75,000 or greater;

(B) The appraised value is less than 50 percent of the unpaid principal balance; or

(C) The appraisal is deemed unacceptable because the as-is value cannot be affirmed using a broker's price opinion or automated valuation model within 10 percent of the value. This section is not applicable to property on Trust Land unless there is a viable real estate market;

(v) The Servicer must note on the variance request the specific reason for the request and attach any supporting documents needed for HUD review;

(vi) The Servicer must obtain HUD approval before authorizing the marketing of the property; and

(vii) All pre-foreclosure appraisals must be accompanied by a broker's price opinion or an automated valuation model, unless the property is located on Trust Land.

(h) *Required documents.* After determining that a Borrower and property meet the pre-foreclosure sale eligibility requirements, the Servicer shall send to the Borrower:

(1) *Pre-foreclosure Sale Approval to Participate Agreement.* The agreement, on a form prescribed by Section 184 Program Guidance, shall list the pre-foreclosure sale requirements, including the date by which the Borrower's sales contract must be executed during the pre-foreclosure sale marketing period and applicable cash reserve amount; and

(2) *Pre-foreclosure addendum.* The addendum shall be in the form prescribed by Section 184 Program Guidance. The pre-foreclosure sale addendum must be fully executed at closing.

(i) *Delivery of documents to Borrower.* Documents listed under paragraphs (h)(1) and (2) of this section must be sent to the Borrower via methods providing delivery confirmation with a date and time stamp of delivery. The Servicer must inform the Borrower that the documents must be signed and returned to the Servicer within 10 days of receipt.

(j) *Copies to HUD.* The Servicer must send signed copies of the documents in paragraphs (h)(1) and (2) of this section to HUD within 15 days of receipt from the Borrower.

(k) *Tribal notification for properties on Trust Land.* At the same time the Servicer sends the approval to participate agreement to the Borrower, in accordance with the requirements as prescribed by Section 184 Program Guidance, the Servicer shall send a notice to the Tribe and the TDHE of the option to assume the Section 184 Guaranteed Loan or purchase the property.

(l) *Use of a real estate broker.* The Borrower is responsible for retaining the services of a HUD-approved real estate broker/agent within seven days of the signed approval to participate agreement. For Trust Land, the Borrower may request, through the Servicer, an exception to this section. If an exception is granted, HUD will work with the Borrower, Servicer and Tribe or TDHE to sell the property or pursue another Loss Mitigation option.

(m) *Required listing disclosure.* The Servicer shall require the listing agreement between the seller and the agent/broker to include the following cancellation clause: ''Seller may cancel this Agreement prior to the ending date of the listing period without advance notice to the Broker, and without payment of a commission or any other consideration if the property is conveyed to HUD or the Holder. The sale completion is subject to approval by the Servicer and HUD.'' This section is not applicable to property on Trust Land unless a HUD-approved real estate broker/agent is utilized.

(n) *Pre-foreclosure sale marketing, settlement period, failure to complete pre-foreclosure sale.* The Borrower has a timeframe, as prescribed by Section 184 Program Guidance, seven days from the date of the signed approval to participate agreement to market the property in the Multiple Listing Service, or other marketing resource if the property is on Trust Land.

(1) The property must be marketed in the Multiple Listing Service or other marketing resource for a timeframe as prescribed by Section 184 Program Guidance before Borrower may consider any offers.

(2) During the marketing period, Servicers must conduct a monthly review of the property's marketing status with the real estate broker/agent or the Tribe or TDHE, for property on Trust Land.

(3) The maximum marketing period for the sale of the property is four months from the execution date of the approval to participate agreement and the date of the property settlement. If

there is a signed contract of sale, but property settlement has not occurred by the end of the fourth month, the marketing period may be extended up to two months to allow for closing to occur.

(4) Within 30 days of the end the marketing period, or no earlier than 120 days of default, whichever is later, if no settlement has occurred, Servicer shall provide electronic or written notice to the Borrower of the Borrower's default under the pre-foreclosure sale agreement and present the agreed upon deed-in-lieu/lease-in-lieu of foreclosure, with title being taken in the name of the Secretary. The Borrower shall have ten days from the date of the notice to respond in writing or by electronic means. If the Servicer receives no response or if the Servicer receives notice of the Borrower's rejection of the alternative to foreclosure, the Servicer must initiate First Legal Action or Tribal First Right of Refusal within five days of the Borrower's deadline to respond or actual rejection response date, whichever is sooner.

(o) *Property inspections and maintenance.* The Servicer shall inspect the property in accordance with § 1005.735 and follow § 1005.739, where applicable.

(p) *Disclosure of damage after pre-foreclosure sale approval.* In the event the property becomes damaged, the Borrower must report damage to the Servicer in accordance with the pre-foreclosure sale agreement. When the Servicer becomes aware that the property has sustained damage after a Borrower has received the approval to participate agreement, the Servicer must evaluate the property to determine if it continues to qualify for the pre-foreclosure sale program or terminate participation if the extent of the damage changes the property's fair market value.

(q) *Hazard insurance claim.* Where applicable, the Servicer must work with the Borrower to file a hazard insurance claim and either: use the proceeds to repair the property; or adjust the claim by the amount of the insurance settlement (non-surchargeable damage) or the Government's repair cost estimate.

(r) *Evaluation of offers.* The Servicer must receive from the listing real estate broker/agent an offer that yields the highest net return to HUD and meets HUD's requirements for bids, as follows:

(1) *Real estate broker/agent to ensure execution of documents.* The real estate broker/agent must ensure that the accepted offer and the pre-foreclosure sale addendum are signed by all applicable parties before submitting to the Servicer for approval.

(2) *Arm's Length Transaction.* The transaction must be an Arm's Length Transaction meaning the transaction must be between two unrelated parties who are each acting in their own best interest.

(3) *Back-up offers.* Once an offer has been submitted to the Servicer for approval, the real estate broker/agent must retain any offer that the seller elects to hold for ''back-up'' until a determination has been made on the previously submitted offer.

(s) *Contract approval by Servicer*—(1) *Review of sales contract.* In reviewing the contract of sale, the Servicer must:

(i) Ensure that the pre-foreclosure sale is an outright sale of the property and not a sale by assumption.

(ii) Review the sales documentation to determine that there are no hidden terms or special agreements existing between any of the parties involved in the pre-foreclosure sale transaction; and no contingencies that might delay or jeopardize a timely settlement.

(iii) Determine that the property was marketed pursuant to HUD requirements in this part.

(iv) Not approve a Borrower for a pre-foreclosure sale if the Servicer knows or has reason to know of the Borrower's fraud or misrepresentation of information.

(2) *Sales Contract Review period.* After receiving an executed contract of sale and pre-foreclosure sale addendum from the Borrower, the Servicer must send to the Borrower a Sales Contract Review, on a form prescribed by Section 184 Program Guidance, no later than five business days after the Servicer's receipt of an executed contract for sale.

(3) *Net sale proceeds.* (i) Net sale proceeds are the proceeds of a pre-foreclosure sale, calculated by subtracting reasonable and customary closing and settlement costs from the property sales price.

(ii) Regardless of the property sale price, a Servicer may only approve a pre-foreclosure sale contract for sale if the net sale proceeds are at or above minimum allowable thresholds established by HUD. The net sale proceeds must conform to the requirements on the Pre-Foreclosure Sale Approval to Participate Agreement.

(iii) The Servicer is liable for any claim overpayment on a pre-foreclosure sale transaction that closes with less than the required net sale proceeds, unless a variance has been granted by HUD.

(4) *Unacceptable settlement costs.* The Servicer must not include the following costs in the Net Sale Proceeds calculation:

(i) Repair reimbursements or allowances;

(ii) Home warranty fees;

(iii) Discount points or loan fees;

(iv) Servicer's title insurance fee; and

(v) Third-party fees incurred by the Servicer or Borrower to negotiate a pre-foreclosure sale.

(5) *Other third-party fees.* (i) With the exception of reasonable and customary real estate commissions, the Servicer must ensure that third-party fees incurred by the Servicer or Borrower to negotiate a pre-foreclosure sale are not included on the Closing Disclosure or similar legal documents unless explicitly permitted by Tribal or State law.

(ii) The Servicer, its agents, or any outsourcing firm it employs must not charge any fee to the Borrower for participation in the pre-foreclosure sale.

(t) *Closing and post-closing responsibilities.* For the purpose of this section, with respect to Trust Land, the closing agent may be selected by the Tribe or TDHE.

(1) *Closing worksheet.* Prior to closing, the Servicer must provide the closing agent with a Closing Worksheet, on a form prescribed by HUD, listing all amounts payable from net sale proceeds; and a pre-foreclosure sale addendum signed by all parties.

(2) *Servicer review of final terms of pre-foreclosure sale transaction.* The Servicer will receive from the closing agent a calculation of the actual net sale proceeds and a copy of the Closing Disclosure or similar legal document. The Servicer must ensure that:

(i) The final terms of the pre-foreclosure sale transaction are consistent with the purchase contract;

(ii) Only allowable settlement costs have been deducted from the seller's proceeds;

(iii) The net sale proceeds will be equal to or greater than the allowable thresholds;

(iv) A Closing Worksheet form is included in the claim case binder; and

(v) It reports the pre-foreclosure sale to consumer reporting agencies.

(3) *Closing agent responsibilities after final approval.* Once the Servicer gives final approval for the pre-foreclosure sale and the settlement occurs, the closing agent must:

(i) Pay the expenses out of the Net Sale Proceeds and forward the Net Sale Proceeds to the Servicer;

(ii) Forward a copy of the Closing Disclosure or similar legal document to the Servicer to be included in the claim case binder no later than three business days after the pre-foreclosure sale transaction closes; and,

(iii) Sign the pre-foreclosure sale addendum on or before the date the pre-

foreclosure sale transaction closes, unless explicitly prohibited by Tribal or State statute.

(4) *Satisfaction of debt.* Upon receipt of the portion of the net sale proceeds designated for Section 184 Guaranteed Loan satisfaction, the Servicer must apply the funds to the outstanding balance and discharge any remaining debt, release the lien in the appropriate jurisdiction, and may file a claim.

(5) *Discharge of junior liens.* The Servicer must verify the pre-foreclosure sale will result in the discharge of junior liens as follows:

(i) If the Borrower has the financial ability, the Borrower must be required to satisfy or otherwise obtain release of liens.

(ii) If no other sources are available, the Borrower may obligate up to a maximum amount from sale proceeds towards discharging the liens or encumbrances, such maximum amount will be prescribed by HUD.

(u) *Early termination of pre-foreclosure participation*—(1) B*orrower-initiated termination.* The Servicer must permit a Borrower to voluntarily terminate participation in the pre-foreclosure sale Loss Mitigation option at any time.

(2) *Servicer-initiated termination.* The Servicer shall terminate a Borrower's pre-foreclosure sale program participation for any of the following reasons:

(i) Discovery of unresolvable title problems;

(ii) Determination that the Borrower is not acting in good faith to market the property;

(iii) Significant change in property condition or value;

(iv) Re-evaluation based on new financial information provided by the Borrower that indicates that the case does not qualify for the pre-foreclosure sale option; or

(v) Borrower has failed to complete a pre-foreclosure sale within the time limits prescribed by Section 184 Program Guidance and no extensions of time have been granted by HUD.

(3) *Notification of pre-foreclosure sale program participation termination.* The Servicer must forward to the Borrower a written explanation for terminating their program participation. This letter is to include the ''end-of-participation'' date for the Borrower.

(4) *Failure to complete a pre-foreclosure sale.* Should the Borrower be unable to complete a pre-foreclosure sale transaction, the Servicer must proceed with a deed-in-lieu/lease-in-lieu of foreclosure in accordance with § 1005.753. If the Servicer is unable to obtain a deed-in-lieu/lease-in-lieu of foreclosure, the Servicer must proceed to First Legal Action or assignment in accordance with §§ 1005.761 and 1005.763.

§ 1005.753 Deed-in-lieu/lease-in-lieu of foreclosure.

(a) *Requirements.* In lieu of instituting or completing a foreclosure, the Servicer or HUD may acquire a property by voluntary Conveyance from the Borrowers. Conveyance of the property by deed-in-lieu/lease-in-lieu of foreclosure is allowed subject to the Servicer's compliance with the following requirements:

(1) The lease-in-lieu of foreclosure for property on Trust Land shall be approved by the Tribe prior to execution and by the BIA at recordation.

(2) The Section 184 Guaranteed Loan is in default at the time of the deed-in-lieu/lease-in-lieu of foreclosure is executed and delivered.

(3) The Section 184 Guaranteed Loan is satisfied of record as a part of the consideration for such Conveyance.

(4) The deed-in-lieu/lease-in-lieu of foreclosure from the Borrower contains a covenant which warrants against the acts of the grantor and all claiming by, through, or under the grantor and conveys Good and Marketable Title, or for leases, assigns without objectionable encumbrances.

(5) With respect to Section 184 Guaranteed Loans on fee simple lands, the Servicer transfers to HUD Good and Marketable Title accompanied by satisfactory title evidence.

(6) With respect to Section 184 Guaranteed Loans on Trust Lands, the Servicer provides to HUD a certified Title Status Report evidencing assignment to HUD without any objectionable encumbrances.

(7) The property must meet the property conditions under § 1005.767. HUD may consent to Conveyance of the property by deed-in-lieu/lease-in-lieu of foreclosure when property does not meet § 1005.767 in accordance with procedures in Section 184 Program Guidance.

(b) *Required documentation.* A written agreement must be executed by the Borrower and Servicer which contains all of the conditions under which the deed-in-lieu/lease-in-lieu of foreclosure will be accepted.

(c) *Conveyance to Servicer.* Upon execution of the deed-in-lieu/lease-in-lieu of foreclosure document(s), the Servicer must file for record no later than two business days from receipt.

(d) *Conveyance to HUD, where applicable.* After evidence of recordation is available, the Servicer shall immediately convey the property to HUD in accordance with § 1005.769.

(e) *Reporting for credit purposes.* The Servicer must comply with all applicable Tribal, Federal, State, and local reporting requirements, including but not limited to reporting to credit reporting agencies.

§ 1005.755 Incentive payments.

As an alternative to foreclosure, or eviction where applicable, HUD may authorize an incentive payment to:

(a) Borrowers that complete certain Loss Mitigation options or for their agreement to vacate the property after foreclosure, under the terms established by the Secretary;

(b) Lenders and Servicers for their completion of certain Loss Mitigation options; and (c) Tribes and TDHEs for their assistance in Loss Mitigation, sale, or transfer of the Trust Land property.

Assignment of the Loan to HUD, Foreclosure, and Conveyance

§ 1005.757 Property on Trust Land—Tribal first right of refusal; foreclosure or assignment.

(a) For any property on Tribal Land, the Servicer shall provide written notice to the Tribe or TDHE of the option to assume the Section 184 Guaranteed Loan or purchase the property at the earlier of:

(1) Any lease provision addressing Tribal First Right of Refusal;

(2) 120 days after default; or

(3) The exhaustion of all Loss Mitigation options.

(b) The Tribe or TDHE shall have either the time frame provided in the lease or, if not defined in the lease, 60 days to accept or decline the option to assume the Section 184 Guaranteed Loan or purchase the property based on the current appraised value or other purchase price.

(c) Unless a Borrower has completed a pre-foreclosure sale or a lease-in-lieu of foreclosure in accordance with §§ 1005.751 and 1005.753, the Servicer must either initiate First Legal Action or assignment to HUD, within the timeframes prescribed in §§ 1005.761 and 1005.763.

(d) Any costs associated with failure to initiate Tribal First Right of Refusal may be deemed ineligible for claim payment.

§ 1005.759 Fee simple land properties—foreclosure or assignment with HUD approval.

(a) Unless a Borrower has completed a pre-foreclosure sale or a deed-in-lieu of foreclosure in accordance with §§ 1005.751 and 1005.753, the Servicer must initiate First Legal Action on the

Section 184 Guaranteed Loan pursuant to § 1005.761.

(b) Under limited circumstances, HUD may approve an assignment of a Section 184 Guaranteed Loan to HUD for fee simple land properties.

§ 1005.761 First Legal Action deadline and automatic extensions.

(a) *Deadline for First Legal Action.* The Servicer must initiate First Legal Action, as defined in § 1005.103, within 180 days of default, unless a later date is authorized under this part.

(b) *Automatic extensions to the First Legal Action deadline.* The Section 184 Program allows for automatic extension to the First Legal Action deadline for the following reasons and separate HUD approval is not required.

(1) If Federal law or the laws of the Tribe or State, in which the Section 184 Guaranteed Loan property is located, do not permit the commencement of First Legal Action within the deadline designated in paragraph (a) of this section, then the Servicer must accomplish First Legal Action within 30 days after the expiration of the time during which First Legal Action is prohibited; or

(2) If the Borrower is in compliance with an approved Loss Mitigation plan. However, upon Borrower's default or failure under the Loss Mitigation plan and expiration of response period in any required notice or Borrower's request to terminate participation in the Loss Mitigation plan, the Servicer shall refer the Loan to legal counsel within five days. First Legal Action must be initiated within 30 days of the default or Borrower's request to terminate the Loss Mitigation plan.

(3) Other necessary and reasonable automatic extensions may be allowed, as prescribed by Section 184 Program Guidance.

(c) *Compliance with Federal law.* The First Legal Action must be in compliance with all applicable Federal law, including but not limited to regulations imposed by the Consumer Financial Protection Bureau.

(d) *Notice to HUD.* The Servicer must provide notice to HUD, in a form as may be prescribed in Section 184 Program Guidance, within 15 days of accomplishing First Legal Action.

§ 1005.763 Assignment of the Section 184 Guaranteed Loan.

(a) *Prerequisites for assignment to HUD.* (1) Prior to assignment to HUD, one of the following conditions must have been met:

(i) The Servicer has completed its review of the Borrower's Loss Mitigation request, determined that the Borrower does not qualify for a Loss Mitigation option, and properly notified the Borrower of this decision and, where the Borrower has initiated a timely appeal, the appeal process has been completed or the Borrower's period to appeal has expired.

(ii) The Borrower has failed to perform under an agreement on a Loss Mitigation option, and the Servicer has determined that the Borrower is ineligible for other Loss Mitigation options or is unable to complete an additional Loss Mitigation option within 180 days of default.

(iii) The Servicer has been unable to determine the Borrower's eligibility for any Loss Mitigation option due to the Borrower's failure to respond to the Servicer's efforts to contact the Borrower.

(2) Where applicable, the Servicer has complied with the Right of First Refusal requirements of § 1005.757(a).

(3) Where applicable, the Servicer has complied with all Tribal law requirements.

(4) The Servicer shall conduct an occupancy inspection in accordance with § 1005.735. (i) If the property is vacant or abandoned, secure the property in accordance with § 1005.737(b)(2).

(ii) If the property is occupied, request and obtain approval from HUD to assign the property.

(b) *Timeframes*—(1) *Fee simple land properties.* The assignment of fee simple land properties requires prior HUD approval. The request for an assignment must be no earlier than 180 days of default, unless the Servicer has determined the property is vacant pursuant to § 1005.737. Upon the Servicer's timely certification of compliance with paragraphs (a)(1) through (4) of this section and HUD's approval of the assignment, the Holder shall have five days to execute and cause the appropriate documents to be filed, to accomplish assignment to HUD and submit to HUD evidence of the filing and a claim in a manner so prescribed by Section 184 Program Guidance.

(2) *Properties* on *Trust Land.* The assignment must be no earlier than 180 days after the date of default, unless the Servicer has determined the property is vacant pursuant to § 1005.737. Upon the Servicer's timely certification of compliance with paragraphs (a)(1) through (4) of this section, the Holder shall have five days cause the appropriate documents to be filed, to accomplish assignment to HUD. The Servicer shall submit to HUD evidence of the filing and of a claim in a manner so prescribed by Section 184 Program Guidance.

§ 1005.765 Inspection and preservation of properties.

(a) If at any time the Servicer knows or should have known the property is vacant or abandoned, the Servicer shall comply with the inspection requirements under § 1005.737.

(b) The Servicer shall take appropriate action to protect and preserve the property until its Conveyance to HUD, if such action does not constitute an illegal trespass. Taking ''appropriate action'' includes the commencement of First Legal Action or assignment within the time required by §§ 1005.761 and 1005.763, as applicable.

§ 1005.767 Property condition.

(a) *Condition at time of transfer.* (1) When the property is transferred, or a Section 184 Guaranteed Loan is assigned to HUD in accordance with § 1005.763, the property must be undamaged by fire, earthquake, flood, tornado, and Servicer neglect, except as set forth in this subpart.

(2) A vacant property must be in broom-swept condition, meaning the property is, at a minimum, reasonably free of dust and dirt, and free of hazardous materials or conditions, personal belongings, and interior and exterior debris.

(3) A vacant property is secured and, if applicable, winterized.

(b) *Damage to property by waste.* The Servicer shall not be liable for damage to the property by waste committed by the Borrower, or heirs, successors, or assigns.

(c) *Servicer responsibility.* The Servicer shall be responsible for:

(1) Damage by fire, flood, earthquake, or tornado;

(2) Damage to or destruction of property which is vacant or abandoned when such damage or destruction is due to the Servicer's failure to take reasonable action to inspect, protect, and preserve such property as required by § 1005.737; and

(3) Any damage, whatsoever, that the property has sustained while in the possession of the Servicer, when the property has been conveyed to HUD without notice or approval by HUD as required by § 1005.763.

§ 1005.769 Conveyance of Property to HUD at or after foreclosure; time of Conveyance.

(a) At or after foreclosure, the Servicer shall convey the property to HUD by one of the following:

(1) *Direct Conveyance to HUD.* The Servicer shall cause for the deed to be transferred directly to HUD. The

Servicer shall be responsible for determining that such Conveyance will comply with all provisions of this part, including conveying Good and Marketable Title and producing satisfactory title evidence to HUD.

(2) *Conveyance by the Servicer to HUD.* The Servicer shall acquire Good and Marketable Title and transfer the property to HUD within 30 days of the earlier of:

(i) Execution of the foreclosure deed;

(ii) Acquiring possession of the property;

(iii) Expiration of the redemption period;

(iv) Such further time as may be necessary to complete the title examination and perfect the title; or

(v) Such further time as HUD may approve in writing.

(b) On the date the deed is filed for record, the Servicer shall notify HUD, on a form prescribed by HUD, advising HUD of the filing of such Conveyance and shall assign all rights without recourse or warranty any or all claims which the Servicer has acquired in connection with the loan transaction, and as a result of the foreclosure proceedings or other means by which the Servicer acquired or conveyed such property, except such claims as may have been released with the approval of HUD. The Servicer must file for record the deed no later than two days after execution. The Servicer must document evidence of the submission in the file.

§ 1005.771 Acceptance of property by HUD.

(a) *Effective date of assignment.* HUD accepts the assignment of a Section 184 Guaranteed Loan when:

(1) The Servicer has assigned the Section 184 Guaranteed Loan to HUD;

(2) The Servicer has provided HUD evidence of the recordation; and

(3) HUD pays a claim for the unpaid principal balance under § 1005.807(a).

(b) *Effective date of Conveyance.* HUD accepts Conveyance of the property when:

(1) The Servicer has deeded the property to HUD;

(2) The Servicer has provided HUD evidence of the recordation; and

(3) HUD pays a claim for the unpaid principal balance under § 1005.807(a)

(c) *Servicer ongoing obligation.* Notwithstanding the assignment of the Section 184 Guarantee Loan or the filing of the deed to the HUD, the Servicer remains responsible for ensuring compliance with this part, including and any loss or damage to the property, and such responsibility is retained by the Servicer until the claim has been paid by HUD.

Subpart H—Claims

Claims Application, Submission Categories, and Types

§ 1005.801 Purpose.

This subpart sets forth requirements that are applicable to a Servicer's submission of an application for Section 184 Guaranteed Loan benefits to HUD. The Servicer's submission of the claim shall be in compliance with this subpart and process details as set forth by HUD in Section 184 Program Guidance. This subpart also sets forth requirements processing and payment of claim.

§ 1005.803 Claim case binder; HUD authority to review records.

(a) A Servicer must maintain a claim case binder for each claim submitted for payment in accordance with § 1005.219(d)(2). The claim case binder must contain documentation supporting all information submitted in the claim.

(b) HUD may review a claim case binder and the associated endorsement case binder at any time. A Servicer's denial of HUD access to any files may be grounds for sanctions in accordance with §§ 1005.905 and 1005.907.

(c) Within three business days of a request by HUD, the Servicer must make available for review, or forward to HUD, copies of identified claim case binders.

§ 1005.805 Effect of noncompliance.

(a) When a claim case binder is submitted to HUD for consideration, HUD may conduct a post-endorsement review in accordance with § 1005.527. If HUD determines that the Section 184 Guaranteed Loan does not satisfy the requirements of subpart D of this part, HUD will take one or more of the following actions:

(1) Reject the claim submission when the Holder is the originating Direct Guarantee Lender.

(2) Pay the claim to the current Holder and demand reimbursement of the claim from the originating Direct Guarantee Lender.

(3) Reconvey the property or reassign the deed of trust or mortgage in accordance with § 1005.849.

(4) Pursue sanctions against the originating Direct Guarantee Lender or Sponsored Entity pursuant to §§ 1005.905 and 1005.907.

(b) When reviewing a claim case binder, if HUD determines one or more of the conditions in paragraph (b)(1) of this section to be true, HUD may take one or more of the actions listed in paragraph (b)(2) of this section:

(1) *Conditions.* (i) The Servicer failed to service the Section 184 Guaranteed Loan in accordance with subpart G of this part;

(ii) The Servicer committed fraud or a material misrepresentation; or

(iii) The Servicer had known or should have known of fraud or a material misrepresentation in violation of this part.

(2) *Actions.* (i) Place a hold on processing the claim for reimbursement of eligible reasonable expenses under § 1005.807(b) and provide the Servicer the opportunity to remedy the deficiency.

(ii) Reject the claim for reimbursement of eligible reasonable expenses under § 1005.807(b) partially or in its entirety.

(iii) Reconvey the property or reassign the deed of trust or mortgage in accordance with § 1005.849, where applicable, and require the Holder to refund the claim payment of the unpaid principal balance under § 1005.807(a) and expenses under § 1005.807(b). The Holder may resubmit the claim when the deficiencies identified by HUD are cured.

(iv) Pursue administrative offset for any unpaid amounts owed to HUD pursuant to 24 CFR part 17.

(v) Pursue sanctions against the Servicer or Holder pursuant to §§ 1005.905 and 1005.907.

(vi) Pursue other remedies as determined by HUD.

(c) If a property is reconveyed or the deed of trust or mortgage is reassigned to the Holder, the Holder may not be reimbursed for any expenses incurred after Conveyance or reassignment.

(d) If a claim is resubmitted after reconveyance or reassignment and HUD determines a decrease in the value of the property at the time of the resubmission, HUD may reduce the claim payment accordingly.

§ 1005.807 Claim submission categories.

There are three claim submission categories:

(a) Payment of the unpaid principal balance;

(b) Reimbursement of eligible reasonable expenses, as prescribed by Section 184 Program Guidance, up to the execution of the assignment or date of Conveyance of the property of the property to HUD or a third party; and

(c) Supplemental claim for eligible reasonable expenses incurred prior to the assignment, Conveyance, or transfer of the property to a third party, for which the expenses were omitted from the Servicer's prior claim or for a calculation error made by either Servicer or HUD.

§ 1005.809 Claim types.

HUD recognizes five different claim types. The Servicer must submit a claim

based upon the type of property disposition. The Servicer shall submit claims within timeframes established in this section. The claim types are:

(a) *Conveyance.* When the property is deeded to HUD through or after foreclosure or by deed-in-lieu or lease-in-lieu of foreclosure:

(1) The Servicer must submit a claim under § 1005.807(a) to HUD no later than 45 days from the date the deed to HUD is executed, unless an extension of time is granted by HUD.

(2)(i) *Fee simple land.* The claim must include the final title policy evidencing HUD's ownership through foreclosure or transfer of the ownership of the property through deed-in-lieu to HUD.

(ii) *Trust Land.* The claim must include a certified Title Status Report evidencing HUD's leasehold interest through foreclosure or the transfer of the mortgage and leasehold interest to HUD through lease-in-lieu.

(3) In cases where the Servicer is unable to comply with paragraph (a)(2)(ii) of this section, the Servicer shall submit the claim pending the certified Title Status Report in accordance with the time frame specified in paragraph (a)(1) of this section.

(4) Servicers must submit claims under § 1005.807(b) no later than 60 days after the date the deed to HUD is executed, unless an extension of time is granted by HUD.

(b) *Assignment of the loan.* When the Holder assigns the Section 184 Guaranteed Loan to HUD:

(1) The Servicer must submit a claim under § 1005.807(a) and (b) no later than 45 days from the date of the assignment of the Section 184 Guaranteed Loan to HUD is executed, unless an extension of time is granted by HUD.

(2)(i) *Trust Land.* The claim must include a certified Title Status Report evidencing the assignment of the mortgage to HUD.

(ii) *Fee simple land.* The claim must include the final title policy providing coverage through the transfer of the mortgage to HUD.

(3) In cases where the Servicer is unable to comply with paragraph (b)(2)(i) of this section, the Servicer shall submit the claim pending the certified Title Status Report in accordance with the time frame specified in paragraph (b)(1) of this section.

(4) At the time of assignment of the Section 184 Guaranteed Loan, the Servicer shall certify to HUD that:

(i) *Priority of Section 184 Guaranteed Loan.* The Section 184 Guaranteed Loan has priority over all judgments, mechanics' and materialmen's liens, or any other liens, regardless of when such liens attached, unless approved by HUD;

(ii) *Amount due.* The amount reported to HUD in accordance with § 1005.707(d) prior to assignment is verified to be due and owing under the Section 184 Guaranteed Loan;

(iii) *Offsets or counterclaims and authority to assign.* There are no offsets or counterclaims thereto and the Holder has the authority to assign; and

(iv) *Assignment.* The assignment of the Section 184 Guaranteed Loan to HUD meets the requirements of § 1005.763.

(c) *Post-foreclosure claims without Conveyance of title.* When a third-party purchases the property at foreclosure, the Servicer must submit a claim under § 1005.807(a) and (b) to HUD no later than 180 days from the date the property is conveyed to the third-party. If the Holder purchases the property at foreclosure and subsequently sells the property, the Servicer may submit a claim under this section.

(d) *Pre-foreclosure sale, deed-in-lieu, or lease-in-lieu.* When a property is sold or conveyed prior to foreclosure in accordance with §§ 1005.751 or 1005.753, the Servicer must submit a claim under § 1005.807(a) and (b) to HUD no later than 45 days from the date the sale or Conveyance is executed.

(e) *Supplemental claim.* The Servicer shall be limited to one supplemental claim for each claim under submission categories in paragraphs (a) and (b) of this section.

(1) The supplemental claim shall be limited to:

(i) Reasonable eligible expenses incurred up to the date of Conveyance of the property or assignment of the Section 184 Guaranteed Loan, when invoices are received after the payment of the claim under § 1005.807(b); or

(ii) Calculation error(s) made by either the Servicer or HUD.

(2) Supplemental claims must be submitted within six months of the claim submission under § 1005.807(b). Supplemental claims received after six months will not be reviewed or paid by HUD.

(3) Any supplemental claim paid by HUD shall be considered final satisfaction of the Loan Guarantee Certificate.

Submission of Claim

§ 1005.811 Claims supporting documentation.

The Servicer shall submit supporting documentation to the satisfaction of HUD for each claim. Such documentation will be provided for in Section 184 Program Guidance.

§ 1005.813 Upfront and Annual Loan Guarantee Fee reconciliation.

(a) The Servicer must include in the claims case binder a reconciliation evidencing the payment of the Upfront and Annual Loan Guarantee Fees to HUD.

(b) Where the Servicer fails to comply with paragraph (a) of this section or the reconciliation shows unpaid amounts owed to HUD, and the unpaid amounts, along with late fees, have not been satisfied by the Servicer, HUD shall reject the claim.

(c) The Servicer may resubmit the claim after providing the reconciliation required under paragraph (a) of this section or after the Annual Loan Guarantee Fee amounts, along with late fees, owed to HUD are paid by the Servicer.

(d) Allowance to resubmit in accordance with paragraph (c) of this section shall not be construed to extend any deadlines to file claims specified in this subpart.

§ 1005.815 Conditions for withdrawal of claim.

With HUD's consent, a Holder may withdraw a claim. When HUD consent is granted, the Holder shall agree, where applicable, in writing that it will:

(a) Accept a reconveyance of the property under a Conveyance which warrants against the acts of HUD and all claiming by, through or under HUD;

(b) Promptly file for record the reconveyance from HUD;

(c) Accept without continuation, the title evidence which the Servicer furnished to HUD; and

(d) Reimburse HUD for the expenditures and amounts set forth in § 1005.851.

Property Title Transfers and Title Waivers

§ 1005.817 Conveyance of Good and Marketable Title.

(a) *Definition.* Good and Marketable Title is defined in § 1005.103.

(b) *Satisfactory Conveyance of title and transfer of possession.* The Servicer shall tender to HUD a satisfactory Conveyance of title and transfer of possession of the property. The deed or other instrument of Conveyance shall convey Good and Marketable Title to the property, which shall be accompanied by title evidence satisfactory to HUD.

(c) *Conveyance of property without Good and Marketable Title.* (1) If the title to the property conveyed by the Servicer to HUD is not Good and Marketable Title, the Servicer must correct any title defect within 60 days after receiving notice from HUD, or

within such further time as HUD may approve in writing.

(2) If the defect is not corrected within 60 days, or such further time as HUD approves in writing, the Servicer must reimburse HUD's costs of holding the property. Such holding costs accrue on a daily basis and include interest on the amount of the loan guarantee benefits paid to the Servicer at an interest rate set in conformity with the Treasury Fiscal Requirements Manual from the date of such notice to the date the defect is corrected or until HUD reconveys the property to the Servicer, as described in paragraph (c)(3) of this section. The daily holding costs to be charged to the Servicer shall also include the costs specified in § 1005.851.

(3) If the title defect is not corrected within a reasonable time, as determined by HUD, HUD will, after notice, reconvey the property to the Servicer and the Servicer must reimburse HUD in accordance with §§ 1005.849 and 1005.851.

§ 1005.819 Types of satisfactory title evidence.

(a) The following types of title evidence shall be satisfactory to HUD:

(1) *Fee or owner's title policy.* A fee or owner's policy of title insurance, a guaranty or guarantee of title, or a certificate of title, issued by a title company, duly authorized by law and qualified by experience to issue such instruments. If an owner's policy of title insurance is furnished, it shall show title in HUD's name and inure to the benefit of the Department. The policy must be drawn in favor of the Servicer and HUD, and their successors and assigns, as their interests may appear, with the consent of the title company endorsed thereon;

(2) *Policy of title insurance.* A Holder's policy of title insurance supplemented by an abstract and an attorney's certificate of title covering the period subsequent to the date of the loan, the terms of the policy shall be such that the liability of the title company will continue in favor of the HUD after title is conveyed to HUD. The policy must be drawn in favor of the Servicer and HUD, and their successors and assigns, as their interests may appear, with the consent of the title company endorsed thereon;

(3) *Abstract and legal opinion.* An abstract of title prepared by an abstract company or individual engaged in the business of preparing abstracts of title and accompanied by the legal opinion as to the quality of such title signed by an attorney at law experienced in examination of titles. If title evidence consists of an abstract and an attorney's certificate of title, the search shall extend for at least forty years prior to the date of the certificate to a well-recognized source of good title;

(4) *Torrens or similar certificate.* A Torrens or similar title certificate;

(5) *Title standard of U.S., Tribal, or State government.* Evidence of title conforming to the standards of a supervising branch of the Government of the United States or of any Tribe, State or Territory thereof; or

(6) *Title Status Report.* Certified Title Status Report issued by the BIA shall not be more than sixty (60) days from the date of the § 1005.807(a) claim submission. Extensions may be granted under certain reasonable circumstances, as prescribed by Section 184 Program Guidance.

(b) [Reserved]

§ 1005.821 Coverage of title evidence.

(a) Evidence of title or Title Status Report shall include the recordation of the Conveyance or assignment to HUD. The evidence of title or the Title Status Report shall further show that, according to the public records, there are no outstanding prior liens, including any past-due and unpaid ground rents, general taxes or special assessments, if applicable, on the date of Conveyance or assignment.

(b) If the title evidence and Title Status Report are acceptable generally in the community in which the property is situated, such title evidence and Title Status Report shall be satisfactory to HUD and shall be considered Good and Marketable Title. In cases of disagreement, HUD will make the final determination in its sole discretion.

§ 1005.823 Waived title objections for properties on fee simple land.

Reasonable title objections for fee simple land properties shall be waived by HUD. Reasonable title objections will be prescribed in Section 184 Program Guidance.

§ 1005.825 Waived title objections for properties on Trust Land.

HUD shall not object to title restrictions placed on the tract of Trust Land by the Tribe or the BIA so long as those restrictions do not adversely impact the property or marketability.

Condition of the Property

§ 1005.827 Damage or neglect.

(a) If the property has been damaged by fire, flood, earthquake, or tornado, or if the property has suffered damage because of the Servicer's failure to take action as required by § 1005.765 or for any other reason, the Servicer must submit a claim to the hazard insurance policy, as applicable and the damage must be repaired before Conveyance of the property or assignment of the Section 184 Guaranteed Loan to HUD.

(b) If the property has been damaged as described in paragraph (a) of this section and the damage is not covered by a hazard insurance policy, the Servicer must provide notice of such damage to HUD. The property may not be conveyed or assigned until directed to do so by HUD. Upon receipt of such notice, HUD will either:

(1) Allow the Holder to convey the damaged property;

(2) Require the Servicer to repair the damage before Conveyance, and HUD will reimburse the Holder for reasonable payments, not in excess of HUD's estimate of the cost of repair, less any hazard insurance recovery; or

(3) Require the Servicer to repair the damage before Conveyance, at the Holder's own expense.

(c) In the event the damaged property is conveyed to HUD without prior notice or approval as provided in paragraph (a) or (b) of this section, HUD may, after notice, reconvey the property and demand reimbursement to HUD for the expenses in accordance with §§ 1005.849 and 1005.851.

§ 1005.829 Certificate of property condition.

(a) As part of the claim submission, the Servicer shall either:

(1) Certify that as of the date of the deed or assignment of the loan to HUD the property was:

(i) Undamaged by fire, flood, earthquake, or tornado;

(ii) Undamaged due to failure of the Servicer to act as required by § 1005.765; and,

(iii) Undamaged while the property was in the possession of the Borrower; or,

(2) Include a copy of HUD's authorization to convey the property in damaged condition.

(b) In the absence of evidence to the contrary, the Servicer's certificate or description of the damage shall be accepted by HUD as establishing the condition of the property, as of the date of the deed or assignment of the Section 184 Guaranteed Loan.

§ 1005.831 Cancellation of hazard insurance.

The Holder shall cancel any hazard insurance policy as of the date of the deed to HUD, subject to the following conditions:

(a) The amount of premium refund due to the Servicer resulting from such cancellation must be deducted from the total amount claimed.

(b) If the Servicer's calculation of the premium refund is less than the actual premium refund, the amount of the difference between the actual refund and the calculated refund shall be remitted to HUD, accompanied by the insurance company's or agent's statement.

(c) If the Servicer's calculation of the premium refund is more than the actual refund, the Servicer must include in a supplemental claim submission in accordance with § 1005.809(c), accompanied by the insurance company's or agent's statement, the amount of the difference as an eligible cost in accordance with § 1005.843(a)(3).

Payment of Guarantee Benefits

§ 1005.833 Method of payment.

If the claim is acceptable to HUD, payment of the guarantee benefits shall be made by electronic transfer of funds to the Holder or other such allowable payment method.

§ 1005.835 Claim payment not conclusive evidence of claim meeting all HUD requirements.

Payment of any claim by HUD is not conclusive evidence of compliance with the subpart D or G of this part. HUD reserves the right to conduct post-claim payment review of claims filed within five years from the date of the last claim payment. Where non-compliance with any requirements of this part is identified, HUD will take appropriate action against the Holder, originating Direct Guarantee Lender, and/or Servicer, including but not limited to HUD's remedies under § 1005.805 and sanctions under §§ 1005.905 and 1005.907.

§ 1005.837 Payment of claim: unpaid principal balance.

HUD will pay a claim under § 1005.807(a) in the amount of the unpaid principal balance less all receipts for the sale or transfer of the property, if applicable, in accordance with the requirements of this subpart.

§ 1005.839 Payment of claim: interest on unpaid principal balance.

(a) HUD shall pay interest on the unpaid principal balance from the date of default to the earlier of the following:

(1) The execution of deed-in-lieu/lease-in-lieu of foreclosure;

(2) The execution of the Conveyance to either Servicer, HUD, or a third-party;

(3) The execution of the assignment of the Section 184 Guaranteed Loan to HUD; or

(4) The expiration of the reasonable diligence timeframe, as prescribed by Section 184 Program Guidance.

(b) [Reserved]

§ 1005.841 Payment of claim: reimbursement of eligible and reasonable costs.

The claim will be paid in accordance with § 1005.807(b) and will include eligible and reasonable costs, as prescribed by Section 184 Program Guidance.

§ 1005.843 Reductions to the claim submission amount.

(a) A Servicer shall reduce the claim when the following amounts are received or held by the Servicer:

(1) All amounts received by the Servicer from account of the loan after default.

(2) All amounts received by the Servicer from any source relating to the property on account of rent, reimbursement, or other income after deducting reasonable expenses incurred in handling the property.

(3) All cash retained by the Servicer including amounts held or deposited for the account of the Borrower or to which it is entitled under the loan transaction that have not been applied in reduction of the principal loan indebtedness.

(b) [Reserved]

§ 1005.845 Rights and liabilities under Indian Housing Loan Guarantee Fund.

(a) No Borrower, Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer shall have any vested right in the Indian Housing Loan Guarantee Fund.

(b) No Borrower, Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer shall be subject to any liability arising under the Indian Housing Loan Guarantee Fund.

(c) The Indian Housing Loan Guarantee Fund will be credited and debited in accordance with 12 U.S.C. 1715z–13a(i)(2).

§ 1005.847 Final payment.

(a) HUD's payment of a claim(s) shall be deemed as final payment to the Holder, notwithstanding the ability to present additional claim(s) in accordance with § 1005.807 as applicable. The Holder shall have no further rights against the Borrower or HUD when there is a final payment. This paragraph (a) does not preclude HUD from seeking reimbursement of costs and return of amounts from the Holder or originating Direct Guarantee Lender pursuant to §§ 1005.849 and 1005.851.

(b) In cases where HUD reconveys the property to the Holder and HUD is reimbursed for all expenses and returns all amounts pursuant to §§ 1005.849 and 1005.851, provisions under paragraph (a) of this section shall not apply. However, the resubmission of the claim, if any, shall be subject to § 1005.849(b) and any reasonable processes requirements as may be prescribed by Section 184 Program Guidance.

§ 1005.849 Reconveyance and reassignment.

(a) HUD may reconvey the property or reassign the deed of trust or mortgage to the Holder due to:

(1) Originating Direct Guarantee Lender or Servicer's noncompliance with this part or any requirements as prescribed by Section 184 Program Guidance; or

(2) An authorized withdrawal of a claim in accordance with § 1005.815.

(b) HUD may take appropriate action against the Holder associated with the reconveyance or reassignment authorized in paragraph (a) of this section, including but not limited to, seeking reimbursement of all claim costs paid by HUD and carrying costs incurred by HUD in accordance with § 1005.851.

(c) Notwithstanding any other provision in this subpart, in cases where HUD has conveyed the property or reassigned the deed of trust or mortgage back to the Holder in accordance with § 1005.851, and where the Servicer resubmits the claim, HUD will not reimburse the Holder any expenses incurred after the date of the HUD Conveyance or assignment.

(d) Additional reasonable and necessary restrictions may be imposed, as prescribed by Section 184 Program Guidance.

§ 1005.851 Reimbursement of expenses to HUD.

Where reconveyance or reassignment is sought by HUD pursuant to § 1005.849 or when HUD determines noncompliance the Holder or the originating Direct Guarantee Lender shall reimburse HUD for:

(a) All claim costs paid by HUD.

(b) HUD's cost of holding the property, including but not limited to expenses based on the estimated taxes, maintenance and operating expenses of the property, and administrative expenses. Adjustments shall be made by HUD for any income received from the property.

(c) The reimbursement shall include interest on the amount of the claim payment returned by the Holder or the originating Direct Guarantee Lender from the date the claim was paid to the date HUD receives the reimbursement from Holder or the originating Direct Guarantee Lender. The interest rate set shall be in conformity with the Treasury Fiscal Requirements Manual.

Subpart I—Lender Program Performance, Reporting, Sanctions, and Appeals

§ 1005.901 Direct Guarantee Lender, Holder, or Servicer performance reviews.

HUD may conduct periodic performance reviews of Direct Guarantee Lenders, Non-Direct Guarantee Lenders, Holders, and Servicers. These may include analytical reviews, customer surveys, and on-site or remote monitoring reviews. These reviews may include, but are not limited to, an evaluation of compliance with this part. HUD will provide a written notice of its assessment and any proposed corrective action, if applicable.

§ 1005.903 Direct Guarantee Lender, Holder, or Servicer reporting and certifications.

(a) The Direct Guarantee Lender, Non-Direct Guarantee Lender, or Servicer shall provide timely and accurate reports and certifications to HUD, which may include but is not limited to reports in connection with performance reviews under § 1005.901, any special request for information from HUD, and any reasonable reports prescribed by Section 184 Program Guidance, within reasonable time frames prescribed by HUD.

(b) The Direct Guarantee Lender, Non-Direct Guarantee Lender, or Servicer's failure to provide timely and accurate reports and certifications to HUD may subject the Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer to sanctions and civil money penalties pursuant to §§ 1005.905 and 1005.907.

§ 1005.905 Direct Guarantee Lender, Holder, or Servicer notice of sanctions.

(a) Prior to the notice of sanctions or civil money penalties, HUD shall inform the Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer of the specific non-compliance with this part and, where applicable, afford the Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer a reasonable time, as prescribed in Section 184 Program Guidance to return to compliance.

(b) If it is determined that the Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer fails to return to compliance within the allowed time, HUD shall provide written notice of the sanction and civil money penalties to be imposed and the basis for the action.

§ 1005.907 Direct Guarantee Lender, Holder, or Servicer sanctions and civil money penalties.

(a) Where the Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer fails to comply with this part, including failure to maintain adequate accounting records, failure to adequately service loans, or failure to exercise proper credit or underwriting judgment, or becomes ineligible to participate pursuant to § 1005.225, or has engaged in practices otherwise detrimental to the interest of a Borrower or the United States, including but not limited to, failure to provide timely reporting, or failure to follow underwriting requirements set forth in this part, or failure to comply with Section 184 Program Guidance when it specifically provides times, processes, and procedures for complying with the requirements in this part, HUD may take any combination of the following actions:

(1) Either temporarily or permanently terminate a Director Guarantee Lender or Non-Direct Guarantee Lender's status. If such action is taken and the terminated Direct Guarantee Lender wishes to maintain servicing rights to the Section 184 Guaranteed Loans, the terminated Direct Guarantee Lender must seek HUD approval as prescribed in Section 184 Program Guidance.

(2) Bar the Direct Guarantee Lender or Holder from acquiring additional Section 184 Guaranteed Loans.

(3) Require that the Direct Guarantee Lender assume not less than 10 percent of any loss on further Section 184 Guaranteed Loans made by the Direct Guarantee Lender.

(4) Require that the Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer comply with a corrective action plan or amend the Direct Guarantee Lender, Non-Direct Guarantee Lender, or Servicer's quality control plan, subject to HUD approval, to remedy the non-compliance with this part and any process prescribed by Section 184 Program Guidance. The plan shall also address methods to prevent the reoccurrence of any practices that are detrimental to the interest of the Borrower or HUD. The corrective action plan or amended quality control plan shall afford the Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer reasonable time to return to compliance.

(5) If HUD determines any Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer has intentionally failed to maintain adequate accounting records, to adequately service loans guaranteed under this section, or to exercise proper credit or underwriting judgment, the Assistant Secretary for Public and Indian Housing (and his/her designee) is authorized pursuant to 12 U.S.C. 1715z–13a(g)(2) to impose civil money penalties upon Direct Guarantee Lenders, Non-Direct Guarantee Lender, Holders, or Servicers, as set forth in 24 CFR part 30. The violations for which a civil money penalty may be imposed are listed in subpart B of 24 CFR part 30.

(b) [Reserved]

§ 1005.909 Direct Guarantee Lender, Holder, or Servicer appeals process.

(a) Lenders denied participation in the Section 184 Program pursuant to subpart B of this part, or a Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder or Servicer subject to sanctions pursuant to § 1005.907, may appeal to HUD's Office of Loan Guarantee within a timeframe prescribed in Section 184 Program Guidance. After consideration of the Lender, Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer's appeal, HUD shall advise the Lender, Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer in writing whether the denial is rescinded, modified or affirmed. The Lender, Direct Guarantee Lender, Non-Direct Guarantee Lender, Holder, or Servicer may then appeal such decision to the Deputy Assistant Secretary for Office of Native American Programs, or his or her designee. A decision by the Deputy Assistant Secretary or designee shall constitute final agency action.

(b) Hearings to challenge the imposition of civil money penalties shall be conducted according to the applicable rules of 24 CFR part 30.

Dominique Blom,

General Deputy Assistant Secretary for Public and Indian Housing.

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Part IV

Department of Energy

10 CFR Parts 433 and 435
Clean Energy for New Federal Buildings and Major Renovations of Federal Buildings; Proposed Rule

DEPARTMENT OF ENERGY

10 CFR Parts 433 and 435

[EERE–2010–BT–STD–0031]

RIN 1904–AB96

Clean Energy for New Federal Buildings and Major Renovations of Federal Buildings

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

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: The Department of Energy (''DOE'') is publishing a supplemental notice of proposed rulemaking (''SNOPR'') to establish revised energy performance standards for the construction of new Federal buildings, including commercial buildings, multi-family high-rise residential buildings, and low-rise residential buildings per the Energy Conservation and Production Act (''ECPA''), as amended by the Energy Independence and Security Act (''EISA'') of 2007. This document presents an updated proposal with a new focus that accounts for the needs of Federal agencies and the goals of President Biden's Administration and responds to comments received on prior notice of proposed rulemaking (''NOPR'') and SNOPR documents. Consistent with the requirements of ECPA and EISA, this document presents revised Federal building energy performance standards that would require reductions in Federal agencies' on-site use of fossil fuels (which include coal, petroleum, natural gas, oil shales, bitumens, tar sands, and heavy oils) consistent with the targets of ECPA and EISA and provides processes by which agencies can petition DOE for the downward adjustment of said targets for buildings.

DATES:

Meeting: DOE will hold a webinar on Thursday, January 5, 2023, from 1:00 p.m. to 4:00 p.m. See section VI, ''Public Participation,'' for webinar registration information, participant instructions, and information about the capabilities available to webinar participants.

Comments: DOE will accept comments, data, and information regarding this SNOPR no later than February 21, 2023. Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov,* under docket number EERE–2010–BT–STD–0031. Follow the instructions for submitting comments. EERE–2010–BT–STD–0031. Alternatively, interested persons may submit comments, identified by docket number EERE–2010–BT–STD–0031, by any of the following methods:

(1) *Email: FossilFuelReduct-2010-STD-0031@ee.doe.gov.* Include the docket number EERE–2010–BT–STD–0031 in the subject line of the message.

(2) *Postal Mail:* Mr. Jeremy Williams, U.S. Department of Energy, Building Technologies Program, Mailstop EE–5B, Fossil Fuel-Generated Energy Consumption Reduction for New Federal Buildings and Major Renovations of Federal Buildings, EERE–2010–BT–STD–0031 and/or RIN 1904–AB96, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–9138. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.

(3) *Hand Delivery/Courier:* Mr. Jeremy Williams, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue SW, Washington, DC 20585–0121. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimiles (''faxes'') will be accepted. For detailed instructions on submitting comments and additional information on this process, see section VI of this document.

FOR FURTHER INFORMATION CONTACT:

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

Mr. Matthew Ring, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–2555. Email: *Matthew.Ring@hq.doe.gov.*

For further information on how to submit a comment, review other public comments and the docket, or participate in the public meeting, contact the Building Energy Codes Program staff at *BuildingEnergyCodes@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

DOE proposes to incorporate by reference the following industry standards:

ANSI/ASHRAE/IES 90.1–2019, Energy Standard for Buildings Except Low-Rise Residential Buildings, I–P Edition, copyright 2019 (''ASHRAE 90.1–2019''), into part 433.

ASHRAE 90.1–2019 is available from the American Society of Heating Refrigerating and Air-Conditioning Engineers, Inc., 180 Technology Parkway NW, Peachtree Corners, GA 30092; (404) 636–8400; *www.ashrae.org.*

ICC 2021, Redline Version, Copyright 2021, (''IECC 2021'') into part 435.

IECC 2021 is available from the International Energy Conservation Code (IECC), 4051 West Flossmoor Road, Country Club Hills, IL 60478, 1–888–422–7233, or go to *https://www.iccsafe.org/.*

See section V.M of this document for a further discussion of these standards.

Table of Contents

I. Introduction

The following section briefly discusses the statutory authority underlying this proposed rule, as well as some of the relevant historical background related to the establishment of a fossil fuel-generated energy consumption reduction rule for Federal buildings.

A. Authority

Section 305 of the Energy Conservation and Production Act (''ECPA'') established energy conservation requirements for Federal buildings. (42 U.S.C. 6834) Section 433(a) of the Energy Independence and Security Act of 2007 (Pub. L. 110–140) (EISA 2007) amended section 305 of ECPA and directed the Department of Energy (''DOE'') to establish regulations that require fossil fuel-generated energy consumption reductions for certain new Federal buildings and Federal buildings undergoing major renovations. (42 U.S.C. 6834(a)(3)(D)(i)) The fossil-fuel generated energy consumption reductions only apply to Federal buildings that: (1) are ''public buildings'' (as defined in 40 U.S.C. 3301) [1] with respect to which the Administrator of General Services is required to transmit a prospectus to Congress under 40 U.S.C. 3307; [2] or (2) those that cost at least $2,500,000 in costs adjusted annually for inflation. (42 U.S.C. 6834(a)(3)(D)(i))

For these buildings, section 305 of ECPA, as amended by EISA 2007, mandates that the buildings be designed so that a building's fossil fuel-generated energy consumption is reduced as compared with such energy consumption by a similar building in fiscal year (''FY'') 2003 (as measured by Commercial Buildings Energy Consumption Survey (''CBECS'') or Residential Energy Consumption Survey (''RECS'') data from the DOE's Energy Information Administration (''EIA'') by 55 percent beginning in FY2010, 65 percent beginning in FY2015, 80 percent beginning in FY2020, 90 percent beginning in FY2025, and 100 percent beginning in FY2030, also shown in the Table I.1. (42 U.S.C. 6834(a)(3)(D)(i)(I))

TABLE I.1—BUILDING PERCENTAGE REDUCTION REQUIREMENTS BY FISCAL YEAR

Fiscal year	Percentage reduction
2010	55
2015	65
2020	80
2025	90
2030	100

In addition, upon petition by an agency subject to the statutory requirements, ECPA, as amended by EISA 2007, permits DOE to adjust the applicable numeric reduction requirement downward with respect to a specific building, if the head of the agency designing the building certifies in writing that meeting such requirement would be technically impracticable in light of the agency's specified functional needs for that building and DOE concurs with the agency's conclusion. (42 U.S.C. 6834(a)(3)(D)(i)(II)) Such an adjustment does not apply to the General Services Administration (''GSA''). (*Id.*)

The term ''fossil fuel-generated energy consumption'' is not defined in section 433 of EISA 2007. In this SNOPR, DOE is proposing to apply the term ''fossil fuel-generated energy consumption,'' for purposes of meeting the reduction targets in EISA section 433, as only energy consumption from on-site fossil fuel used by equipment and systems designed to support building operations (also referred to as Scope 1 uses). In this SNOPR, DOE proposes that these initial standards would not cover certain process loads, manufacturing/industrial activities, unique research activities or back-up emergency generators nor would the standards cover electricity or other purchased utility consumption supplied from the grid and generated using fossil fuels off-site. However, DOE may re-examine the scope of this term and coverage in future updates of these standards.

B. Background

This SNOPR proposes to amend certain portions of 10 CFR parts 433 and 435, the regulations governing energy efficiency in Federal buildings. DOE previously published a notice of proposed rulemaking (''NOPR'') in the **Federal Register** on October 15, 2010, which outlined a proposal to implement section 433 of EISA. 75 FR 63404. A public meeting on the NOPR was held on November 12, 2010, and public

[1] Under 40 U.S.C. 3301(a)(5), ''public building'' is a building, whether for single or multitenant occupancy, and its grounds, approaches, and appurtenances, which is generally suitable for use as office or storage space or both by one or more federal agencies or mixed-ownership Government corporations. ''Public building'' includes federal office buildings, post offices, customhouses, courthouses, appraisers stores, border inspection facilities, warehouses, record centers, relocation facilities, telecommuting centers, similar federal facilities, and any other buildings or construction projects the inclusion of which the President considers to be justified in the public interest. The definition does not include a building or construction project that is on the public domain (including that reserved for national forests and other purposes); that is on property of the Government in foreign countries; that is on Native American and Native Alaskan property held in trust by the Government; that is on land used in connection with federal programs for agricultural, recreational, and conservation purposes, including research in connection with the programs; that is on or used in connection with river, harbor, flood control, reclamation or power projects, for chemical manufacturing or development projects, or for nuclear production, research, or development projects; that is on or used in connection with housing and residential projects; that is on military installations (including any fort, camp, post, naval training station, airfield, proving ground, military supply depot, military school, or any similar facility of the Department of Defense); that is on installations of the Department of Veterans Affairs used for hospital or domiciliary purposes; or the exclusion of which the President considers to be justified in the public interest.

[2] 40 U.S.C. 3307 describes the minimum construction, alteration and lease costs that would trigger a prospectus to Congress.

comments were accepted through December 14, 2010. DOE received a number of comments expressing concern and encouraging DOE to re-examine the proposed regulations.[3] In response to these comments, DOE identified additional areas for clarification and consideration that would benefit from further public comment. DOE issued a supplemental notice of proposed rulemaking (2014 SNOPR) on October 14, 2014. 79 FR 61694. Comments were accepted through December 15, 2014.[4] To ensure alignment with the decarbonization goals of the Biden Administration, DOE is revising its proposal and issuing a second SNOPR. This revised SNOPR will take into consideration previous relevant comments from the 2014 SNOPR as well as considerations of Administration objectives to reduce emissions across federal operations, as appropriate.

In this second SNOPR, DOE makes a number of changes from the 2014 SNOPR that would apply to both 10 CFR part 433 and 10 CFR part 435 unless otherwise noted. Details of these changes with a discussion of each are described in section III of this document. This second SNOPR:

- Converts the proposed rule from a kBtu per ft^2 accounting of total fossil fuel use (including both on-site fossil fuel use and the embedded fossil fuels in on-site electricity use) to use kBtu per ft^2 of on-site fossil fuel usage or Scope 1 GHG emissions in CO_2e (''Carbon Dioxide Equivalent Gases'') per ft^2.
- Implements a shift multiplier for Federal buildings that operate on extended schedules compared to the private sector buildings sampled in CBECS. This multiplier will apply solely to Federal commercial buildings regulated in 10 CFR part 433 as residential buildings of all types in both the private sector and Federal sector are assumed to be operated 24 hours a day.
- Revises the calculation of fossil fuel usage for the proposed design to make it consistent with how DOE tracks fossil fuel usage and greenhouse gas emissions in reporting related to EISA 2007 section 432.
- Clarifies applicability of the rule to EISA-subject major renovations in three categories—renovations of all Scope 1 fossil fuel-using systems, Scope 1 fossil fuel-using system level renovations, and Scope 1 fossil fuel-using component level renovations.
- Clarifies applicability of the rule to leased facilities, noting that the only leases subject to this proposed rule are new leases for buildings built specifically for the purpose of being leased to the Federal government.
- Clarifies an approach to determine required fossil fuel-generated energy consumption levels for EISA-subject major renovations that are limited to system or component level retrofits.
- Clarifies an alternative compliance method for buildings with process loads that are not included in CBECS and RECS.
- Clarifies that process loads of building types not included in CBECS are not subject to the fossil fuel reductions, including, for example, process loads associated with the charging of electric vehicles and the fueling of natural gas fueled vehicles.
- Clarifies that renewable fossil fuels such as biomethane and biopropane qualify as exemptions from the calculation of fossil fuel usage.
- Clarifies the definition of Scope 1 fossil fuel-generated energy consumption as the metric being used for this rule (only including consumption for on-site fossil fuel use, not embedded fossil fuels in on-site electricity use).
- Clarifies the definition of technical impracticability for purposes of the petition process.
- Modifies definitions of major renovations to reflect focus on Scope 1 fossil fuel-generated energy consumption and fossil fuel-using systems as opposed to the whole building fossil-fuel generated energy consumption and all building systems.

Over the past few years, DOE has addressed energy efficiency requirements for Federal buildings as mandated in ECPA. DOE published a final rule updating Federal building energy efficiency standards for commercial or multi-family high-rise residential buildings to ASHRAE Standard 90.1–2019 on April 7, 2022. 87 FR 20293. DOE also published a final rule updating Federal building energy efficiency standards for low-rise residential buildings to the 2021 International Energy Conservation Code (''IECC'') on April 5, 2022. 87 FR 19613. Prior to that, DOE published a final rule updating the Federal building energy efficiency standards for low-rise residential buildings to the 2015 IECC on January 10, 2017 (82 FR 2857), and a final rule updating Federal building energy efficiency standards for commercial and multi-family high-rise residential buildings to ASHRAE Standard 90.1–2013 on November 6, 2015. 80 FR 65749. DOE also published a final rule regarding green building certification systems for Federal buildings that applied to Federal commercial or multi-family high-rise residential buildings and low-rise residential buildings on October 14, 2014. 79 FR 61563.

C. Coverage of the Regulation

This SNOPR applies to a defined subset of new Federal buildings and major renovations to Federal buildings, as specified in section 433 of EISA 2007. (*See* 42 U.S.C. 6834(a)(3)(D)(i)) The term ''Federal building'' means any building to be constructed by, or for the use of, any Federal agency, including buildings built for the purpose of being leased by a Federal agency, and privatized military housing. (42 U.S.C. 6832(6)).

The subset of Federal buildings for which this rule will apply fall under two categories and will be referred collectively to as ''EISA-subject buildings.'' The first qualifying category of EISA-subject buildings includes any new Federal buildings or major renovations to Federal buildings that are public buildings, as defined in 40 U.S.C. 3301,[5] for which transmittal of a prospectus to Congress is required under 40 U.S.C. 3307. Under 40 U.S.C. 3307(a)(1), a transmittal of a prospectus to Congress is required if a total expenditure in excess of $1,500,000 is required to construct, alter, or acquire

[3] Complete contents of the docket folder may be found at *www.regulations.gov/#!docketDetail;D=EERE-2010-BT-STD-0031.*

[4] *Id.*

[5] Under 40 U.S.C. 3301(a)(5), ''public building'' is a building, whether for single or multitenant occupancy, and its grounds, approaches, and appurtenances, which is generally suitable for use as office or storage space or both by one or more federal agencies or mixed-ownership Government corporations. ''Public building'' includes federal office buildings, post offices, customhouses, courthouses, appraisers stores, border inspection facilities, warehouses, record centers, relocation facilities, telecommuting centers, similar federal facilities, and any other buildings or construction projects the inclusion of which the President considers to be justified in the public interest. The definition does not include a building or construction project that is on the public domain (including that reserved for national forests and other purposes); that is on property of the Government in foreign countries; that is on Native American and native Alaskan property held in trust by the Government; that is on land used in connection with federal programs for agricultural, recreational, and conservation purposes, including research in connection with the programs; that is on or used in connection with river, harbor, flood control, reclamation or power projects, for chemical manufacturing or development projects, or for nuclear production, research, or development projects; that is on or used in connection with housing and residential projects; that is on military installations (including any fort, camp, post, naval training station, airfield, proving ground, military supply depot, military school, or any similar facility of the Department of Defense); that is on installations of the Department of Veterans Affairs used for hospital or domiciliary purposes; or the exclusion of which the President considers to be justified in the public interest.

the public building.[6] Under 40 U.S.C. 3307(h), the GSA Administrator may adjust this value annually to account for construction cost increases. GSA's annual prospectus threshold for FY 2022 is $3,375,000.[7] GSA also provides a separate dollar threshold for alterations in leased public buildings for which a prospectus is required. In FY 2022, the cost threshold for alterations in leased buildings for public purposes is $1,687,500.

The second qualifying category of EISA-subject buildings covers any new Federal buildings or major renovations to Federal buildings that are not public buildings and for which the construction cost or major renovation cost is at least $2,500,000 (in 2007 dollars, adjusted for inflation). Agencies can calculate what that adjusted cost threshold would be currently by visiting (*https://data.bls.gov/cgi-bin/cpicalc.pl*). As noted previously, GSA also provides a separate dollar threshold for alterations in leased public buildings ($1,687,500 in FY2022). DOE will use both of these thresholds (*i.e.,* the $2,500,000 in FY 2007 dollars, and the $1,687,500 in FY2022, each adjusted for inflation) for this second category of EISA-subject buildings (*i.e.,* buildings for which a prospectus is not required). With respect to the threshold for alterations in leased buildings, while section 433 of EISA prescribes a $2,500,000 (in 2007 dollars) threshold for major renovations for which a prospectus is not required, DOE proposes to use the lower GSA prospectus threshold for alterations in leased buildings for this second category of EISA-subject buildings because it is consistent with: (1) current agency practice for such buildings, and (2) the scheme Congress established in EISA section 433 where the prospectus dollar thresholds (*e.g.,* $2,500,000 in 2007 dollars) are nonetheless applied to buildings and renovations for which a prospectus is not required.

For example, a building in the first category would include a federal office building for which design for construction began in FY 2022 and with construction or renovation costs that are more than $3,375,000. A building in the second category would include a residential building (which is excluded from the definition of ''public building'' under 40 U.S.C. 3301) with construction or renovation costs of at least $3,375,000 in FY22 ($2,500,000 (in 2007 dollars, adjusted for inflation)). DOE expects that the majority of low-rise residential buildings that meet the cost threshold will be low-rise multi-family buildings or low-rise dormitories as Federal low-rise single-family homes are not likely to meet the cost threshold.

When identifying major renovation projects within an EISA-subject building which could be subject to this regulation because of the cost thresholds, agencies should consider any energy conservation measures (''ECMs'') which have been identified in that building and reported to DOE, as per 42 U.S.C. 8253(f)(3)(A). If identified ECMs include projects which would impact on-site fossil fuel usage, the agency should consider the total of those project costs bundled together when implementing those ECMs to determine whether the total cost triggers EISA compliance. ECMs that impact on-site fossil fuel usage may include, for example: adding new fossil fuel-using heating, hot water, or cooking systems to an existing building; direct replacement of existing fossil fuel-using heating, hot water, or cooking systems in an existing building; and modification or replacement of any building systems (including systems such as lighting or building envelope systems that do not use fossil fuel directly) that lead to an increase or decrease in fossil fuel use). Such an approach would address a situation where individual pieces of on-site fossil fuel consuming technology are replaced with similar technologies in a piecemeal approach instead of a more strategic and comprehensive way that furthers the goals of EISA along with the Administration's priorities to reduce Federal agencies' reliance on fossil fuels and reduce on-site Federal building emissions.

II. Discussion of Proposed Standards

A. Performance Standards for Fossil Fuel-Generated Energy Consumption

To provide flexibility while adhering to the statutory origins of the rule, DOE is proposing to keep the performance standards for fossil fuel-generated energy consumption metric from the 2014 SNOPR (expressed in kBtu per ft^2 of building gross area) while also providing an equivalent conversion of the energy metric measured in greenhouse gas (GHG) metrics. As mentioned earlier, DOE has chosen to focus on on-site fossil fuels or Scope 1 emissions, at least initially. This is a shift from the proposed scope of the 2014 SNOPR, which also included consideration of off-site fossil fuel consumption. DOE determined to focus this rule on onsite fossil fuel use in light of recent Federal building initiatives and efforts to address fossil fuel use and emissions generated off-site (*e.g.,* Executive Order 14057). DOE may address emissions generated off-site (*i.e.,* Scope 2 emissions) at a later time.

This SNOPR provides agencies with two separate but equivalent sets of fossil fuel generated energy consumption targets—(1) fossil fuel-generated energy consumption based on a summation of on-site fossil fuel usage expressed in kBtu per ft^2 of building gross area and (2) a new carbon dioxide equivalent (''CO_2e'') per ft^2 metric based on the emissions associated with the on-site fossil fuel-generated energy consumption. Both metrics are based directly on the reported usage of fossil fuels in CBECS and RECS, with the fossil fuel-generated energy consumption metric simply adding up the fossil fuel usage and converting it to kBtu and the CO_2e metric converting the amount of each fuel used to CO_2e.

Agencies will be allowed to use either metric for their design targets. DOE opted to include the GHG metric, which will measure Scope 1 emissions, because agencies are already required to track and report their GHG emissions annually utilizing the ''Federal Greenhouse Gas Accounting and Reporting Guidance'' (Council on Environmental Quality (''CEQ''), January 17, 2016). DOE is proposing to align the quantifications and terminologies with those established in the Federal Greenhouse Gas Accounting and Reporting Guidance, which categorizes Scope 1 emissions into ''Generation of electricity, heat, cooling, or steam'', ''Mobile sources'', ''Fugitive emissions'', and ''Process emissions''. As mentioned earlier, at this time, DOE is proposing that the scope of this rule to be focused only on the on-site fossil fuel associated with the ''Generation of electricity, heat, cooling, or steam''.

DOE is proposing two exceptions to the scope of coverage of the standards in this SNOPR which differ from how emissions are instructed to be tracked by the Federal Greenhouse Gas Accounting and Reporting Guidance. First, DOE is proposing to exclude on-site fossil fuel energy generation or Scope 1 emissions associated with emergency backup generation of electricity from the scope of this rule. The Federal Greenhouse Gas Accounting and Reporting Guidance for the category of Scope 1 emissions from ''generation of electricity, heat, cooling,

[6] 40 U.S.C. 3307(a) also contains a second prospectus threshold in 40 U.S.C. 3307(a)(3) which applies to alterations of buildings which are under lease by the Federal Government for use for a public purpose if the cost of the alteration will exceed $750,000. This threshold is one-half of the threshold for all other new construction or alterations of existing buildings.

[7] *See* GSA Annual Prospectus Thresholds at *www.gsa.gov/real-estate/design-construction/gsa-annual-prospectus-thresholds.*

or steam'' requires tracking and reporting for emergency generators. However, DOE intends for agencies to include all on-site fossil fuel use or Scope 1 emissions associated with non-emergency generation from backup generators (such as those for peak shaving or peak shifting) in the scope of this rule. DOE may revisit the issue of whether to include these on-site fossil fuel uses in the future. DOE also notes that if agencies use their backup generators for both purposes, they will be required to calculate what fraction of their backup generator Scope 1 emissions is associated with emergency use and what fraction is associated with non-emergency use.

Second, DOE proposes to exclude any energy generation or Scope 1 emissions associated with biomass fuels from this rule, as they are not fossil fuel based and thus fall outside the coverage of this rule. DOE acknowledges that CEQ's guidance is different on biomass but is complimentary to provide additional coverage outside the fossil fuel scope mandated by statute for this proposed rulemaking. The Federal Greenhouse Gas Accounting and Reporting Guidance, unlike this rule, is not limited to fossil fuel-based emissions, and states that Scope 1 emissions include ''emissions from biomass combusted for production of electricity, heat, cooling, or steam''. However, because EISA 2007 directed DOE to establish regulations that require fossil fuel-generated energy consumption reductions, and biomass is not a fossil fuel, DOE has intentionally left biomass out of the CBECS and RECS targets developed for this rule. Agencies therefore would not include any energy consumption or Scope 1 emissions from biomass in their calculations.

Also, at this time DOE is focusing the scope of the SNOPR to regulate on-site fossil fuel use or Scope 1 on-site emission from stationary combustion sources. As such, any emissions associated with natural gas for alternatively fueled vehicles (''AFVs'') (or any other alternative fuel defined at 42 U.S.C. 13211 that is provided at a Federal building) would be excluded from coverage of these standards. In addition, for buildings with manufacturing or industrial process loads, DOE notes that the CBECS and RECS data that provide the targets for this rule do not contain manufacturing or industrial process loads. Therefore, DOE proposes to exclude these loads from coverage as well. For buildings with such process loads, the process loads will need to be accounted for in the analysis of the building's fossil fuel consumption and GHG emissions but would not be subject to the percentage reductions in fossil fuel-generated energy consumption (Scope 1 GHG emissions) required for the building related loads.

B. Compliance With Performance Standards for New Construction and Major Renovations of a Whole Building

DOE has developed quantitative requirements to determine compliance with the fossil fuel performance standards for new construction and major renovations (*i.e.,* major renovation of all Scope 1 fossil fuel-using systems in a building) of EISA-subject buildings. Consistent with the changes proposed in this SNOPR, DOE is proposing to define the term ''Major renovation of all Scope 1 fossil fuel-using systems in a building,'' which DOE proposes to define as a renovation of all Scope 1 fossil fuel-using systems on an existing building that is so extensive that it replaces all scope 1 fossil fuel-using systems in the building. This term includes, but is not limited to, comprehensive replacement or restoration of most or all major systems, interior work (such as ceilings, partitions, doors, floor finishes, etc.), or building elements and features. DOE also refers to such major renovations as ''whole building'' renovations throughout this preamble.

The proposed quantitative requirements would require agencies to calculate the on-site fossil fuel-generated energy consumption in kBtu of fossil fuels or the Scope 1 GHG emissions in CO_2e of their proposed building design and compare that estimate to the allowable fiscal year percentage reduction target found in the target tables in appendix A. Per statute (42 U.S.C. 6834), DOE has provided three compliance years in this SNOPR, those EISA-subject buildings for which the design for construction or major renovation begins in the FY2024, FY2025 to FY2029, and for those which the design for construction or major renovation begins during or after FY2030.

Fundamentally, the calculation would require agencies to determine the allowable target (in either kBtu of on-site fossil fuels or Scope 1 greenhouse gas (''GHG'') emissions attributed to the generation of electricity, heat, cooling, or steam) for stationary combustion sources as per ''Federal Greenhouse Gas Accounting and Reporting Guidance'' (Council on Environmental Quality (''CEQ''), January 17, 2016). The kBtu values or the metric tons of CO_2e from the Scope 1 emissions can then be divided by the floor area of the building and converted to per square foot (metric tons of CO_2e per square foot) value that can be compared with the target values in appendix A. For buildings that combine two or more building types, area-weighted averaging by square footage for each building type would be used to calculate the maximum allowable fossil fuel-generated energy consumption of the combined building.

For EISA-subject buildings for which design for construction or whole building renovation begins in the FY2024 to FY2029, tables of the proposed maximum allowable on-site fossil fuel-generated energy consumption (expressed in both kBtu per ft^2 and Scope 1 GHG emissions in CO_2e per ft^2) by building type and climate zone are provided. The proposed values in the tables come from DOE's EIA CBECS (for commercial buildings) and RECS (for multi-family high-rise and low-rise residential buildings), both of which are converted from site energy consumption to kBtu and Scope 1 GHG emissions in CO_2e. As noted previously, DOE is proposing to define the term ''Major renovation of all Scope 1 fossil fuel-using systems in a building'' as a major renovation of all scope 1 fossil fuel-using systems in a building that is so extensive that it replaces all scope 1 fossil fuel-using systems in the building. This term includes, but is not limited to, comprehensive replacement or restoration of most or all major systems, interior work (such as ceilings, partitions, doors, floor finishes, etc.), or building elements and features. DOE also uses the term ''whole building renovation'' in reference to these types of renovations throughout this preamble.

For EISA-subject buildings for which design for construction or whole building renovation begins in fiscal year 2030 or beyond, the fossil fuel-generated energy consumption of the building must be zero for all building types and climate zones, based on the calculation established in the regulations.

C. Compliance With Performance Standards for Major Renovations Within a Building

To determine compliance with the fossil fuel performance standards for major renovations of systems or components within EISA-subject buildings, DOE has developed streamlined proposed prescriptive requirements. The proposed prescriptive requirements in this case would be that the systems within the building undergoing major renovation would be brought up to the performance requirements of the individual sections of ASHRAE 90.1–2019 (chapters 5–10).

DOE is not proposing fiscal year timeframes for these requirements to apply, but rather, agencies would begin implementing them upon effective date of the rule. For major renovations in EISA-subject buildings which meet the project cost threshold and coverage requirements that are less than whole building renovations (*i.e.,* projects within the existing building comprising of retrofits to a single system or component such as a HVAC system or a chiller), agencies would be required to follow the following prescriptive requirements.

A major renovation within a building is defined as a major renovation of a scope 1 fossil fuel-using building system or scope 1 fossil fuel-using component that provide significant opportunities for energy efficiency or reduction in fossil fuel-related energy consumption. This includes, but is not limited to, replacement of the HVAC system, hot water system, or cooking system, or other fossil fuel-using systems or components of the building that have a major impact on fossil fuel usage. For component level renovations, meaning just a product or piece of equipment, agencies would be required to utilize electric or non-fossil fuel using Federal Energy Management Program (''FEMP'') designated or ENERGY STAR equipment, which follow existing Federal requirements for equipment efficiency (found in 10 CFR part 436, subpart C, ''Agency Procurement of Energy Efficient Products'').

For system level renovations, agencies would be required to utilize electric or non-fossil fuel using FEMP designated or ENERGY STAR equipment, in alignment with 10 CFR part 436, subpart C and would also be required to meet the system level requirements for the systems being renovated in the model energy codes used to establish baseline energy efficiency standards for Federal buildings (*i.e.,* the current ASHRAE Standard 90.1 for Federal commercial and high-rise multi-family buildings covered under 10 CFR part 433 or the current IECC for Federal low-rise buildings covered under 10 CFR part 435.)

While this SNOPR would only cover systems and components that utilize on-site fossil fuels, agencies should ensure that projects that could have secondary impacts on fossil fuel using equipment, such as lighting or window replacement projects are considered. DOE encourages agencies to consider whole building optimization for any type of major renovation project to ensure no adverse impacts to on-site fossil fuel use. DOE also encourages on-site renewables such as solar and storage as good practice. DOE is not including on-site solar as a means to offset on-site fossil fuel consumption because it will not reduce the overall on-site contribution even though it is a means to reduce emissions from the electricity use of Federal building. DOE requests that agencies provide comments on how to ensure major renovations which do not directly replace on-site fossil fuel using equipment could be incorporated in this rule (*e.g.,* lighting replacement projects that indirectly increase onsite fossil fuel usage through decreased internal gains and higher subsequent heating loads).

D. Development of Fossil Fuel-Generated Energy Consumption Target

To develop the target values in appendix A, DOE utilized CBECS and RECS data to determine the on-site fossil fuel usage by fossil fuel type for each building in CBECS or RECS and then applied two transformations to that data.

The CBECS and RECS data was parsed into the 19 climate zones used in the current Federal baseline standards for commercial and multi-family high-rise residential buildings, which rely on ASHRAE Standard 90.1–2019. The same 19 climate zones are used in the current Federal baseline standards for low-rise residential buildings, which rely on the 2021 IECC.

The first transformation DOE performed was converting the fossil fuel consumption data collected and reported in CBECS and RECS by building and by fossil fuel into kBtu, dividing by the building area, applying the weighting factors associated with the building, and assigning each building to one of the building type/climate zone bins. The resulting target is expressed in terms of allowable kBtu per square foot by building type and climate zone.

The second transformation was taking the same fossil fuel consumption data reported in CBECS and RECS for each building, multiplying the fossil fuel usage for each fuel type by the applicable GHG coefficient from the CEQ guidance for each fuel type, dividing by the building area, applying the weighting factors associated with the building, and assigning each building to one of the building type/climate zone bins. The resulting target is expressed in terms of allowable CO_2e (in metric tons of CO_2e) per square foot by building type and climate zone. The resulting targets are shown in appendix A to subpart B of parts 433 and 435 in Table A–1a and Table A–1b.

E. Petitions for Downward Adjustment

Under section 433 of EISA 2007, agencies other than GSA may petition DOE for an adjustment to the fossil fuel-generated energy consumption requirement with respect to a specific building if meeting the requirement is technically impracticable in light of the agency's functional needs for the building. The 2014 SNOPR proposed allowing GSA tenant agencies with significant control over building design to petition DOE, and that proposal is carried forward into this second SNOPR. This SNOPR proposes a list of what information would be required in a petition for a downward adjustment for a new building and for major renovations that are whole building renovations. This includes a description of the building and associated components and equipment, an explanation of why compliance with the requirements is technically impracticable considering the functional needs of the building, a demonstration that all cost-effective energy efficiency and on-site renewable energy measures were included in the building design, the largest feasible reduction in fossil fuel-generated energy consumption that can reasonably be achieved, and a description of measures that were evaluated but rejected. As proposed, the Director of FEMP will review the petition and make a best effort to return the complete petition in 45 calendar days of submittal (*see* 42 U.S.C. 8253(i)(3)(B)(iv)*;* incomplete petitions will not be subject to this timeframe and may result in delays.

Additionally, this rulemaking proposes a separate downward adjustment process for major renovations that are system or component level retrofits. Upon application, a major renovation that is limited to a component level retrofit will receive a downward adjustment equal to the energy efficiency level that would be achieved through the use of products that represent a level of energy efficiency that is life-cycle cost-effective if such products are commercially available. This would be demonstrated using ENERGY STAR or FEMP designated products. Upon application, a major renovation that is limited to a single system or multiple systems will receive a downward adjustment equal to the energy efficiency level that would be achieved through the use of the same ENERGY STAR or FEMP designated products as required for component renovations and through use of the system level requirements for renovations found in the baseline energy efficiency standards in 10 CFR

part 433 (ASHRAE Standard 90.1–2019) or 10 CFR part 435 (the 2021 IECC). If the petition only contains component level retrofits for adjustment consideration, the Director of FEMP will review the petition and make a best effort to return the complete petition within 20 calendar days of submittal (*see* 42 U.S.C. 8253(i)(3)(B)(iv)); incomplete petitions will not be subject to this timeframe and may result in delays. DOE is also considering a separate petition process for Department of Defense projects that serve critical national security functions. Under this separate process, the head of the agency designing the building (or his or her designee) must certify that meeting the Scope 1 fossil fuel-based energy consumption targets would be technically impracticable because the building, system, or component serves a critical national security function and providing basic facility or project design information may divulge sensitive national security information. The petition must be accompanied by a statement that the agency has reduced the fossil fuel-based energy consumption of the building, system or component and complied with the other requirements of this part to the maximum extent practicable. DOE believes this separate process would be protective of critical national security projects and information, while also ensuring that DOE meets its petition obligations under 42 U.S.C. 6834. However, DOE recognizes that the term ''critical national security function'' is potentially ambiguous. DOE also recognizes that agencies may need flexibility in defining what buildings or projects serve critical national security functions, and that a pending petition may delay projects that serve critical national security functions.

DOE requests comment on (i) a separate petition process for buildings and projects serving critical national security functions, (ii) if and how DOE should define ''critical national security functions'', (iii) whether such buildings or projects (or some of them) should be exempt from the scope of the proposed rule, and (iv) how agencies should use their own discretion in determining what buildings or projects serve critical national security functions.

F. Terminology To Be Defined in This Rulemaking

This SNOPR adds definitions for ''construction cost,'' ''design for renovation,'' ''fiscal year (''FY''),'' ''major renovation,'' ''major renovation cost,'' ''major renovation of a whole building,'' ''major renovation of a building system or component,'' ''multi-family high-rise residential building,'' and revises the definition for ''proposed building.'' For the purposes of establishing the targets, this proposed rulemaking establishes the definitions of 16 categories of commercial buildings and 5 categories of residential dwelling units which cover all residential buildings, including low-rise (single-family and multi-family), mid-rise apartment buildings, and high-rise apartment building.

The 16 categories of commercial buildings defined are education, food sales, food service, health care (inpatient), health care (outpatient), laboratory, lodging, mercantile (enclosed and strip shopping malls), office, public assembly, public order and safety, religious worship (not applicable), retail (other than mall), service, and warehouse and storage. Many of these commercial building categories are further divided into building types, providing a total of 48 commercial building types. These building categories and building types represent the high-level Principle Building Activity (''PBA'') and low-level Principle Building Activity Plus categories in the 2003 CBECS.

The five categories of residential buildings are divided into five building/activity types: mobile, multi-family in 2–4-unit buildings, multi-family in 5 or more unit buildings, single-family attached, and single-family detached. These building types represent the housing unit types in the 2005 RECS. Residential buildings that fall under 10 CFR part 435 and multi-family mid-rise and high-rise buildings that fall under 10 CFR part 433 will use these same categories. For the purposes of analysis of the rule, DOE assumes that most multi-family high-rise residential buildings will fall into the ''multi-family in 5 or more unit buildings'' based on the most typical buildings representative of the Federal building.

Federal agencies would be required to select from these 53 categories to identify the fossil fuel-generated energy consumption target (expressed in both kBtu per ft^2 and Scope 1 GHG emissions in CO_2e per ft^2), for their new construction or building undergoing a major renovation. DOE notes that the building types available from CBECS and RECS do not correspond directly to the building types used in the Federal Real Property Profile (''FRPP''). Thus, agencies may need to area-weight the floor space these CBECS and RECS targets for Federal buildings that do not correspond directly to the CBECS or RECS building types. For example, a DOD Post Exchange building might have aspects of Food Sales, Food Service, and Mercantile, necessitating the development of an area-weighted target. Similarly, a DOD barracks building might include aspects of Lodging or Residential, Education, and Warehouse, again necessitating the use of an area-weighted mapping.

III. Additional Discussion Including Related Comments

DOE received 179 comments on the 2014 SNOPR from 27 different entities.[8] The comments were analyzed and categorized into the same six major categories used to categorize comments on the NOPR: Scope and Applicability of the Proposed Rule, Baseline, Methodology, Impacts, Petition for Downward Adjustment, Impacts of the Rule, and Guidance. Each major category of comment was broken down into multiple subcategories for discussion purposes.

DOE believes that many of the prior comments may no longer be appropriate or applicable given recent Federal building initiatives (*e.g.,* Executive Order 14057) and the significant change in the scope of the rule in this second SNOPR. Therefore, in this SNOPR, DOE only discusses comments relevant to DOE's current proposal, and only in a manner applicable to this proposal. DOE encourages those agencies and other stakeholders who commented on the 2014 SNOPR to read this proposed rule and provide further comment on this updated proposal.

A. Scope and Applicability of the Proposed Rule

This section discusses the scope and applicability of the proposed rule and the comments received on the 2014 SNOPR regarding that topic. The subcategories of comments are determining the $2.5 million threshold for applicability of the rule, compliance date of the rule, major renovations, multiple buildings, leased buildings, Federal buildings overseas, residential buildings, privatized military housing, and other relevant comments.

1. Determining the $2.5 Million Threshold for Applicability of the Rule

DOE received four comments including the Clean Energy Rule'' should apply to all new construction without consideration of the $2.5 million threshold,'' ''the $2.5 million threshold implies that low-rise residential buildings (such as military

[8] Comments received on the proposed rule are designated by the commenter or commenting organization, the DOE assigned number of the individual comment, and the page number of the commenters or commenting organizations submission.

family housing) will not be included,'' ''replace the mention of the $2.5 million in 2007 dollars with a table of year by year amounts,'' and ''do not use the $2.5 million threshold for major renovations as the definition of those renovations already mentions 'significant opportunities' ''. In light of the comment to provide tables with the year-by-year the $2.5 million in 2007 dollars, DOE has provided a link to the GSA website where such a table resides. See *www.gsa.gov/real-estate/design-construction/gsa-annual-prospectus-thresholds.* In response to comments suggesting different cost thresholds, the cost threshold at 42 U.S.C. 6834(3)(D)(I) forms the basis of the $2.5 million in 2007 cost threshold. DOE maintained use of this threshold in this SNOPR for consistency with the statutory requirement.

2. Compliance Date of the Rule

DOE received two comments on this topic, including a comment that the rule is overdue and another that DOE should finalize this rule only when DOE feels that agencies can meet the requirements in the rule, especially for the requirements in year 2030 and beyond. DOE is issuing this SNOPR with the intent of establishing these standards expeditiously. DOE also believes that agencies can now meet the requirements of this revised SNOPR as the new proposal would simply require elimination of on-site fossil fuel usage in the years 2030 and beyond.

3. Major Renovations

DOE received four comments on the 2014 SNOPR related to major renovations, including (1) agencies might break up their renovations into smaller pieces to avoid the rule's scope, (2) DOE should eliminate requirements for major renovations that involve single components or systems, (3) DOE should provide instructions for how to deal with major renovations for part of a building, and (4) agreement with DOE's previous decision to drop a 25 percent replacement cost threshold that appeared in the original NOPR. In response, DOE accepted the first, third, and fourth comments, but rejected the second comment. DOE will attempt to discourage the possibility of ''breaking up renovation projects to get around the cost threshold'' in the guidance document that will accompany this rule. DOE notes that section 433 states that ''[i]n establishing criteria for identifying major renovations that are subject to the requirements of this subparagraph, [DOE] shall take into account the scope, degree, and types of renovations that are likely to provide significant opportunities for substantial improvements in energy efficiency.'' 42 U.S.C. 6834(a)(3)(D)(ii). This indicates Congressional intent that the term ''major renovations'' should be construed broadly to include projects for which agencies can practicably implement the energy efficiency and fossil fuel reduction goals of ECPA and EISA. DOE believes that major renovations that are less than whole building renovations, *i.e.,* component and system level renovations, can provide significant opportunities for substantial improvements in efficiency and reduction of fossil fuel usage across the Federal building portfolio. Accordingly, this proposed rule addresses how building systems and components should be addressed if only part of the building is renovated, and the requirements for these renovations are not based on the whole building targets that apply to new construction and major renovations of the whole building.

4. Multiple Buildings

DOE received one comment in this category supporting DOE's decision to apply the $2.5 million threshold to individual buildings rather than to multiple buildings in a single project. DOE concludes that the $2.5 million threshold should apply to individual buildings in order to determine whether they are covered buildings under this rule. The statute mandates that the requirements apply to ''buildings,'' not ''projects'' or ''developments.'' (42 U.S.C. 6834(a)(3)(D)(i))

5. Leased Buildings

DOE asked for and received two comments on leased buildings. One comment pointed out that applying this rule to short term leases would preclude the use of Utility Energy Service Contracts (''UESCs'') or Energy Savings Performance Contracts (''ESPCs''). DOE notes that agencies may implement UESCs and ESPCs in leased buildings.[9] Therefore, the rule's requirements would apply to renovations of such leased buildings where the cost thresholds are met. However, DOE does not anticipate that many, if any, agencies would implement such renovations in short-term leases, and expects that most renovations of short-term leases would likely fall under the cost thresholds of the rule. However, the rule would not apply in cases of Federal agencies leasing space in buildings where the entire building is not leased to the Federal Government. This proposed rule only applies to major renovations of buildings originally built to be leased to the Federal Government with the exclusion that if the building at issue is not entirely leased to the Federal Government at the time of renovation, this proposed rule does not apply. DOE also received a comment objecting to DOE removing mention of ''significant design control'' as a limitation to the rule. In response to this comment, DOE points out that it addressed a similar comment in the issuance of the Green Building Certification Rule. (79 FR 61563) In that rule, DOE stated that it has not expressly added the significant control restriction to the rule for leased buildings because the ECPA definition of Federal building is limited to buildings that are built specifically for the Federal government. *See* 42 U.S.C. 6832. Construction design for a building built specifically for use of the Federal government, including under lease to a Federal agency, is, presumably, under the significant control of the Federal owner or Federal lessee. DOE reaffirms its previous decision on significant control in this proposed rule.

6. Federal Buildings Overseas

DOE received no comments on this topic in the 2014 SNOPR. DOE re-affirms its statement that this proposed rule will apply to the extent that the requirements are consistent with applicable law. DOE does not intend for the rule to cause any Federal agency to violate other legal authorities. This proposed rule does not expressly address the extent to which it may be applicable to buildings overseas, as each individual agency is best positioned to understand the various and sometimes unique authorities that may be applicable to overseas buildings of that agency. In applying the proposed rule to any given building, Federal agencies must also decide whether the building meets the definition of Federal building at 42 U.S.C. 6832(6) and either the requirement that the building be a ''public building'' for which a prospectus is required, or the requirement that the building or major renovation cost at least $2.5 million. (42 U.S.C. 6834(a)(3)(D)(i)).

7. Residential Buildings

DOE received no comments on residential buildings in the 2014 SNOPR. Therefore, DOE does not believe any changes to the proposed

[9] More guidance on considerations and implementation of ESPCs and UESCs in leased spaces may be found on FEMP's web page. For ESPCs: *https://www.energy.gov/sites/default/files/2022-07/espc_faq_42-usc-8287-0622.pdf.* For UESCs: *https://www.energy.gov/eere/femp/frequently-asked-questions-about-federal-utility-energy-service-contracts.*

language in the 2014 SNOPR are needed. The statute requires the inclusion of all Federal buildings, including residential buildings that are EISA-subject buildings.

8. Privatized Military Housing

DOE received no comments on this topic in the 2014 SNOPR. Therefore, DOE will confirm its use of the EISA 2007-modified ECPA definition of ''Federal building'' to apply to any building to be constructed by, or for the use of, any Federal agency. Such term includes buildings built for the purpose of being leased by a Federal agency, and privatized military housing. (42 U.S.C. 6832(6)) In addition, Congress again mentioned privatized military housing in ECPA when it specified that, ''with respect to privatized military housing, the Secretary of Defense, after consultation with the Secretary [of Energy] may, through rulemaking, develop alternative criteria to those established in subclauses (I) [fossil fuel reduction requirements] and (III) [sustainable design requirements] of clause (i)'' of section 433 of EISA. (42 U.S.C. 6834(a)(3)(D)(vi)) Although privatized military housing may not meet the definition of ''public building'' at 40 U.S.C. 3301(a)(5), the rule will apply to privatized military housing with construction costs of at least $2.5 million. As described in this preamble, this cost threshold applies on an individual building basis.

9. Other Relevant Comments

DOE received three comments in this category. One comment from electric utilities indicated that fossil fuel generated energy consumption of a building should only apply to on-site energy consumption. DOE agrees with this comment and this proposed rule is based solely on on-site fossil fuel usage. A second comment indicated that the rule should include all Federal buildings due to the long term ecological and economic benefits of the rule. DOE notes that under section 433 of EISA 2007, there is a clear limit to the application of this rule to larger and costlier buildings and major renovations so DOE declines to expand the rule to additional Federal buildings. A third comment indicated that the use of energy efficient buildings is not only ecologically sound but also of great strategic value, due to the increases in energy costs and the reduction of government funds to pay for programs and these costs. DOE agrees with this comment.

B. Establishing and Using the Baseline

This category was divided into nine subcategories: CBECS and RECS baselines, climate adjustment, plug and process loads, differentiating between fossil fuels, regional fossil fuel factors, marginal source of electricity, residential common areas, major renovations, and other relevant comments.

1. CBECS and RECS Baselines

DOE received two comments in this category—one asking if DOE was planning to update the rule to refer to the 2012 CBECS when that data became available and another questioning the statistical significance of the CBECS data when it is split at the building category level. In response, DOE notes that EISA 2007 requires the use of 2003 CBECS and RECS as a baseline. DOE also notes that because this proposed rule includes a gradual increase to 100 percent fossil fuel-based energy consumption reduction in 2030, the use of a single, unchanging baseline is necessary.

DOE believes that while there may be some loss of statistical significance by using disaggregated building types and climate zones, the flexibility the disaggregation provides agencies in terms of selecting a building type and climate zone that much more accurately reflects an agency's building and its location outweighs the loss of statistical significance.

2. Climate Adjustment

DOE received no comments on this topic in the 2014 SNOPR. Therefore, DOE re-affirms its commitment to including fossil fuel-based energy consumption reduction targets based on both building type and climate zone in the rule.

3. Plug and Process Loads

DOE requested comments on how the proposed rule could be designed such that the assumptions used in the whole building simulations would accurately reflect the final building design and operation, including plug and process loads. In response, DOE received 15 comments on plug and process loads. Given that DOE has revised the scope of this proposed rule to apply only to on-site fossil fuel usage associated with heating, hot water, generation of electricity, and cooking, virtually all these comments are no longer applicable. Plug loads (entirely electric) are excluded from this proposed rule. Certain process loads that use fossil fuel may be applicable in the petition process.

4. Differentiating Between Fossil Fuels

DOE received several comments on the NOPR about differentiating between fossil fuels *i.e.,* natural gas versus crude oil. The comments varied, although most favored differentiating between fossil fuels. DOE received three comments on the 2014 SNOPR on this topic, with two comments agreeing that not differentiating between fossil fuel was appropriate and one comment focusing on the source emissions factors used by DOE. In response, DOE notes that this proposed rule focuses on only on-site fossil fuel emissions. DOE notes that the targets, while based on the actual fossil fuels used in CBECS and RECS buildings, are expressed only in terms of overall kBtu per ft^2 of fossil fuels or CO_2e per ft^2 of emissions, thus keeping with DOE's original intent of not differentiating between fossil fuels. DOE also notes that since the rule is now focused on on-site fossil fuel use only, the issue of source emission factors for electricity is now less important as DOE is no longer proposing to regulate the fossil fuel content of electricity used in Federal buildings. DOE does acknowledge that the source emission factors related to electricity are used in DOE's analysis of the impacts of the rule and that DOE will use the latest available source emission factors from DOE and EPA.

5. Regional Fossil Fuel Factors

DOE indicated in the 2010 NOPR that it was considering a regional approach to establishing the fossil fuel fraction associated with electricity and asked for comments. In the 2014 SNOPR, DOE decided to use the national electric power mix in determining the fossil fuel portion of electricity consumption in the rule. DOE received no comments on this topic in the 2014 SNOPR, so DOE re-affirms those decisions in this second SNOPR. DOE also notes that this issue is much less important in this proposed rule as DOE is no longer regulating the fossil fuel content of grid electricity used in Federal buildings. DOE does acknowledge that the source emission factors related to electricity are used in DOE's analysis of the impacts of the rule and that DOE will use the latest available source emission factors from DOE and EPA.

6. Marginal Source of Electricity

DOE received a number of comments on this topic in the NOPR and proposed in the 2014 SNOPR to not use marginal electric source factors. DOE received two comments on this topic in the 2014 SNOPR, both agreeing with DOE's decision not to use marginal electrical

rates. Receiving no other comments, DOE re-affirms its tentative decision to not use marginal electricity rates in second SNOPR.

7. Residential Common Areas

The NOPR stated that the RECS baseline for multi-family residential buildings only includes the energy use for individual dwelling units, not any associated conditioned common areas. DOE proposed applying the RECS-derived fossil fuel requirements to all applicable floor space, including both common and non-common areas. Because common areas often have a lower energy intensity than individual dwelling units, using only non-common areas in the calculation for the proposed design's fossil fuel consumption is likely to result in a slightly higher maximum allowable fossil fuel-generated energy requirement than using both common areas and non-common areas in the calculation. This approach will make it easier for building designers to demonstrate compliance for a residential building overall. Because common areas account for only a small fraction of the floor space in multi-family residential buildings, however, the actual effect on fossil fuel reductions would be minimal. DOE received no comments on this topic in the 2014 SNOPR and re-affirms the approach taken in the NOPR and 2014 SNOPR in this second SNOPR.

8. Major Renovations

As noted previously in this document, the CBECS and RECS data that provide the baseline for this proposed requirement are building level data. For major renovations that are whole building renovations, the maximum fossil fuel-generated energy consumption values generated from CBECS and RECS provide requirements that are comparable to the energy consumption of the whole building renovation. However, DOE believes that the maximum consumption levels presented in the proposed tables may not be appropriate for major renovations that are system or component level retrofits. As such, in the 2014 SNOPR, DOE proposed that the requirements for system and component level retrofits be based on the percentage of whole building fossil fuel consumption represented by the retrofitted system or component. The applicable table value would be multiplied by this percentage to arrive at the maximum allowable energy use of the retrofitted system or component. DOE requested comment on this approach, as well as comment on other approaches that could be used to determine the requirement for system and component level retrofits. DOE received five comments on this topic in the 2014 SNOPR. Comments ranged from agreement with DOE's approach to not require major renovations of systems or components to meet the full target to opposition to DOE's approach because it did not require specific evaluation of the renovation petitions, to comments that DOE should expand the scope of the rule to all renovations, even those that did meet the cost threshold, and other comments that DOE should apply the requirements of ASHRAE Standard 90.1 and the IECC to renovations, and comments that DOE should not even consider major renovations that do not involve the whole building, but which happen to meet the cost-threshold.

In response, DOE notes major renovations are required to be part of this proposed rule by statute, and that DOE believes any renovation that meets the cost-threshold of the rule and falls within the scope of the rule should comply with the rule unless agencies go through the petition process for specific considerations of a given project. DOE is proposing this approach to allow agencies to take a more holistic view of their renovation projects over time, so that projects resulting in load reductions (such as insulation improvements) as well as electrifying end-uses can be implemented in a complimentary fashion. DOE also notes that for major renovations involving only replacement of equipment (such as boilers), there is little else DOE can direct agencies to do other than to use high efficiency equipment (as is required under 10 CFR part 436, subpart C) and to require that that equipment uses electricity and not fossil fuels. DOE cannot require agencies to renovate other parts of the building. For major renovations that involve renovation of individual systems (such as hot water or heating, ventilation, and air-conditioning (''HVAC'') systems), DOE is requiring agencies to use high efficiency equipment that uses electricity and not fossil fuels and meet the renovation requirements of the baseline standards in 10 CFR part 433 (ASHRAE Standard 90.1–2019) or 10 CFR part 435 (the 2021 IECC), as appropriate. DOE notes and encourages on-site renewables such as solar and storage as good practice.

9. Other Relevant Comments

Three additional comments were submitted that do not fit into one of the scope subcategories. One comment recommended using embodied energy in the rule. DOE noted that it was required to use CBECS and RECS data per statute and that CBECS and RECS do not contain embodied energy. Two other comments recommended that DOE implement a multiplier based on hours of operation for Federal buildings that are in operation longer than corresponding private sector buildings found in CBECS. DOE found these two comments persuasive because many types of Federal buildings are operated longer hours than typical buildings covered in CBECS and RECS. In addition, DOE notes that hours of operation are already considered in tools such as ENERGY STAR Portfolio Manager which agencies are required to use as part of their building benchmarking activities. (42 U.S.C. 8253(f)(8)) The hours of operation of a building are also implicit in any whole building simulation done on a building design, with longer hours of operation typically leading to higher energy usage. The proposed shift multiplier in this proposed rule is based on analysis by Oak Ridge National Laboratory and was originally developed for ASHRAE Standard 100–2018 and is expressed in ''number of operating shifts'' as opposed to actual hours of operation. Shift multipliers provided are both less than and greater than 1 depending on building type. For government offices, for example, operating the building for 2 shifts does not increase the energy usage, but operating the building 3 shifts increases the energy use by a multiplier of 1.4. DOE notes that residential buildings, by their very nature, are already considered to be 24-hour operation and, therefore, this multiplier will only apply to Federal commercial buildings regulated under 10 CFR part 433.

C. Methodology To Determine Compliance

DOE categorized comments on the methodology to determine compliance in six subcategories: whole building simulation, off-site and on-site renewable energy and renewable energy certificates, use of source energy, fuel conversion efficiency, and on-site energy generation from natural gas. Each of these subcategories is discussed below.

1. Whole Building Simulation

To determine energy use in the proposed building design, DOE proposed in the 2010 NOPR and re-affirmed in the 2014 SNOPR that the fossil fuel-generated energy consumption of a proposed new Federal building or major renovation of a Federal building be estimated using the Performance Rating Method found in Appendix G of ANSI/ASHRAE/IESNA Standard 90.1–2004 for commercial and multi-family high-rise residential

buildings, and the IECC 2004 Supplement for low-rise buildings. 75 FR 63409. Because of the complexity involved in estimating fossil fuel-generated energy consumption, this requirement would effectively require the use of a whole building simulation tool, which can be difficult and increases cost.

In the 2014 SNOPR, DOE recognized that the whole building approach is likely not appropriate for major renovations that are limited to system or component level retrofits. For major renovations that are less than whole building renovations (*i.e.,* system or component level-retrofits) DOE proposed establishing the maximum allowable fossil fuel consumption in fiscal years 2018 through 2029 based on the percentage of whole building consumption represented by retrofitted system or component. The applicable table value would be multiplied by this percentage value to arrive at the maximum allowable fossil fuel consumption of the retrofitted system or component. For determining compliance, DOE proposed basing the subject fossil fuel-generated energy consumption on the system or component as retrofitted. This will require the design engineer to estimate both the energy consumption of the systems or components as renovated and the energy consumption of the entire building as renovated.

DOE received no comments on the use of whole building simulation, but DOE has changed its adopted approach to major renovations to system and components in a manner which will no longer require whole building simulation, as described in this section. Instead, component and system level renovations will be required to use electric or non-fossil fuel using FEMP designated or ENERGY STAR equipment and system level major renovations will be required to use the same electric or non-fossil fuel using FEMP designated or ENERGY STAR equipment and major renovation requirements in the baseline standards for 10 CFR part 433 and 10 CFR part 435. (ASHRAE 90.1–2019 is the current baseline standard for 10 CFR part 433 and the 2021 IECC is the current baseline standard for 10 CFR part 435.)

2. Off-Site and On-Site Renewable Energy and Renewable Energy Certificates

In the NOPR and 2014 SNOPR for this rule, DOE considered both the on-site fossil fuel usage and the fossil fuel use associated with the electricity used on site. As part of compliance with the NOPR and 2014 SNOPR versions of the rule, renewable energy and renewable energy certificates were allowed for compliance with this rule. This topic area was the single most commented on topic area in the 2014 SNOPR, with 51 comments being received. However, given that DOE has chosen to refocus this rule on just on-site fossil fuel usage, the entire concept of using (or not using) renewable energy or renewable energy certificates to meet this rule is no longer relevant. Therefore, DOE will not list all the comments related to the use of renewable energy and renewable energy certificates from the 2014 SNOPR.

3. Use of Source Energy

DOE previously made use of source energy for both on-site fossil fuel usage and electrical usage in the NOPR and 2014 SNOPR. DOE received six comments on this topic in response to the 2014 SNOPR. However, with the refocus of the rule to just on-site fossil fuel usage, consideration of source energy is no longer relevant. DOE will use on-site fossil fuel usage using the directions provided for Federal greenhouse gas emission calculation as noted previously in this proposed rule. The six comments will not be discussed in this SNOPR.

4. Fuel Conversion Efficiency

In the NOPR, DOE proposed that the electricity source energy factor would be based on the average utility delivery ratio in Table 6.2.4 of the 2010 DOE Building Energy Data Book (*See https://buildingsdatabook.eere.energy.gov*). 75 FR 63410. The ratio accounts for fuel conversion losses to produce electricity, as well as transmission and distribution losses. DOE used the electricity source energy factor of 0.316 from the most recent year data was available, 2008.

DOE made several definition changes in the 2014 SNOPR and added a new source energy multiplier for other fuels. DOE received no comments on this topic on the 2014 SNOPR, but DOE has made one further refinement to its treatment of fuel conversion efficiency in this proposed rule. DOE has added reference to ''coke'' [10] and used the same source energy multiplier as for coal and other fossil fuels. This action brings this proposed rule more into alignment with how fossil fuel usage is reported to FEMP under the requirements of EISA 2007 Section 432. The new fuel conversion efficiencies are taken from FEMP's Annual Reporting Template for agencies.

5. On-Site Energy Generation From Natural Gas

The 2010 NOPR indicated DOE's interest in the effect of the fossil fuel-generated energy consumption reduction requirements on distributed energy technologies that provide on-site electrical generation from natural gas, such as Combined Heat and Power (''CHP'') systems, to generate both heat and electricity. A building with a CHP system could potentially be an all-gas building in terms of utility purchases and would, therefore, be required to reduce natural gas consumption in accordance with the fossil fuel-generated energy consumption reduction requirements. DOE indicated its interest in minimizing the penalty in order to not discourage the use of on-site CHP systems, within the limits of the statutory language. DOE invited comments on the NOPR on how appropriate credit may be given for CHP systems through the compliance determination methodology. 75 FR 63410.

DOE received several comments related to distributed energy technologies on the 2010 NOPR. Based on the comments received and a technical review of the issues raised, DOE proposed specificity on how CHP and district heating systems should be considered in the 2014 SNOPR. Under this proposed rule, for district heating or cooling systems using fossil fuel as the source, the fossil fuel-generated energy consumption would be determined by adjusting the building load for the plant fuel conversion efficiency and estimated distribution losses as reflected in the Other Fuels Energy Source Multiplier. If a non-fossil fuel is used as the sole source (*e.g.,* geothermal) of energy for the district heating system, there would be no contribution to fossil fuel-generated energy consumption.

For CHP district heating systems, the electricity attributed to the proposed building would be determined by multiplying the building's pro-rated share of the total delivered heat from the system times the total electricity produced by the CHP system. For CHP systems serving only one building, fossil fuel consumption of the CHP system would be added to the direct fossil fuel consumption in Equation 1 proposed below. Because the electricity is produced from waste heat, the amount of electricity produced by either the CHP system serving a single building or a CHP district heating system, as determined previously, would be

[10] Coke is defined as a solid carbonaceous residue derived from low-ash, low-sulfur bituminous coal from which the volatile constituents are driven off by baking in an oven at temperatures as high as 2,000 degrees Fahrenheit so that the fixed carbon and residual ash are fused together. Coke is used as a fuel and as a reducing agent in smelting iron ore in a blast furnace.

deducted from the proposed design site electricity in Equation 1 under the renewable energy and CHP deduction.

In response to the 2014 SNOPR, DOE received 22 comments from natural gas associations, utilities, and manufacturers of gas turbines and fuel cells, most opposing the application of this rule to natural gas as doing so would will preclude the use of natural gas in the future which is problematic not only because it is an economical and environmentally beneficial domestic fuel, but also because doing so would be fundamentally inconsistent with the then Administration's support of CHP and the then Administration's goals to promote greater use of alternative fuels by Federal agencies. This subcategory was the second most commented on topic in the 2014 SNOPR.

In response to these comments, DOE emphasizes, once again, that this proposed rule is based directly on congressionally mandated language in section 433 of EISA 2007, which governs fossil fuel-generated energy consumption. DOE notes that the use of natural gas, CHP, and alternative fuels is not entirely prohibited by this rule (until 2030), although all fossil fuel usage must be accounted for and is regulated by this proposed rule.

6. Other Relevant Comments

DOE received fourteen additional comments relating to methodology that did not fit into one of the other subcategories in this larger topic. These comments covered potential exclusions for thermal and electrical energy storage systems, making this rule be based on an agency portfolio (as opposed to on a building-by-building basis), exemption of emergency backup systems, exemptions for fuel use for alternatively fueled vehicles (''AFVs''), potential credits for nuclear and hydropower electricity, and the need to rewrite the main equation in the rule.

In response to the comments about energy storage systems, DOE's rewrite of the rule to focus only on on-site combustion of fossil fuels makes any discussion of electrical energy storage moot. If agencies choose to burn fossil fuels to store heat in a thermal energy storage system, that fossil fuel would be counted as part of the consumption of the building. DOE notes that this rule applies to individual buildings based on statutory requirements, so DOE cannot change this rule to a portfolio approach. DOE notes that while emergency backup systems are part of the Scope 1 emissions covered by this rule, DOE has implemented a specific exemption for emergency backup generators that are used solely for emergency backup. Any use of these backup generators for peak shaving, peak shifting, or other demand management activities must be included in the building consumption.

With respect to mobile sources, section 433 of EISA refers to the fossil fuel-generated energy use of ''Federal buildings.'' 42 U.S.C. 6834(a)(3)(D)(i). Under ECPA, the term ''building'' means ''any structure to be constructed which includes provision for a heating or cooling system, or both, or for a hot water system.'' 42 U.S.C. 6832. This does not include mobile sources. Accordingly, mobile sources are excluded from the scope of this rule. Finally, DOE notes that credits for nuclear and hydropower electricity are no longer relevant to this proposed rule and that the governing equation in this proposed rule has been extensively rewritten and simplified in accordance with the change of scope.

D. Petitions for Downward Adjustment

Upon petition by an agency subject to the statutory requirements, ECPA permits DOE to adjust the applicable numeric fossil fuel-generated energy consumption percentage reduction requirement downward with respect to a specific building, if the head of the agency designing the building certifies in writing that meeting the requirement would be technically impracticable in light of the agency's specified functional needs for the building and DOE concurs with the agency's conclusion. (42 U.S.C. 6834(a)(3)(D)(i)(II)) ECPA further directs that such an adjustment does not apply to GSA, however, DOE proposes that GSA tenant agencies that have design control over their buildings and make significant design decisions that will allow for compliance with the rule may petition DOE for a downward adjustment, even if that building is owned by GSA. DOE also proposes a downward adjustment process for new construction and major renovations that are whole building renovations, as well as for major renovations that are limited to system or component level renovations.

1. Technical Impracticability as a Basis for Downward Adjustment

Technical impracticability is defined as a situation in which achieving the Scope 1 fossil fuel-based energy consumption targets would: (1) not be feasible from an engineering design or execution standpoint due to existing physical or site constraints that prohibit modification or addition of elements or spaces; (2) significantly obstruct building operations and the functional needs of a building, specifically for industrial process loads, research operations, and critical national security functions, mission critical information systems as defined in NIST SP 800–60 Vol. 2 Rev. 1; or 3) significantly degrade energy resiliency and energy security of building operations as defined in 10 U.S.C. 101(e)(6) and 10 U.S.C. 101(e)(7), respectively. Upon determination that complying with these standards is technically impracticable, the building would still be required to reduce fossil fuel consumption to the maximum extent practicable. Technical impracticability may include technology availability and cost considerations but may not be based solely on cost considerations.

The 2010 NOPR noted that the downward adjustment provision of ECPA does not expressly include cost considerations, but that DOE was considering incorporating cost considerations as part of a ''technically impracticable'' determination. Cost would not be the sole rationale for a determination of ''technically impracticable,'' but high costs could be part of the evaluation. 75 FR 63412. DOE also invited comments on what kind of technical impracticability would constitute grounds for a petition for downward adjustment. DOE received a number of comments on this topic in the NOPR and restated its position in the 2014 SNOPR that cost could not be the sole rationale for a determination of ''technically impracticable.'' DOE also emphasized in the 2014 SNOPR that it would be appropriate and permissible to consider a petition for downward adjustment based on the impact to an agency's functional needs for the building of achieving the fossil fuel-generated energy consumption reductions. DOE recognizes that an agency's functional needs for a building may be inextricably linked with costs, but cost should not be the primary basis for a petition for downward adjustment. DOE received no further comments on this topic in the 2014 SNOPR and thus reaffirms its intent to not allow cost as the sole rationale for a determination of technically impracticable, but also to consider an agency's functional needs in that determination.

2. Bundling of Petitions

The bundling of petitions was not an issue addressed in the NOPR. However, three comments were submitted on whether an agency could submit a single petition for downward adjustment for multiple agency buildings of the same building type, rather than requiring a petition for each building separately, to minimize agency burden.

DOE agreed that bundling of petitions by an agency for buildings of the same building type and function would help streamline the petitioning process and relieve the burden on agencies and DOE by avoiding duplication of effort. In the 2014 SNOPR, DOE stated that although DOE would require an individual petition containing the information required under this proposed rule for each building, if the petitions for similar buildings are submitted jointly, a petition may reference the downward adjustment justification in another petition in the bundle. DOE also noted in the 2014 SNOPR that DOE is considering allowing agencies to bundle petitions for new buildings or whole renovations to buildings: (1) that are of the same building type and of similar size and location; (2) that are being designed and constructed to the same set of targets for fossil fuel-generated energy consumption reduction; and (3) that would require similar measures to reduce fossil fuel-generated energy consumption and similar adjustment to the numeric reduction requirement. The bundled petitions should clearly state any differences between the buildings and explain why the differences do not warrant the submission of separate evaluations. Projects involving multiple new buildings would need to submit separate petitions for each building if they do not meet criteria (1)–(3) previously listed. For component-level major renovations, the 2014 SNOPR stated that DOE is considering allowing bundling petitions that are of the same component and building type.

In response, DOE received one comment on bundling of petitions. AGA and other utilities supported the concept of bundling of petitions. (AGA et al No. 18 at p.6). DOE agrees that bundling of petitions for buildings of the same building type and function in a similar location is a useful feature of the process and bundling is being proposed. DOE encourages agencies to submit a singular petition with all of the information on groups of similarly situated buildings to help streamline the review process.

3. DOE Review Process

The 2010 NOPR stated that DOE will review petitions in a timely manner and if the petitioning agency has successfully demonstrated the need for a downward adjustment per the previous discussion, DOE will concur with the agency's conclusion and notify the agency in writing. If DOE does not concur, it will forward its reasons to the petitioning agency with suggestions as to how the fossil fuel-generated energy consumption percentage reduction requirement may be achieved. 75 FR 63412.

Several comments were submitted about the DOE review process in the NOPR. In response, DOE recognized that agencies want assurance that DOE will respond to petitions in a timely manner in order to avoid project delays. For petitions for new construction, DOE proposes to make a best effort to notify an agency in 45 calendar days of submittal whether a petition is approved or rejected, granted the petition is complete. If DOE rejects the petition, it would include its reasons for doing so in its response to the agency. Additionally, for new construction, DOE proposed a provision under which DOE could establish an adjusted value, other than the one presented in a petition, if DOE finds that the petition does not support the conclusion of the submitting agency but that the statutorily required level was nonetheless technically impracticable in light of the agency's specific functional needs for the building. This provision is intended to provide flexibility in the petition process and reduce the need for agencies to resubmit in the instance of a rejection. For petitions for downward adjustments to the requirements applicable to major renovations, DOE proposed that the downward adjustment would be granted upon submission of specified certifications. The necessary certifications are discussed in greater detail in section III.D.5 in this document. In response, DOE received five comments on its review process.

The Department of Defenses (''DOD's'') Office of the Under Secretary of Defense (''OUSD'') [11] and the Office of the Deputy Under Secretary of Defense (Installations and Environment) (''ODUSD(I&E)'') stated that regardless of project type, all petitions for downward adjustments should be deemed approved upon submittal to DOE. (OUSD–AF 9 at p.6 and ODUSD(I&E) 16 at p.4) In response, DOE notes that approving all petitions for downward adjustment without reviewing the petitions to ensure that the Secretary of DOE concurs with the petition would be contrary to the statutory requirement that DOE review and concur on each petition submitted. (42 U.S.C. 6834(a)(3)(D)(i)(II)) The American Gas Association (''AGA'') and other utilities commented that they support DOE's proposed review process (AGA et al No. 18 at p.6) and they also requested that DOE consider the cost-effectiveness of fossil fuel energy reduction measures to the greatest extent possible in the downward reduction process. (AGA et al No. 17 at p.6) In response, DOE notes that the statutory requirement for adjusting the fossil fuel-generated energy consumption requirements is technical impracticability. As previously noted, DOE will consider cost and cost-effectiveness through that lens; however, cost or cost-effectiveness impacts cannot be the only reason a petition is approved. (*See* section E.1 of this proposed rule for additional discussion of cost.)

Earthjustice noted that despite mention in the preamble, the regulatory text of the 2014 SNOPR fails to recognize that, to evaluate petitions for downward adjustments, DOE needs a description of all technologies and practices that an agency evaluated and rejected, including a justification as to why the technologies were not included in the design. (Earthjustice No. 4 at p.3)

DOE agrees with Earthjustice with respect to documentation requirements for downward petitions for whole building renovations. This documentation should be identical to that required for new construction petitions. This change was made in this proposed rule. DOE expanded the type of building specific information that DOE is requesting in petitions as requested by Earthjustice but is doing so in a manner that allows DOE to analyze what possibilities each petitioner has to meet the rule in its renovation. DOE changed the rule to require the director of FEMP to approve each petition after reviewing this building-specific information.

4. Information Required in Petitions for New Construction

The NOPR proposed that a petition for downward adjustment of the numeric requirement should include an explanation of what measures would be required to meet the fossil fuel-generated energy consumption reduction requirement, and why those measures would be technically impracticable in light of the agency's specified functional needs for the building. DOE also proposed that the petition should demonstrate that the adjustment requested by the agency represents the largest feasible reduction in fossil fuel-generated energy consumption that can reasonably be achieved. DOE solicited comments on those issues. 75 FR 63412.

DOE received several comments on the NOPR and provided more detailed

[11] OUSD submitted 4 sets of comments—one set on behalf of the Air Force (marked ''-AF''), another set on behalf of the U.S. Army Corps of Engineers (marked ''-USACE''), a third set on behalf of the Army (marked ''-Army''), and a final set on behalf of OUSD's Facility Energy and Privatization director (marked ''-FEP'').

petition requirements in the 2014 SNOPR that allows DOE to determine more comprehensively whether a downward adjustment should be approved. DOE proposed a modified provision that requires a Federal agency to demonstrate that the requested adjustment represents the largest feasible fossil fuel reduction that the agency can reasonably achieve by providing evidence that the agency included all life-cycle cost-effective energy efficiency and on-site renewable energy measures in the design and by providing a description of the technologies and practices that the agency evaluated and rejected, including a justification as to why these technologies and practices were rejected. Finally, agencies would also be permitted to provide additional information they think will help justify the request for downward adjustment.

As per the 2014 SNOPR, petitions would also be required to include the maximum allowable fossil fuel-generated energy consumption for the proposed building, the estimated fossil fuel-generated energy consumption of the proposed building, the total estimated project cost, and a description of the building and the building energy systems. A description of the building would include, but would not be limited to, location, use type, floor area, stories, expected number of occupants and occupant schedule, and functional needs of the building, and any other information the agency deems pertinent. The building energy Federal agencies must describe includes the HVAC systems and service water heating system, as well as the loads in the building, including any specialized process, specialized research loads, electric vehicle charging stations, alternatively fueled vehicle fueling stations, and emergency backup generators. This information should provide DOE the necessary information to review petitions, and help agencies ensure key questions and options are addressed in the design process.

DOE received one comment on the information required in petitions for new construction. An individual commenter suggested that to discourage excessive petitions for downward adjustment, DOE should require a comprehensive analysis of the selected and rejected energy efficiency measures or technologies, similar to methods employed in a Level II energy audit as defined by the American Society of Heating, Refrigeration and Air-Conditioning Engineers (''ASHRAE''). In response, DOE notes that Federal agencies are already required to perform audits on 25 percent of their buildings every year under the provisions of section 432 of EISA 2007. DOE believes that dividing major renovations into three categories that each have their own threshold for DOE granting of a petition for downward adjustment (*e.g.,* whole building renovations, system level renovation, and component level renovations) should keep the number of petitions submitted by agencies to a minimum.

5. Downward Adjustments for Major Renovations

As noted previously, for major renovations, DOE proposes that the fossil fuel reduction requirements apply only to the energy use associated with the portions of the building or building systems that are being renovated and only to the extent that the scope of the renovation provides an opportunity for compliance with the applicable fossil fuel-generated energy consumption reduction requirements.

Recognizing the practical limitations on improving energy efficiency through retrofits, DOE proposes separate downward adjustment processes for major renovations. For major renovations that are whole building renovations, a downward adjustment will be provided at a level equal to the energy efficiency level that would be achieved were the proposed building designed to meet the baseline energy efficiency standard applicable to new construction in 10 CFR parts 433 or 435. DOE proposed in the 2014 SNOPR that this adjustment would be available to GSA-tenant agencies with significant control over building design and DOE re-affirms this proposal.

The energy efficiency standards for new construction are established in 10 CFR part 433, for commercial and multi-family high-rise residential buildings, and 10 CFR part 435, for low-rise residential buildings. The energy efficiency standards require a building be designed to, at minimum, achieve the energy efficiency levels of the applicable referenced voluntary consensus code: ASHRAE 90.1 for commercial buildings multi-family high-rise residential buildings and IECC for low-rise residential buildings. The energy efficiency standards for new Federal buildings further require that buildings be designed to achieve energy efficiency levels that are at least 30 percent beyond the levels established in the referenced codes, if life-cycle cost-effective.

For major renovations that are limited to system or component level retrofits, DOE proposed in the 2014 SNOPR to provide downward adjustments at a level equal to the energy efficiency level that would be achieved through the use of commercially available systems and/or components that provide a level of energy efficiency that is life cycle cost effective, *i.e.,* ENERGY STAR or FEMP designated products. For system level renovations, agencies would adopt as renovation requirements the relevant parts of new building baseline energy efficiency standard in 10 CFR part 433 or 435 on a system level (*i.e.,* brought up to the performance requirements of the individual sections of ASHRAE 90.1–2019 (chapters 5–10)) where appropriate and cost effective, and additionally would follow the replacement guidance for all equipment that is included in the renovation with ENERGY STAR or FEMP designated products, per 10 CFR part 436, subpart C. For component level retrofits, agencies will replace all equipment that is part of the renovation with ENERGY STAR or FEMP designated products as defined at 10 CFR part 436, subpart C.

In setting efficiency requirements, both FEMP and ENERGY STAR choose levels that are among the highest 25 percent of efficiency for a given product category. ENERGY STAR estimates that its program saves more than 200 billion kWh of electricity each year, and FEMP estimates that compliance with its efficiency requirements can save the government more than 30 trillion BTUs each year. Both programs have integrated life-cycle cost effectiveness into their guiding principles and, as such, Federal buyers can have confidence that required products have both good energy performance and a total cost of ownership that is equal to or less than products below set efficiencies. Prescriptive requirements of ASHRAE 90.1 and IECC demonstrate similarly high levels of efficiency. Together, these requirements cover more than 70 product types and will help ensure that the products used within Federal facilities are among the highest energy efficiencies available. Federal buildings that install and use these products will realize lower energy intensities compared to using non-compliant products.

6. Make Information Publicly Available

DOE received some comments on the NOPR that petitions for downward adjustment should be made publicly available on a DOE website. Commenters stated that making this information publicly available would make the process transparent, hold agencies accountable, and could reduce unsupported petitions. As a result of these comments on the NOPR, DOE proposed in the 2014 SNOPR to report petition summary level information in

the DOE Annual Report to Congress on Federal Energy Management and Conservation Programs (See *www.energy.gov/about/budget.htm*).

DOE received two comments on its proposal. Earthjustice commented that to ensure public accountability, all petitions and DOE responses should be made publicly available. (Earthjustice No. 9 at p.7) An individual commenter commented that transparency is an important factor that will influence the effectiveness of this regulation and create accountability for meeting the target requirements and deadlines. (Dirogene No. 3 at p.1) DOE agrees that transparency is important and will publish any petitions that are filed, deemed complete, and screened for national security reasons for downward adjustment that are received (subject to potential filtering for national security reasons) on the DOE website.

7. Narrow the Use of Petitions

DOE received a few comments on the NOPR related to narrowing the use of petitions for downward adjustment. In response to these comments, DOE proposed changes in the 2014 SNOPR that would reduce the number of petitions submitted for downward adjustment and improve the content of submitted petitions. DOE expanded the number of building types covered in Tables A–1a and A–1b to A–2a and A–2b in appendix A of part 433 and added a methodology for calculating the maximum allowable fossil fuel-generated consumption values for buildings with process loads. This was expected to greatly reduce the number of building types without baselines and fossil fuel reduction targets, eliminating a significant potential source of petitions. In addition, in response to some of the public comments received, the 2014 SNOPR proposed that additional information be provided as part of the petition process, including that Federal agencies must: (1) demonstrate that the requested adjustment represents the largest feasible fossil fuel reduction that can be achieved, given agency mission and building purpose; and (2) describe all technologies and practices that were evaluated and rejected, including a justification as to why they were not included in the design. The rule requires Federal agencies to provide specific information about the energy efficiency and on-site renewable energy measures included in the proposed building design to enable DOE to evaluate the request for downward adjustment.

DOE received no comments on this topic in the 2014 SNOPR, so DOE proposes to require evidence of these additional criteria in petitions for downward adjustments.

8. GSA Tenant Agencies

ECPA, as amended, does not provide GSA the option of petitioning DOE for a downward adjustment of the applicable percentage reduction requirement. (42 U.S.C. 6834(a)(3)(D)(i)(II)) In the NOPR, DOE proposed that a new Federal building or a Federal building undergoing major renovations for which a GSA tenant that is a Federal agency is providing substantive and significant design criteria may be the subject of a petition. 75 FR 63412. Under this approach, DOE proposed that a GSA building that is designed to meet the specifications provided by a tenant agency may be considered for a downward adjustment if a petition is submitted by the head of the tenant agency.

In response to the NOPR, DOE received one comment on this issue stating that allowing GSA tenant agencies to petition for downward adjustments contradicts the statute. DOE noted in the 2014 SNOPR that while the statute prohibits GSA from petitioning DOE for a downward adjustment, it makes no reference to GSA tenant agencies. DOE will allow GSA tenant agencies that have significant control over building design to submit a petition. In such cases, it will be the tenant agency, not GSA, that is making the design choices that will allow for compliance with the rule. Allowing GSA tenant agencies to submit a petition for downward adjustment will provide an option for some buildings for which the required fossil fuel reductions may be technically impracticable in light of the building's functional needs, but for which GSA may not submit a petition.

DOE received one comment on this topic in response to the 2014 SNOPR. Earthjustice commented that DOE may not allow tenants of GSA buildings to petition for downward adjustments of the fossil fuel reductions because the statute specifically excludes only GSA from the downward adjustment petition process, expanding the number of buildings eligible for such adjustments in a manner that directly contravenes the plain statutory language and that is arbitrary and capricious. (Earthjustice No. 8 at p.6) DOE reiterates that while the statute prohibits GSA from petitioning DOE for a downward adjustment, it makes no reference to GSA tenant agencies. The statute allows for an ''agency'' to petition for a downward adjustment. The term ''Federal agency'' means any department, agency, corporation, or other entity or instrumentality of the executive branch of the Federal Government, including the United States Postal Service, the Federal National Mortgage Association, and the Federal Home Loan Mortgage Corporation. 42 U.S.C. 6832(5). As the commenter notes, the statute only prohibits GSA from submitting a petition. Thus, in cases in which the tenant agency exercises significant control of design choices in the building, and GSA does not, it makes little sense to prohibit the tenant agency form petitioning for an adjustment where the statute does not expressly require it. Moreover, these petitions are still subject to the same criteria and review process as other petitions and would need to justify any downward adjustment in accordance with such. Accordingly, in this SNOPR, DOE has decided to continue to allow GSA tenant agencies to petition in those cases where GSA tenants have design control.

9. Other Relevant Comments

In this category, DOE received two comments on the 2014 SNOPR. Earthjustice commented that it is unnecessary to limit the scope of major renovations covered by the rule to the extent that the renovation permits compliance with applicable requirements. Earthjustice argues that as the rule does not apply to unaltered portions of buildings or buildings systems that are undergoing major renovations it is not necessary to further limit the scope. Moreover, because ''the scope of the renovation'' is not a defined term, it may be subject to a broad interpretation by agencies subject to the fossil fuel reduction requirement. (Earthjustice No. 5 at p.4)

In response, DOE also notes that this rule is not the only requirement that mandates that Agencies implement and upgrade their facilities. Per 42 U.S.C. 8253(f), agencies are required to complete their annual comprehensive energy and water evaluation for approximately 25 percent of their covered facilities each calendar year and through those evaluations agencies will identify and plan for significant updates and modifications to those covered facilities. This proposed rule is not the appropriate vehicle for requiring significant facility upgrades beyond the portions being replaced.

ODUSD(I&E) also commented that requiring individual renovation projects that have difficulty in meeting the requirements, (regardless of size, renovation type, scope, funding, climatic conditions, etc.) to petition

DOE for downward adjustment may pose significant challenges. (ODUSD(I&E) No. 1 at p.1) DOE recognizes that petition submittals may add burden for agencies undertaking major renovations in buildings. However, EISA provides no recourse to agencies other than petitioning DOE for major renovations subject to the scope of these standards. As noted previously, pursuant to the intent indicated by EISA, DOE construes the term ''major renovations'' broadly to include projects for which agencies can practicably implement the energy efficiency and fossil fuel reduction goals of ECPA and EISA, including component and system level renovations subject to the $2.5 million threshold. Accordingly, agencies will need to submit a petition to adjust the relevant reduction targets for such projects. DOE notes that, in this SNOPR, DOE is proposing to make best efforts to complete review of petitions within 45 calendar days of receipt for new construction and major building retrofits and 20 calendar days for component level retrofits for adjustment consideration. DOE believes this will help obviate any burden experienced by agencies that submit petitions.

E. Impacts of the Rule

As part of the 2014 SNOPR, DOE requested comments on the impacts of the proposed rule. DOE received comments in two categories—Cost Impacts and Other Impacts.

1. Cost Impacts

In response to the 2014 SNOPR, DOE received eight comments on cost impacts. Several comments recommended referring to the Office of Management and Budget (''OMB'') Circular A–94 to the rule. In response, DOE notes that while OMB Circular A–94 is an important document, section 544 of the National Energy Conservation Policy Act (''NECPA''), as amended by section 441 of EISA 2007, directed DOE to establish practical and effective present value methods for estimating and comparing life-cycle costs for Federal buildings, based on capital and operating costs during a period of the expected life of the building's energy system or 40 years, whichever is shorter. *See* 42 U.S.C. 8254. Further, Federal agencies must use the DOE-established methods in the design of new Federal buildings and the application of energy conservation measures to existing Federal buildings. *Id.* at (b)(1). DOE established life-cycle cost analyses methodologies and procedures in 10 CFR part 436, subpart A. Federal agencies are already using the methodologies and procedures in 10 CFR part 436, subpart A when meeting the energy efficiency obligations in 10 CFR parts 433 and 435. To ensure consistency across Federal buildings regulations, DOE will continue to use the same methodologies and procedures.

Other comments suggested that the life-cycle costs of implementing new requirements under the fossil energy reduction rule are underestimated and that costs for compliance should be more closely examined. In response to these comments, DOE based its costs on the best available estimates it had at the time.

Several comments stated that while the 2014 SNOPR explicitly did not consider costs, because of the obligations imposed by the statute, exorbitant additional expenditures remain unjustified. Further comments implied that because of the inherent efficiency of natural gas used directly on site, the overall impact of displacing natural gas use with electrically powered alternatives will be an increase in total GHG emissions, a decrease in energy productivity of Federal buildings, and increased energy costs to Federal agencies and ultimately to taxpayers. In response, DOE notes that had Congress intended for DOE to consider costs in establishing the fossil fuel use reduction targets in this rule or in adjudicating petitions it would have specified to do so. Instead, Congress directed DOE to use the specific reduction targets contained in 42 U.S.C. 6834(a)(3)(d)(i)(I), and base DOE's petition adjudication decisions on agency determinations of technical impracticability.

However, while DOE did not consider costs in setting the reduction targets or petition requirements, as part of its obligations under Executive Order 12866 to inform the public of the impacts of the proposed rule, DOE analyzed the costs and benefits of the rule proposed in the 2014 SNOPR and in this proposed rule, and has tentatively concluded that the rule as a whole saves both site energy and life-cycle cost.

Other commenters also requested that DOE present its construction cost increases as a percentage of total cost on both a year and cumulative basis and provide more detail about DOE's assumptions underlying the analysis. The commenters further requested that DOE also explain why its year 2020 costs and beyond are relatively constant, stating that they believe that compliance costs will grow much more significantly as permitted fossil fuel energy consumption nears zero. All assumptions used in the RIA are documented in the RIA document. The costs for year 2020 and beyond are relatively constant because DOE assumed that by 2020, agencies would be able to achieve the maximum estimated savings for major renovations by that time.

Another comment was made that a problem with the cost estimate is that the RIA makes no reference to life cycle costs, even though section 109 of Energy Policy Act of 2005 (''EPAct 2005'') requires technologies employed be life-cycle cost- effective. (ODUSD(I&E) No. 4 at p.1) DOE notes that section 109 of EPAct 2005 amended section 305 of ECPA, which was later amended by section 433 of EISA, which provides the authority for this rulemaking. The amendments made by section 433 of EISA did not include requirements or references to life-cycle cost-effectiveness with respect to the fossil fuel-generated energy consumption reduction targets of EISA section 433. If Congress intended for life-cycle cost-effectiveness to be considered as part of these reduction targets, it would have specifically stated so in section 433 of EISA as it did in the amendments in section 109 of EPAct 2005. Moreover, DOE does not see a conflict between this rule and the Federal building energy efficiency rules in 10 CFR parts 433 and 435 in terms of life-cycle cost-effectiveness.

2. Other Impacts

DOE also received eighteen comments on other impacts of the rule. One comment stated this rule is an action that would have a significant adverse effect on energy, and therefore DOE must prepare a Statement of Energy Effects pursuant to E.O. 13211. *See* 79 FR 61722. In response, DOE states that this rule is not a significant energy action requiring a Statement of Energy Effects pursuant to E.O. 13211, because it is not expected to have a significant adverse effect on the supply, distribution, or use of energy. According to the Office of Management and Budget, ''adverse effects'' requiring a statement under E.O. 13211 include significant (1) reductions in the production or supply of crude oil, coal, natural gas, or other fuel; (2) increases in energy use; or (3) increases in the cost of energy production or distribution. The current action implements a statutory mandate to reduce fossil fuel energy use in Federal buildings. As such, this action cannot reasonably be expected to reduce the production or supply of fuel, increase energy use, or significantly increase the cost of energy production.

Several other comments suggested that the proposed mandate is not only

costly and impractical, but also infeasible, not flexible enough, or absolutely unattainable. In response, DOE notes that DOE's rule is based directly on Congressionally mandated language in section 433 of EISA 2007, which governs fossil fuel-generated energy consumption. Per the statute, however, the rule does allow for the downward adjustments of the required reductions in some cases.

Other comments supported the rule, by pointing out that this rule presents DOE with a significant opportunity not only to reduce the Federal Government's own energy costs and environmental footprint, but also to influence the design of both state and local government buildings as well as all new residential and commercial buildings. Therefore, this proposed rulemaking is an opportunity for the Federal Government to use its large purchasing power to drive and transform markets for greater efficiency and reduced fossil fuel consumption in all buildings. Two additional supportive comments commended DOE for working with stakeholders to craft the 2014 SNOPR and pointed out that the rule will increase the ability to design and build facilities that use less energy, save energy, save taxpayers money, and protect the environment; and also that stakeholders from varying industries have been working with the Department of Energy to implement this rule in a way that is smart, efficient, and effective, noting that some have argued that these targets are not achievable, but building and sustainability professionals are already succeeding in making Federal facilities meet sustainability targets, including DOE's new Research Support Facilities (''RSF'') in Colorado, which opened in 2010. More importantly, private sector owners are increasingly adopting these technologies and strategies for their buildings.

DOE also received six comments on the use of the social cost of carbon (''SCC''). DOE is presenting monetized benefits in accordance with the applicable Executive Orders and DOE would reach the same tentative conclusion presented in this SNOPR in the absence of the social cost of greenhouse gases, including the February 2021 Interim Estimates presented by the Interagency Working Group on the Social Cost of Greenhouse Gases.

F. Guidance and Other Topics

DOE requested specific comment in the 2010 NOPR and 2014 SNOPR on what additional training and guidance would help agencies meet the reductions called for by this statute. DOE received a single comment on this topic in the 2014 SNOPR. That comment focused on the fact that DOE had not included implementation of sub-metering as a requirement for new Federal buildings and major renovations for Federal buildings because the compulsory implementation of sub-metering should alleviate future stresses related to clarification of major renovations, improve accuracy of process load baselines for future Federal building construction, and aid in verification of building simulation models developed during the design stage (especially since they are enforced under this rule for current and future projects). The commenter further stated that dissemination of sub-metering in Federal buildings is instrumental in achieving an intelligent grid capable of improving delivered power quality and inducing energy efficient behavior from building owners and operators. In response, DOE notes that agencies are already subject to certain metering and advanced metering requirements. 42 U.S.C. 8253(e). DOE has issued metering guidance for Federal agencies in accordance with the Energy Policy Act of 2005, EISA 2007, and the Presidential Memorandum ''Federal Leadership on Energy Management''. See *www.energy.gov/eere/femp/articles/doe-releases-Federal-building-metering-guidance* for more details. DOE notes this guidance addresses metering, and not sub-metering, in accordance with Congressional and Presidential direction. Neither sub-metering nor metering is expressly mentioned in section 433 of EISA 2007. Therefore, those topics are not addressed in this SNOPR.

IV. Methodology, Analytical Results, and Conclusion

DOE acknowledges exchanging on-site fossil fuel generated energy for reliance on the electric grid, which may still be generating energy with fossil fuels, doesn't necessarily lead to an immediate reduction in emissions of GHGs and SO_2 and in some cases (and as a whole) may result in increased energy costs. However, this proposed rule is intended to prepare federal buildings for a green energy future. By ensuring that federal buildings are designed—either from the ground up, or when being renovated—to rely on the electric grid, the rule ensures that long-term, as the grid integrates more carbon free energies, emissions will be reduced. In addition, DOE expects emerging and improving technological advancements in electric equipment such as heat pumps will lead to additional and dramatic site energy savings further improving the emissions and cost savings cases for this rule.

A. Cost-Effectiveness

DOE's assumptions and methodology for the cost-effectiveness of this rule are built upon the cost-effectiveness analysis of ASHRAE Standard 90.1–2019 conducted by DOE's State building energy codes program,[12] as well as DOE's Environmental Assessment (EA) for this proposed rulemaking.[13] As described in the EA, DOE identified a rate of new Federal commercial construction of 13.3 million square feet per year with a distribution of building types as shown in Table IV.1. Starting in the year 2030, section 205(c)(ii) of Executive Order 14057, ''Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability.'' (December 8, 2021) requires to ''design new construction and modernization projects greater than 25,000 gross square feet to be net-zero emissions by 2030''. This effectively reduces the impact of this rule to apply to new construction and major renovation projects that fall above the cost threshold but are also below 25,000 gross square feet. For the year 2030 and beyond the estimated new Federal commercial and multi-family high-rise residential building construction volume per year will be 2.2 million square feet per year with a distribution of building types as shown in Table IV.2. The distribution of building types is based on an extraction of the latest 10 years of new construction data entered into the Federal Real Property Portfolio Management System (''FRPP MS'') that meets the required cost threshold of the proposed rule for cases both before and after the 25,000 Sf minimum triggering E.O. 14057 compliance.[14] Additionally DOE identified an estimated rate of federal major renovation projects that would be influenced by this rule. To do so DOE utilized data from the Federal Compliance Tracking System (''CTS'') where agencies report data on building efficiency improvement projects. The

[12] *See* DOE's analysis of the cost savings of the 2016 and 2019 ASHRAE 90.1 Standards at *www.energycodes.gov/sites/default/files/2020-07/90.1-2016_National_Cost-Effectiveness.pdf* and *www.energycodes.gov/sites/default/files/2021-07/90.1-2019_National_Cost-Effectiveness.pdf,* respectively.

[13] The Environmental Assessment (EA) (DOE/EA–2165) is entitled, ''Environmental Assessment for Final Rule, 10 CFR part 433, 'Energy Efficiency Standards for New Federal Commercial and Multi-Family High-Rise Residential Buildings' Baseline Standards Update''. The EA may be found in the docket for this proposed rulemaking and at *www.energy.gov/node/472482.*

[14] See *www.realpropertyprofile.gov/FRPPMS/FRPP_Login.*

data from CTS was queried to include only those projects which would meet the cost threshold and have impacts on site fossil fuel energy consumption. As not all agencies are compliant in reporting data into CTS, results were scaled up to account for agencies out of compliance. CTS does not supply data on the types of buildings for the reported projects, as such the distribution of eligible federal buildings for a renovation that would meet the cost threshold was applied to the estimated project square footage. DOE identified a rate of new Federal major renovation construction of 1.36 million square feet per year with a distribution of building types as shown in Table IV.1. Starting in the year 2030, section 205(c)(ii) of Executive Order 14057 ''Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability.'' (December 8, 2021) requires agencies to ''design new construction and modernization projects greater than 25,000 gross square feet to be net-zero emissions by 2030''. This part of the Executive Order effectively reduces the impact of this rule to apply only to new construction and major renovation projects that fall above the cost threshold but are also below 25,000 gross square feet. Taking this into account for the year 2030 and beyond, the estimated new Federal commercial and multi-family high-rise residential building major renovation construction volume per year will be 0.4 million square feet per year with a distribution of building types as shown in Table IV.1 and Table IV.2 of this document. These tables also show the prototype buildings incorporated into computer simulations that are used to estimate energy use in each building type. DOE derived these prototype buildings from 16 building types in 17 climate zones [15] using its Commercial Prototype Building models.[16] Of the 16 prototype buildings, DOE developed costs for 6 prototype buildings to determine the cost effectiveness of ASHRAE Standard 90.1–2016 and ASHRAE Standard 90.1–2019. DOE then extracted the cost-effectiveness information for those prototype buildings and weighted those values as appropriate to obtain an average cost effectiveness value for building types found in the Federal commercial sector.

TABLE IV.1—NEW FEDERAL COMMERCIAL AND HIGH-RISE MULTI-FAMILY CONSTRUCTION VOLUME BY BUILDING TYPE FOR BUILDINGS CONSTRUCTED IN YEARS 2025–2029

Building type	Fraction of Federal construction volume (by floor area) (%)	Assumed BECP prototypes for energy savings	Assumed BECP prototypes for cost effectiveness
Office	17.77	Small Office, Medium Office, Large Office	Small Office, Large Office.
Dormitories and Barracks	14.57	Small Hotel, Mid-rise Apartment, High-rise Apartment.	Small Hotel, Mid-rise Apartment.
School	15.65	Secondary School	Primary School.
Service	15.16	Stand-alone Retail, Non-refrigerated Warehouse	Stand-alone Retail.
Other Institutional Uses	5.76	None*	None.
Hospital	7.80	Hospital	Small Office, Large Office.
Warehouses	2.95	Non-Refrigerated Warehouse	None.
Laboratories	4.24	Medium Office, Hospital	Small Office, Large Office.
All Other	2.74	None	None.
Outpatient Healthcare Facility	5.00	Outpatient Healthcare	Small Office.
Industrial	1.63	None	None.
Child Care Center	0.89	Primary School	Primary School.
Communications Systems	1.42	None	None.
Prisons and Detention Centers	0.18	None	None.
Family Housing	1.06	Mid-rise Apartment	Mid-rise Apartment.
Navigation and Traffic Aids	0.53	None	None.
Land Port of Entry	0.68	Non-refrigerated Warehouse	None.
Border/Inspection Station	0.64	Small Office, Non-refrigerated Warehouse	Small Office.
Facility Security	0.25	Small Office	Small Office.
Data Centers	0.34	None	None.
Museum	0.74	None	None.
Comfort Station/Restrooms	0.01	Non-refrigerated Warehouse	None.
Public Facing Facility	0.02	Stand-alone Retail	Stand-alone Retail.
Aviation Security Related	0.00	Small Office	Small Office.
Post Office	0.00	Stand-alone Retail	Stand-alone Retail.

*Note that energy savings and cost-effectiveness mapping are not available for a number of Federal building types, with other institutional uses, warehouses, and all other being the largest Federal building types with no reliable mapping. As described in this section, DOE considered energy savings and costs for these unmapped Federal building types to be equivalent to the weighted energy savings and cost for the mapped Federal building types.

[15] Briggs, R.S., R.G. Lucas, and Z.T. Taylor. 2003. ''Climate classification for building energy codes and standards: Part 1—Development Process.'' ASHRAE Transactions 109(1): 109:121. American Society of Heating, Refrigerating and Air-Conditioning Engineers. Atlanta, Georgia.

[16] DOE's prototype buildings are described at *www.energycodes.gov/prototype-building-models.*

TABLE IV.2—NEW FEDERAL COMMERCIAL AND HIGH-RISE MULTI-FAMILY CONSTRUCTION VOLUME BY BUILDING TYPE FOR BUILDINGS CONSTRUCTED IN YEARS 2030–2054

Building type	Fraction of Federal construction volume (by floor area) (%)	Assumed BECP prototypes for energy savings	Assumed BECP prototypes for cost effectiveness
Office	14.24	Small Office, Medium Office	Small Office, Large Office.
Dormitories and Barracks	4.02	Small Hotel, Mid-rise Apartment, High-rise Apartment.	Small Hotel, Mid-rise Apartment.
School	10.88	Secondary School	Primary School.
Service	18.34	Stand-alone Retail, Non-refrigerated Warehouse	Stand-alone Retail.
Other Institutional Uses	12.63	None *	None.
Hospital	2.97	Hospital	Small Office, Large Office.
Warehouses	6.88	Non-Refrigerated Warehouse	None.
Laboratories	4.37	Medium Office, Hospital	Small Office, Large Office.
All Other	5.58	None	None.
Outpatient Healthcare Facility	7.66	Outpatient Healthcare	Small Office.
Industrial	2.05	None	None.
Child Care Center	2.67	Primary School	Primary School.
Communications Systems	0.87	None	None.
Prisons and Detention Centers	0.26	None	None.
Family Housing	1.49	Mid-rise Apartment	Mid-rise Apartment.
Navigation and Traffic Aids	1.95	None	None.
Land Port of Entry	0.99	Non-refrigerated Warehouse	None.
Border/Inspection Station	0.36	Small Office, Non-refrigerated Warehouse	Small Office.
Facility Security	1.36	Small Office	Small Office.
Data Centers	0.19	None	None.
Museum	0.10	None	None.
Comfort Station/Restrooms	0.03	Non-refrigerated Warehouse	None.
Public Facing Facility	0.09	Stand-alone Retail	Stand-alone Retail.
Aviation Security Related	0.00	Small Office	Small Office.
Post Office	0.00	Stand-alone Retail	Stand-alone Retail.

* Note that energy savings and cost-effectiveness mapping are not available for a number of Federal building types, with other institutional uses, warehouses, and all other being the largest Federal building types with no reliable mapping. As described in this section, DOE considered energy savings and costs for these unmapped Federal building types to be equivalent to the weighted energy savings and cost for the mapped Federal building types.

DOE has determined incremental construction first cost information for the building types and climate zones analyzed for buildings compliant with this proposed rule (''Clean Energy Rule Compliant'' buildings) versus ASHRAE Standard 90.1–2019 (see Table IV.3).[17]

TABLE IV.3—INCREMENTAL CONSTRUCTION FIRST COST (2021$) FOR ASHRAE STANDARD 90.1–2019 VS. FOSSIL FUEL COMPLIANT BUILDING DESIGN

Prototype	Value	ASHRAE climate zone *				
		2A	3A	3B	4A	5A
Small Office	First Cost	$673	$584	$515	$1,666	$641
	$/ft²	0.12	0.11	0.09	0.30	0.12
Large Office	First Cost	261,781	268,194	196,408	354,808	223,553
	$/ft²	0.52	0.54	0.39	0.71	0.45
Stand-alone Retail	First Cost	19,608	20,240	19,740	21,563	19,363
	$/ft²	0.79	0.82	0.80	0.87	0.78
Primary School	First Cost	(126,946)	(121,994)	(116,139)	(94,722)	(122,894)
	$/ft²	(1.72)	(1.65)	(1.57)	(1.28)	(1.66)
Small Hotel	First Cost	(104,866)	(104,624)	(104,396)	(101,194)	(103,044)
	$/ft²	(2.43)	(2.42)	(2.42)	(2.34)	(2.38)
Mid-rise Apartment	First Cost	(18,343)	(17,490)	(18,113)	(12,445)	(25,126)
	$/ft²	(0.54)	(0.52)	(0.54)	(0.37)	(0.74)

* Negative costs (shown in parentheses) indicate a reduction in cost due to changes in the code, usually due to reduced HVAC capital cost and reduction of venting required for onsite combustion.

[17] Note that the values in Table IV.3 have been adjusted to reflect 2021$ from the table that appears in DOE's determination of energy savings for Standard 90.1–2016, which were in 2018$. This adjustment was made using the GDP deflator value to correct for inflation between 2018 and 2021. Organization for Economic Co-operation and Development, GDP Implicit Price Deflator in United States, retrieved from FRED, Federal Reserve Bank of St. Louis; *fred.stlouisfed.org/series/USAGDPDEFAISMEI,* Updated February 17, 2021. These values have also been adjusted to reflect the same underlying economic assumptions as the 2019 version, and sales tax has also been removed.

DOE used data from Table IV.3 to calculate preliminary values for overall incremental first cost of construction for Federal commercial and high-rise, multi-family residential buildings. DOE calculated the incremental first cost of the Federal building types based on the DOE cost prototypes shown in the far-right column of Table IV.1 of this document. DOE then calculated the weighted average incremental cost for mapped Federal building types based on their corresponding BECP prototypes, which represent an estimated 79.3 percent of new Federal construction. This weighted incremental cost was assigned to un-mapped Federal building types, and a total weighted incremental cost was calculated by multiplying the incremental cost for each Federal building type by the fraction of Federal construction shown in Table IV.1.

The national incremental first cost for building types was developed by multiplying the average (across climate zones) incremental first cost of the prototypes (determined from the DOE State building energy codes program ASHRAE Standard 90.1 cost-effectiveness analysis) by the fraction of the Federal sector construction volume shown in Table IV.1, and then multiplying that by the total estimate of Federal new construction floorspace.[18] DOE estimates that total first cost outlays for new Federal buildings will be less under Clean Energy Rule compliant designs than ASHRAE Standard 90.1–2019, primarily due to lower HVAC equipment costs for some building types (See Table IV.3). The resulting total incremental first cost estimate is a savings of $8.62 million per year. The average first cost decrease is $1.86 per square foot. These first cost decreases are a result of the lower capital costs of the assumed electric equipment types as dictated in the ASHRAE and IECC energy codes (as mandated in 10 CFR part 433 and 10 CFR part 435 and are the baseline for this modified building efficiency standard). Minimally compliant electric equipment was assumed in the proposed case as hitting the 30% better than baseline performance goal as generally required by regulation and does include a cost effectiveness caveat that can reduce the goal down to minimal compliance. As can be seen in Table IV.4, most building types switch their space heating systems from a fossil fuel burning system over to an electric resistance-based system. DOE seeks comment on the efficiency of the electric equipment used in its analyses.

TABLE IV.4—BREAKDOWN OF PROPOSED HEATING SYSTEM BY BUILDING PROTYPE

Building prototype	Yearly constructed SF—Post 2030 (%)	Yearly constructed SF—Pre 2030 (%)	Baseline gas unit efficiency	Proposed electric unit efficiency	Space heat notes
Small Office	12.8	14.8	0.81	99% Electric Boilers	Convert using AFUE for gas furnace and AFUE Estimate for Electric Furnace.
Medium Office	2.6	5.5	0.79	99% Electric Furnaces	Convert using pre 1/1/2023 Et estimated Et for Furnaces assuming 0.75% casing loss.
Large Office	0.0	2.3	0.82	99% Electric Boilers	Convert using Et Estimate for boilers.
Stand-Alone Retail	13.2	8.8	0.79	1.76 COP RTU Heat Pump	Convert using national weight heat pump efficiency from office analysis.
Primary School	3.8	1.0	0.81	99% ¼ Furnaces, ¾ boilers.	¼ Furnaces, ¾ boilers. Convert both to electric equivalents.
Secondary School	15.5	18.1	0.82	99% Electric Boilers	Convert using Et Estimate for boilers.
Outpatient Health Care	10.9	5.8	0.82	99% Electric Boilers	Convert using Et Estimate for boilers.
Hospital	8.9	12.7	0.82	99% Electric Boilers	Convert using Et Estimate for boilers.
Small Hotel	0.4	1.2	0.81	99% Electric Furnaces	Convert using AFUE for Gas and AFUE Estimate for Electric.
Warehouse	24.4	13.1	0.79	99% Electric Furnaces	Note Model uses a 0.8 gas AFUE for office space, but 0.7925 for Fine storage and unit heater.
Mid-Rise Apartment	4.7	8.7	0.81	2.4 COP Residential Heat Pump.	Convert using AFUE Estimate to residential HSPF.
High-Rise Apartment	2.7	8.2	0.82	99% Electric Boilers	Convert using Et Estimate for boilers.

An estimated 17.7 percent of the projects would utilize heat pumps in their proposed ''all electric'' case (those that map to Stand Alone Retail and Mid-Rise Apartment prototype models) with assumed efficiency performance metrics as noted. Service hot water systems (when not already specified as an electric system per 10 CFR parts 433 and 435 requirement) are similarly assumed to be minimally compliant electric resistance systems with 99 percent efficiencies. Cooking systems where present are assumed to switch from 40 percent efficient gas systems to 70 percent standard efficiency electric systems.

It should be noted that in all cases higher efficiency electric equipment is available on the market, but the statutory authority of this rule is limited to total building reduction targets and does not specify specific equipment types or efficiency levels. An agency is free to design a project per their own site, cost, and usage specific needs, while complying with the applicable efficiency targets. As such, the analysis presented in this SNOPR intends to capture the base-level compliance cases only. An agency is free and encouraged to select higher efficiency equipment (such as even higher efficiency heat pumps and/or more widespread adoption) as project details accommodate. DOE encourages the higher efficiency equipment to be carefully considered by agencies as it can often provide projects with a lifecycle cost effective solution that saves even more energy and emissions (albeit usually with higher up-front capital costs) than presented for base compliance with this rule.

DOE is seeking comment with regard to heat pump pricing, availability, efficiency levels, and weather incentivizing higher performing equipment is likely to increase utilization amongst federal facilities.

DOE also analyzed the relative impact of the final rule on the first cost of new constructed Federal buildings as a

[18] For the Federal office building, the small and large office prototype first costs were averaged. For the Federal education building, the primary school prototype first cost was used. For the Federal dormitories/barracks building type, the small hotel and mid-rise apartment prototype first costs were averaged.

percentage of the overall annual cost of newly constructed Federal commercial and high-rise buildings. In order to estimate the total cost of construction for new Federal buildings, DOE obtained estimated construction costs for new Federal commercial and high-rise multifamily buildings were obtained from RS Means (2020) [19] for the six building types analyzed in DOE's cost-effectiveness report. These new construction costs were weighted by the percent of Federal floorspace to develop an average cost of a new Federal building of $198 per square foot, as shown in Table IV.5. This average construction cost may be multiplied by the overall total of 19.54 million square feet of new Federal construction per year used in this rulemaking to estimate the annual total cost of all new Federal commercial and high-rise multi-family construction of $3.86 billion. As previously noted, first cost savings associated with this rulemaking are estimated at $8.62 million per year, indicating a potential cost reduction in new Federal construction costs of 0.223 percent ($8.62 million divided by $3.86 billion).

TABLE IV.5—FIRST COST OF TYPICAL NEW FEDERAL BUILDING IN $/ft^2

Federal building type	Weight (%)	First cost *	Weighted cost
Office	20.74	$210	$43.51
Barracks and Dormitories	14.85	217	32.18
School	14.33	225	32.25
Service	13.31	116	15.44
Hospital	5.57	200	11.14
Laboratories	4.37	200	8.73
Outpatient Healthcare Facility	3.35	220	7.38
Child Care Center	1.18	225	2.67
Family Housing >3 Stories	0.68	218	1.48
Border/Inspection Station	0.49	220	1.07
Facility Security	0.31	220	0.69
Aviation Security Related	0.01	220	0.02
Public Facing Facility	0.05	116	0.06
Post Office	0.01	116	0.01
Remaining Federal Stock	20.75	198	41.00
Federal Average	100.00	198	197.62

* All building first cost data from RS Means 2020.

DOE determined that the total incremental first cost estimate for Federal buildings (as mapped to the prototype buildings in Table IV.1) is a savings of $139.4 million (at a 3 percent discount rate) and a cost of $85.5 million (based on a 7 percent discount rate), with an average first cost decrease of $1.0 per square foot (at a 3 percent discount rate) and $0.61 per square foot (at a 3 percent discount rate).

For annualized energy cost savings, DOE used a similar approach to that used for incremental first cost. That is, DOE developed the national annualized energy cost savings [20] for building types by multiplying the average (across climate zones) energy cost savings (determined from the DOE ASHRAE Standard 90.1 cost-effectiveness analysis) by the fraction of the Federal sector construction volume shown in Table IV.1, and then multiplying that by the total estimate of Federal new construction floorspace.[21] Table IV.6 [22] shows the annual energy cost savings by prototype buildings for a Clean Energy Rule compliant building compared to ASHRAE Standard 90.1–2019. There are increases in energy costs across the board, this is because despite the increases in equipment efficiency and overall site energy savings the difference between the cost of fossil fuels (primarily natural gas) and purchased electricity at a national level are too high for the improvements to overcome. The EIA AEO 2021 energy outlook rate projections indicate that per the same amount of site energy consumed, electricity is about 4.3x more expensive than natural gas, this number gradually reduces over time per this projection down to 3.2x by the year 2050.

As was done for the incremental cost analysis, the 2019 energy cost savings analysis was adjusted to use the same underlying economic assumptions as the Clean Energy Rule Compliant version, including fuel prices, fuel price escalations, labor and material costs, and the removal of sales tax. The resulting total annualized energy cost impacts for the Clean Energy Rule affected buildings' 14.7 million square feet of annual construction for years 2025–2029 and 2.6 million square feet of annual construction for years 2030–2054 was estimated to be an additional cost of $10.6 million/yr (at a 3 percent discount rate) and $8.3 million/yr (at a 7 percent discount rate). The annualized energy cost impacts were estimated to be an additional $2.28 per square foot (at a 3 percent discount rate) and −1.78 per square foot (at a 3 percent discount rate). Note the annual energy cost impacts are for one year of Federal commercial and high-rise multi-family residential construction and that those

[19] RS Means. 2020. RS Means Building Construction Cost Data, 78th Ed. Construction Publishers & Consultants. Norwell, MA.

[20] The energy costs used were the national average energy costs used by ASHRAE in the development of Standard 90.1–2019. To quote the cost-effectiveness analysis report ''Energy rates used to calculate the energy costs from the modeled energy usage were $0.98/therm for fossil fuel and $0.1063/kWh for electricity. These rates were used for the 90.1–2019 energy analysis and derived from the EIA data. These were the values approved by the SSPC 90.1 for cost-effectiveness for the evaluation of individual addenda during the development of 90.1–2019.''

[21] For the Federal office building, the small and large office prototype LCCs were weighted by estimated fraction of small and large offices observed in the FRPP MS database over the past 10 years of construction. For the Federal education building, the primary school prototype LCC was used. For the Federal dorm/barracks building type, the small office, small hotel and mid-rise apartment prototype LCCs were averaged.

[22] Note that the values in Table IV.5 have been adjusted to reflect 2020$ from the table that appears in DOE's determination of energy savings for Standard 90.1–2016, which were in 2018$. This adjustment was made using the GDP deflator value to correct for inflation between 2018 and 2020. Organization for Economic Co-operation and Development, GDP Implicit Price Deflator in United States, retrieved from FRED, Federal Reserve Bank of St. Louis; *fred.stlouisfed.org/series/USAGDPDEFAISMEI,* Updated February 17, 2021. These values have also been adjusted to reflect the same underlying economic assumptions as the 2019 version.

impacts accumulate over the evaluation period.

TABLE IV.6—ANNUALIZED ENERGY COSTS (2021$) FOR ASHRAE STANDARD 90.1–2019 VS. FOSSIL FUEL COMPLIANT BUILDING DESIGN

Building prototype	Total prototype usage (%)	Annualized energy cost savings (M$2021)		Annualized energy cost savings intensity (M$2021/SF)	
		3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate
Small Office	14.78	($1.57)	($1.23)	($0.34)	($0.26)
Medium Office	5.53	(0.59)	(0.46)	(0.13)	(0.10)
Large Office	2.26	(0.24)	(0.19)	(0.05)	(0.04)
Stand-Alone Retail	8.76	(0.93)	(0.73)	(0.20)	(0.16)
Strip Mall	0.00	0.00	0.00	0.00	0.00
Primary School	1.02	(0.11)	(0.08)	(0.02)	(0.02)
Secondary School	18.06	(1.91)	(1.50)	(0.41)	(0.32)
Outpatient Health Care	5.76	(0.61)	(0.48)	(0.13)	(0.10)
Hospital	12.68	(1.34)	(1.05)	(0.29)	(0.23)
Small Hotel	1.18	(0.12)	(0.10)	(0.03)	(0.02)
Large Hotel	0.00	0.00	0.00	0.00	0.00
Quick-service Restaurant	0.00	0.00	0.00	0.00	0.00
Full-service Restaurant	0.00	0.00	0.00	0.00	0.00
Mid-Rise Apartment	8.95	(0.95)	(0.74)	(0.20)	(0.16)
High-Rise Apartment	7.90	(0.84)	(0.66)	(0.18)	(0.14)
Non-Refrigerated Warehouse	13.12	(1.39)	(1.09)	(0.30)	(0.23)
Total	100.00	(10.60)	(8.30)	(2.28)	(1.78)

Note: Negative numbers represent an increase cost.

For LCC net savings, DOE used a similar approach to that used for incremental first cost and first year energy cost savings. That is, DOE developed the national annual LCC net savings [23] for the entire rule by multiplying the average (across climate zones) LCC net savings (determined from the DOE ASHRAE Standard 90.1 cost-effectiveness analysis) by the fraction of the Federal sector construction volume shown in Table IV.1, and then multiplying that by the total estimate of Federal new construction floorspace.[24] Table IV.7 shows annual LCC net savings by prototype buildings for the Clean Energy Rule Compliant Case compared to ASHRAE Standard 90.1–2019. As was done for the incremental cost analysis, the 2019 LCC analysis was adjusted to use the same underlying economic assumptions as the Clean Energy Rule Compliant Case, including fuel prices, fuel price escalations, labor and material costs, and the removal of sales tax. The resulting total LCC net savings for 14.7 million square feet of annual construction for years 2025–2029 and 2.6 million square feet of annual construction for years 2030–2054 was estimated to be a cost of $56.13 million (at a 3 percent discount rate) and a cost of $4.07 million (based on a 7 percent discount rate). The average LCC net impacts in year 1 was estimated to be a cost of $12.09 million (at a 3 percent discount rate) and a cost of $0.88 million (based on a 7 percent discount rate. Note the annual LCC savings are for one year of Federal commercial and high-rise multi-family residential construction and that those savings would accumulate over the LCC evaluation period. For the purpose of this analysis, DOE relied on a 30-year period.[25]

TABLE IV.7—ANNUAL NET LIFE-CYCLE COST (LCC) (2021$) FOR ASHRAE STANDARD 90.1–2019 VS. FOSSIL FUEL COMPLIANT BUILDING DESIGN

Building prototype	Total prototype usage (%)	Cumulative LCC cost savings, (M$2021)		Annualized LCC cost savings, annualized (M$2021)	
		3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate
Small Office	14.78	($8.30)	($0.60)	($0.45)	($0.13)
Medium Office	5.53	(3.10)	(0.23)	(0.17)	(0.05)
Large Office	2.26	(1.27)	(0.09)	(0.07)	(0.02)
Stand-Alone Retail	8.76	(4.92)	(0.36)	(0.27)	(0.08)

[23] The energy costs used were the national average energy costs used by ASHRAE in the development of Standard 90.1–2019. To quote the cost-effectiveness analysis report ''Energy rates used to calculate the energy costs from the modeled energy usage were $0.98/therm for fossil fuel and $0.1063/kWh for electricity. These rates were used for the 90.1–2019 energy analysis and derived from the EIA data. These were the values approved by the SSPC 90.1 for cost-effectiveness for the evaluation of individual addenda during the development of 90.1–2019.''

[24] For the Federal office building, the small and large office prototype LCCs were weighted by estimated fraction of small and large offices observed in the FRPP MS database over the past 10 years of construction. For the Federal education building, the primary school prototype LCC was used. For the Federal dorm/barracks building type, the small office, small hotel and mid-rise apartment prototype LCCs were averaged.

[25] Lavappa, P and J Kneifel. 2021. Energy Price Indices and Discount Factors for Life-Cycle Cost Analysis-2021 Annual Supplement to NIST Handbook 135.

TABLE IV.7—ANNUAL NET LIFE-CYCLE COST (LCC) (2021$) FOR ASHRAE STANDARD 90.1–2019 VS. FOSSIL FUEL COMPLIANT BUILDING DESIGN—Continued

Building prototype	Total prototype usage (%)	Cumulative LCC cost savings, (M$2021)		Annualized LCC cost savings, annualized (M$2021)	
		3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate
Strip Mall	0.00	0.00	0.00	0.00	0.00
Primary School	1.02	(0.57)	(0.04)	(0.03)	(0.01)
Secondary School	18.06	(10.13)	(0.73)	(0.55)	(0.16)
Outpatient Health Care	5.76	(3.24)	(0.23)	(0.17)	(0.05)
Hospital	12.68	(7.12)	(0.52)	(0.38)	(0.11)
Small Hotel	1.18	(0.66)	(0.05)	(0.04)	(0.01)
Large Hotel	0.00	0.00	0.00	0.00	0.00
Quick-service Restaurant	0.00	0.00	0.00	0.00	0.00
Full-service Restaurant	0.00	0.00	0.00	0.00	0.00
Mid-Rise Apartment	8.95	(5.02)	(0.36)	(0.27)	(0.08)
High-Rise Apartment	7.90	(4.43)	(0.32)	(0.24)	(0.07)
Non-Refrigerated Warehouse	13.12	(7.37)	(0.53)	(0.40)	(0.12)
Total	100.00	(56.13)	(4.07)	(0.45)	(0.88)

Note: Negative numbers represent an increase cost or disbenefit.

DOE also conducted a net benefits and costs analysis using a 30-year analysis period and an assumed building lifetime of 30 years. The building lifetime assumption was made to correspond with availability of underlying data from the cost-effectiveness analysis conducted by DOE's State building energy codes program.

DOE calculated the net present value (''NPV'') of the change in equipment cost and reduced operating cost associated with the difference between the Clean Energy Rule compliant case and ASHRAE 90.1–2019. The NPV is the value in the present of a time-series of costs and savings, equal to the present value of savings in operating cost minus the present value of the increased total equipment cost.

DOE determined the total increased equipment cost for each year of the analysis period (2024–2053) using the incremental construction cost described previously. DOE determined the present value of operating cost savings for each year from the beginning of the analysis period to the year when all Federal buildings constructed by 2054 have been retired, assuming a 30-year lifetime of the building.

The average annual operating cost includes the costs for energy, repair, or replacement of building components (*e.g.,* heating and cooling equipment, lighting, and envelope measures), and maintenance of the building. DOE determined the per-unit annual increase in operating cost based on the differences in energy costs plus replacement and maintenance cost savings, which were calculated in the underlying cost-effectiveness analysis by DOE's State building energy codes program. While DOE used the methodology and prices described above to calculate first year energy cost savings and LCC net savings, for the NPV calculations, DOE determined the per-unit annual savings in operating cost by multiplying the per square foot annual electricity and natural gas savings in energy consumption by the appropriate energy price from EIA's *AEO2021*.[26] DOE forecasted energy prices based on projected average annual price changes in EIA's *AEO2021* to develop the operating cost savings through the analysis period.

DOE uses national discount rates to calculate national NPV. DOE estimated NPV using both a 3-percent and a 7-percent real discount rate, in accordance with the Office of Management and Budget's guidance to Federal agencies on the development of regulatory analysis, particularly section E therein: *Identifying and Measuring Benefits and Costs*.[27] The NPV is the sum over time of the discounted net savings.

The present value of increased equipment costs is the annual total cost increase in each year (the difference between The Clean Energy Rule Compliant Case and ASHRAE 90.1–2019), discounted to the present, and summed throughout the analysis period (2024 through 2053) plus 30-year lifetime. Because new construction is held constant through the analysis period, the installed cost is constant.

The present value of savings in operating cost is the annual savings in operating cost (the difference between The Clean Energy Rule Compliant Case and ASHRAE 90.1–2019), discounted to the present and summed through the analysis period (2024 through 2053) plus 30-year lifetime. Savings are decreases in operating cost associated with the higher energy efficiency associated with buildings designed to the Clean Energy Rule Compliant Case compared to ASHRAE 90.1–2019. Total annual savings in operating cost are the savings per square foot multiplied by the number of square feet that survive in a particular year through the lifetime of the buildings constructed in the last year of the analysis period.

B. Emissions Analysis

The emissions analysis consists of two components. The first component estimates the effect of potential Federal building energy standards on power sector and site (where applicable) combustion emissions of CO_2, NO_X, SO_2, and Hg. The second component estimates the impacts of potential Federal building energy standards on emissions of two additional greenhouse gases, CH_4 and N_2O, as well as the changes to emissions of other gases due to ''upstream'' activities in the fuel production chain. These upstream activities comprise extraction, processing, and transporting fuels to the site of combustion.

The analysis of electric power sector emissions of CO_2, NO_X, SO_2, and Hg uses emissions factors intended to

[26] DOE—U.S. Department of Energy. 2022. Annual Energy Outlook 2022 with Projections to 2050. Washington, DC. Available at *www.eia.gov/outlooks/aeo/*.

[27] Office of Management and Budget. OMB Circular A–4, Regulatory Analysis. 2003. OMB: Washington, DC, September 17, 2003. *www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*.

represent the marginal impacts of the change in electricity consumption associated with Federal building energy standards. The methodology is based on results published for the *AEO,* including a set of side cases that implement a variety of efficiency-related policies. The analysis presented in this notice uses projections from *AEO2022*. Power sector emissions of CH_4 and N_2O from fuel combustion are estimated using Emission Factors for Greenhouse Gas Inventories published by the Environmental Protection Agency (''EPA'').[28]

Until 2030, the on-site operation of construction subject to this proposed rule allows combustion of fossil fuels and results in emissions of CO_2, NO_X, SO_2, CH_4, and N_2O where these products are used. Site emissions of these gases were estimated using Emission Factors for Greenhouse Gas Inventories and, for NO_X and SO_2 emissions intensity factors from an EPA publication.[29]

FFC upstream emissions, which include emissions from fuel combustion during extraction, processing, and transportation of fuels, and ''fugitive'' emissions (direct leakage to the atmosphere) of CH_4 and CO_2, are estimated based on the methodology described in chapter 1 of the NOPR TSD.

The emissions intensity factors are expressed in terms of physical units per MWh or MMBtu of site energy savings. For power sector emissions, specific emissions intensity factors are calculated by sector and end use. Total emissions changes are estimated using the energy savings calculated in the national impact analysis with energy savings derived from a load shifting modeling analysis of ASHRAE Prototype models.

1. Air Quality Regulations Incorporated in DOE's Analysis

DOE's no-new-standards case for the electric power sector reflects the *AEO,* which incorporates the projected impacts of existing air quality regulations on emissions. *AEO2022* generally represents current legislation and environmental regulations, including recent government actions, that were in place at the time of preparation of *AEO2022,* including the emissions control programs discussed in the following paragraphs.[30]

SO_2 emissions from affected electric generating units (''EGUs'') are subject to nationwide and regional emissions cap-and-trade programs. Title IV of the Clean Air Act sets an annual emissions cap on SO_2 for affected EGUs in the 48 contiguous States and the District of Columbia (D.C.). (42 U.S.C. 7651 *et seq.*) SO_2 emissions from numerous States in the eastern half of the United States are also limited under the Cross-State Air Pollution Rule (''CSAPR''). 76 FR 48208 (Aug. 8, 2011). CSAPR requires these States to reduce certain emissions, including annual SO_2 emissions, and went into effect as of January 1, 2015.[31] *AEO2022* incorporates implementation of CSAPR, including the update to the CSAPR ozone season program emission budgets and target dates issued in 2016. 81 FR 74504 (Oct. 26, 2016).[32] Compliance with CSAPR is flexible among EGUs and is enforced through the use of tradable emissions allowances. Under existing EPA regulations, for states subject to SO_2 emissions limits under CSAPR, excess SO_2 emissions allowances resulting from the lower electricity demand caused by the adoption of an efficiency standard could be used to permit offsetting increases in SO_2 emissions by another regulated EGU.

However, beginning in 2016, SO_2 emissions began to fall as a result of the Mercury and Air Toxics Standards (''MATS'') for power plants. 77 FR 9304 (Feb. 16, 2012). In the MATS final rule, EPA established a standard for hydrogen chloride as a surrogate for acid gas hazardous air pollutants (''HAP''), and also established a standard for SO_2 (a non-HAP acid gas) as an alternative equivalent surrogate standard for acid gas HAP. The same controls are used to reduce HAP and non-HAP acid gas; thus, SO_2 emissions are being reduced as a result of the control technologies installed on coal-fired power plants to comply with the MATS requirements for acid gas. In order to continue operating, coal power plants must have either flue gas desulfurization or dry sorbent injection systems installed. Both technologies, which are used to reduce acid gas emissions, also reduce SO_2 emissions. Because of the emissions reductions under the MATS, it is unlikely that excess SO_2 emissions allowances resulting from the lower electricity demand would be needed or used to permit offsetting increases in SO_2 emissions by another regulated EGU.

CSAPR also established limits on NO_X emissions for numerous States in the eastern half of the United States. Impacts from this Clean Energy Rule would have little effect on NO_X emissions in those States covered by CSAPR emissions limits if excess NO_X emissions allowances resulting from the lower electricity demand could be used to permit offsetting increases in NO_X emissions from other EGUs. In such case, NOx emissions would remain near the limit even if electricity generation goes down. A different case could possibly result, depending on the configuration of the power sector in the different regions and the need for allowances, such that NO_X emissions might not remain at the limit in the case of lower electricity demand. In this case, Federal building standards might reduce NO_X emissions in covered States. Despite this possibility, DOE has chosen to be conservative in its analysis and has maintained the assumption that standards will not reduce NO_X emissions in States covered by CSAPR. Federal building standards would be expected to reduce NO_X emissions in the States not covered by CSAPR.

DOE estimated mercury emissions reduction using emissions factors based on AEO2022, which incorporates the MATS.

C. Monetization of Emissions Changes

As part of the development of this rule, for the purpose of complying with the requirements of Executive Order 12866, DOE considered the estimated monetary climate and health benefits and disbenefits from the changes in

[28] Available at *www.epa.gov/sites/production/files/2021-04/documents/emission-factors_apr2021.pdf* (last accessed July 12, 2021).

[29] U.S. Environmental Protection Agency. External Combustion Sources. In *Compilation of Air Pollutant Emission Factors.* AP–42. Fifth Edition. Volume I: Stationary Point and Area Sources. Chapter 1. Available at *https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emissions-factors* (last accessed April 15, 2022).

[30] For further information, see the Assumptions to *AEO2022* report that sets forth the major assumptions used to generate the projections in the Annual Energy Outlook. Available at *www.eia.gov/outlooks/aeo/assumptions/* (last accessed April 15, 2022).

[31] CSAPR requires states to address annual emissions of SO_2 and NO_X, precursors to the formation of fine particulate matter ($PM_{2.5}$) pollution, in order to address the interstate transport of pollution with respect to the 1997 and 2006 $PM_{2.5}$ National Ambient Air Quality Standards (''NAAQS''). CSAPR also requires certain states to address the ozone season (May–September) emissions of NO_X, a precursor to the formation of ozone pollution, in order to address the interstate transport of ozone pollution with respect to the 1997 ozone NAAQS. 76 FR 48208 (Aug. 8, 2011). EPA subsequently issued a supplemental rule that included an additional five states in the CSAPR ozone season program; 76 FR 80760 (Dec. 27, 2011) (Supplemental Rule), and EPA issued the CSAPR Update for the 2008 ozone NAAQS. 81 FR 74504 (Oct. 26, 2016).

[32] In Sept. 2019, the D.C. Court of Appeals remanded the 2016 CSAPR Update to EPA. In April 2021, EPA finalized the 2021 CSAPR Update which resolved the interstate transport obligations of 21 states for the 2008 ozone NAAQS. 86 FR 23054 (April 30, 2021); *see also,* 86 FR 29948 (June 4, 2021) (correction to preamble). The 2021 CSAPR Update became effective on June 29, 2021. The release of AEO 2021 in February 2021 predated the 2021 CSAPR Update.

emissions of CO_2, CH_4, N_2O, NO_X, and SO_2 that are expected to result from this rule. DOE considered the emissions changes expected to result over the lifetime of buildings constructed in the analysis period. This section summarizes the basis for the values used for monetizing the emissions changes and presents the values considered in this rule.

On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits and disbenefits of changing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits and disbenefits where appropriate and permissible under law.

1. Monetization of Greenhouse Gas Emissions

For the purpose of complying with the requirements of Executive Order 12866, DOE estimates the monetized benefits and disbenefits of the changes in emissions of CO_2, CH_4, and N_2O by using a measure of the social cost (''SC'') of each pollutant (*e.g.,* SC-CO_2). These estimates represent the monetary value of the net harm to society associated with a marginal increase in emissions of these pollutants in a given year, or the benefit of avoiding that increase. These estimates are intended to include (but are not limited to) climate-change-related changes in net agricultural productivity, human health, property damages from increased flood risk, disruption of energy systems, risk of conflict, environmental migration, and the value of ecosystem services. DOE exercises its own judgment in presenting monetized climate benefits and disbenefits as recommended by applicable Executive orders and guidance, and DOE would reach the same conclusion presented in this notice in the absence of the social cost of greenhouse gases, including the February 2021 Interim Estimates presented by the Interagency Working Group on the Social Cost of Greenhouse Gases.

DOE estimated the climate benefits and disbenefits of CO_2, CH_4, and N_2O changes (*i.e.,* SC-GHGs) using the estimates presented in the Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990 published in February 2021 by the Interagency Working Group on the Social Cost of Greenhouse Gases (IWG) (IWG, 2021).[33] The SC-GHGs is the theoretically appropriate value to use in conducting benefit-cost analyses of policies that affect CO_2, N_2O and CH_4 emissions. As a member of the IWG involved in the development of the February 2021 SC-GHG TSD, the DOE agrees that the interim SC-GHG estimates represent the most appropriate estimate of the SC-GHG until revised estimates have been developed reflecting the latest, peer-reviewed science.

The SC-GHGs estimates presented here were developed over many years, using transparent process, peer-reviewed methodologies, the best science available at the time of that process, and with input from the public. Specifically, in 2009, an interagency working group (''IWG'') that included the DOE and other executive branch agencies and offices was established to ensure that agencies had access to the best available information when quantifying the benefits of reducing CO_2 emissions in benefit-cost analyses. The IWG published estimates of the social cost of carbon (''SC-CO_2'') in 2010 that were developed from an ensemble of three widely cited integrated assessment models (''IAMs'') that estimate climate damages using highly aggregated representations of climate processes and the global economy combined into a single modeling framework. The three IAMs were run using a common set of input assumptions in each model for future population, economic, and CO_2 emissions growth, as well as equilibrium climate sensitivity (''ECS'')—a measure of the globally averaged temperature response to increased atmospheric CO_2 concentrations. These estimates were updated in 2013 based on new versions of each IAM. In August 2016 the IWG published estimates of the social cost of methane (''SC-CH_4'') and nitrous oxide (''SC-N_2O'') using methodologies that are consistent with the methodology underlying the SC-CO_2 estimates. The modeling approach that extends the IWG SC-CO_2 methodology to non-CO_2 GHGs has undergone multiple stages of peer review. The SC-CH_4 and SC-N_2O estimates were developed by Marten et al. (2015) and underwent a standard double-blind peer review process prior to journal publication.

In 2015, as part of the response to public comments received to a 2013 solicitation for comments on the SC-CO_2 estimates, the IWG announced a National Academies of Sciences, Engineering, and Medicine review of the SC-CO_2 estimates to offer advice on how to approach future updates to ensure that the estimates continue to reflect the best available science and methodologies. In January 2017, the National Academies released their final report, Valuing Climate Damages: Updating Estimation of the Social Cost of Carbon Dioxide, and recommended specific criteria for future updates to the SC-CO_2 estimates, a modeling framework to satisfy the specified criteria, and both near-term updates and longer-term research needs pertaining to various components of the estimation process (National Academies, 2017).[34] Shortly thereafter, in March 2017, President Trump issued Executive Order 13783, which disbanded the IWG, withdrew the previous TSDs, and directed agencies to ensure SC-CO_2 estimates used in regulatory analyses are consistent with the guidance contained in OMB's Circular A–4, ''including with respect to the consideration of domestic versus international impacts and the consideration of appropriate discount rates'' (E.O. 13783, Section 5(c)). Benefit-cost analyses following E.O. 13783 used SC-GHG estimates that attempted to focus on the U.S.-specific share of climate change damages as estimated by the models (and so did not reflect many pathways by which physical impacts outside the United States affect the welfare of U.S. citizens and residents) and were calculated using two default discount rates recommended by Circular A–4, 3

[33] *See* Interagency Working Group on Social Cost of Greenhouse Gases, *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide. Interim Estimates Under Executive Order 13990,* Washington, DC, February 2021. Available at: *www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostofCarbonMethaneNitrousOxide.pdf* (last accessed March 17, 2021).

[34] *See* National Academies of Sciences, Engineering, and Medicine. 2017. Valuing Climate Damages: Updating Estimation of the Social Cost of Carbon Dioxide. Washington, DC: The National Academies Press. *doi.org/10.17226/24651.*

percent and 7 percent.[35]All other methodological decisions and model versions used in SC-GHG calculations remained the same as those used by the IWG in 2010 and 2013, respectively.

On January 20, 2021, President Biden issued Executive Order 13990, which re-established the IWG and directed it to develop updated estimates of the social cost of carbon and other greenhouse gases that reflect the best available science and the recommendations of the National Academies (2017). The IWG was tasked with first reviewing the SC-GHG estimates currently used in Federal analyses and publishing interim estimates within 30 days of the E.O. that reflect the full impact of GHG emissions, including by taking global damages into account.

As noted previously, DOE participated in the IWG but has also independently evaluated the interim SC-GHG estimates published in the February 2021 TSD and determined they are appropriate to use here to estimate the climate benefits and disbenefits associated with this proposed rule. DOE and other agencies intend to undertake a fuller update of the SC-GHG estimates that takes into consideration the advice of the National Academies (2017) and other recent scientific literature. The DOE has also evaluated the supporting rationale of the February 2021 TSD, including the studies and methodological issues discussed therein, and concludes that it agrees with the rationale for these estimates presented in the TSD and summarized below.

The February 2021 SC-GHG TSD provides a complete discussion of the IWG's initial review conducted under E.O. 13990. In particular, the IWG found that the SC-GHG estimates used under E.O. 13783 fail to reflect the full impact of GHG emissions in multiple ways. First, the IWG found that the SC-GHG estimates used under E.O. 13783 fail to fully capture many climate impacts that affect the welfare of U.S. citizens and residents, and those impacts are better reflected by global measures of the SC-GHG. Examples of effects omitted from the E.O. 13783 estimates include direct effects on U.S. citizens, assets, and investments located abroad, supply chains, U.S. military assets and interests abroad, and tourism, and spillover pathways such as economic and political destabilization and global migration that can lead to adverse impacts on U.S. national security, public health, and humanitarian concerns. In addition, assessing the benefits of U.S. GHG mitigation activities requires consideration of how those actions may affect mitigation activities by other countries, as those international mitigation actions will provide a benefit to U.S. citizens and residents by mitigating climate impacts that affect U.S. citizens and residents. A wide range of scientific and economic experts have emphasized the issue of reciprocity as support for considering global damages of GHG emissions. If the United States does not consider impacts on other countries, it is difficult to convince other countries to consider the impacts of their emissions on the United States. The only way to achieve an efficient allocation of resources for emissions reduction on a global basis—and so benefit the U.S. and its citizens—is for all countries to base their policies on global estimates of damages. As a member of the IWG involved in the development of the February 2021 SC-GHG TSD, DOE agrees with this assessment and, therefore, in this rule DOE centers attention on a global measure of SC-GHG. This approach is the same as that taken in DOE regulatory analyses from 2012 through 2016. A robust estimate of climate damages to U.S. citizens and residents that accounts for the myriad of ways that global climate change reduces the net welfare of U.S. populations does not currently exist in the literature. As explained in the February 2021 TSD, existing estimates are both incomplete and an underestimate of total damages that accrue to the citizens and residents of the U.S. because they do not fully capture the regional interactions and spillovers discussed previously, nor do they include all of the important physical, ecological, and economic impacts of climate change recognized in the climate change literature. As noted in the February 2021 SC-GHG TSD, the IWG will continue to review developments in the literature, including more robust methodologies for estimating a U.S.-specific SC-GHG value, and explore ways to better inform the public of the full range of carbon impacts. As a member of the IWG, DOE will continue to follow developments in the literature pertaining to this issue.

Second, the IWG found that the use of the social rate of return on capital (7 percent under current OMB Circular A–4 guidance) to discount the future benefits and disbenefits of reducing GHG emissions inappropriately underestimates the impacts of climate change for the purposes of estimating the SC-GHG. Consistent with the findings of the National Academies (2017) and the economic literature, the IWG continued to conclude that the consumption rate of interest is the theoretically appropriate discount rate in an intergenerational context (IWG 2010, 2013, 2016a, 2016b),[36] and recommended that discount rate uncertainty and relevant aspects of intergenerational ethical considerations be accounted for in selecting future discount rates.

Furthermore, the damage estimates developed for use in the SC-GHG are estimated in consumption-equivalent terms, and so an application of OMB Circular A–4's guidance for regulatory analysis would then use the consumption discount rate to calculate the SC-GHG. DOE agrees with this assessment and will continue to follow developments in the literature pertaining to this issue. DOE also notes that while OMB Circular A–4, as published in 2003, recommends using 3% and 7% discount rates as ''default'' values, Circular A–4 also reminds agencies that ''different regulations may call for different emphases in the analysis, depending on the nature and complexity of the regulatory issues and the sensitivity of the benefit and cost

[35] DOE regulatory analyses under E.O. 13783 included sensitivity analyses based on global SC-GHG values and using a lower discount rate of 2.5%. OMB Circular A–4 (2003) recognizes that special considerations arise when applying discount rates if intergenerational effects are important. In the IWG's 2015 *Response to Comments,* OMB—as a co-chair of the IWG—made clear that ''Circular A–4 is a living document,'' that ''the use of 7 percent is not considered appropriate for intergenerational discounting,'' and that ''[t]here is wide support for this view in the academic literature, and it is recognized in Circular A–4 itself.'' OMB, as part of the IWG, similarly repeatedly confirmed that ''a focus on global SCC estimates in [regulatory impact analyses] is appropriate'' (IWG 2015).

[36] Interagency Working Group on Social Cost of Carbon. *Social Cost of Carbon for Regulatory Impact Analysis under Executive Order 12866.* 2010. United States Government. (Last accessed April 15, 2022.) *www.epa.gov/sites/default/files/2016-12/documents/scc_tsd_2010.pdf;* Interagency Working Group on Social Cost of Carbon. *Technical Update of the Social Cost of Carbon for Regulatory Impact Analysis Under Executive Order 12866.* 2013. (Last accessed April 15, 2022.) *www.federalregister.gov/documents/2013/11/26/2013-28242/technical-support-document-technical-update-of-the-social-cost-of-carbon-for-regulatory-impact;* Interagency Working Group on Social Cost of Greenhouse Gases, United States Government. Technical Support Document: Technical Update on the Social Cost of Carbon for Regulatory Impact Analysis-Under Executive Order 12866. August 2016. (Last accessed January 18, 2022.) *www.epa.gov/sites/default/files/2016-12/documents/sc_co2_tsd_august_2016.pdf;* Interagency Working Group on Social Cost of Greenhouse Gases, United States Government. Addendum to Technical Support Document on Social Cost of Carbon for Regulatory Impact Analysis under Executive Order 12866: Application of the Methodology to Estimate the Social Cost of Methane and the Social Cost of Nitrous Oxide. August 2016. (Last accessed January 18, 2022.) *www.epa.gov/sites/default/files/2016-12/documents/addendum_to_sc-ghg_tsd_august_2016.pdf.*

estimates to the key assumptions.'' On discounting, Circular A–4 recognizes that ''special ethical considerations arise when comparing benefits and costs across generations,'' and Circular A–4 acknowledges that analyses may appropriately ''discount future costs and consumption benefits . . . at a lower rate than for intragenerational analysis.'' In the 2015 Response to Comments on the Social Cost of Carbon for Regulatory Impact Analysis, OMB, DOE, and the other IWG members recognized that ''Circular A–4 is a living document'' and ''the use of 7 percent is not considered appropriate for intergenerational discounting. There is wide support for this view in the academic literature, and it is recognized in Circular A–4 itself.'' Thus, DOE concludes that a 7% discount rate is not appropriate to apply to value the social cost of greenhouse gases in the analysis presented in this analysis. In this analysis, to calculate the present and annualized values of climate benefits and disbenefits, DOE uses the same discount rate as the rate used to discount the value of damages from future GHG emissions, for internal consistency. That approach to discounting follows the same approach that the February 2021 TSD recommends ''to ensure internal consistency—*i.e.,* future damages from climate change using the SC-GHG at 2.5 percent should be discounted to the base year of the analysis using the same 2.5 percent rate.'' DOE has also consulted the National Academies' 2017 recommendations on how SC-GHG estimates can ''be combined in RIAs with other cost and benefits estimates that may use different discount rates.'' The National Academies reviewed ''several options,'' including ''presenting all discount rate combinations of other costs and benefits with [SC-GHG] estimates.''

As a member of the IWG involved in the development of the February 2021 SC-GHG TSD, DOE agrees with this assessment and will continue to follow developments in the literature pertaining to this issue. While the IWG works to assess how best to incorporate the latest, peer reviewed science to develop an updated set of SC-GHG estimates, it recommended the interim use of the mot SC-GHG estimates developed by the IWG prior to the group being disbanded in 2017. The estimates rely on the same models and harmonized inputs and are calculated using a range of discount rates. As explained in the February 2021 SC-GHG TSD, the IWG has recommended that agencies to revert to the same set of four values drawn from the SC-GHG distributions based on three discount rates as were used in regulatory analyses between 2010 and 2016 and subject to public comment. For each discount rate, the IWG combined the distributions across models and socioeconomic emissions scenarios (applying equal weight to each) and then selected a set of four values recommended for use in benefit-cost analyses: an average value resulting from the model runs for each of three discount rates (2.5 percent, 3 percent, and 5 percent), plus a fourth value, selected as the 95th percentile of estimates based on a 3 percent discount rate. The fourth value was included to provide information on potentially higher-than-expected economic impacts from climate change. As explained in the February 2021 SC-GHG TSD, and DOE agrees, this update reflects the immediate need to have an operational SC-GHG for use in regulatory benefit-cost analyses and other applications that was developed using a transparent process, peer-reviewed methodologies, and the science available at the time of that process. Those estimates were subject to public comment in the context of dozens of proposed rulemakings as well as in a dedicated public comment period in 2013.

There are a number of limitations and uncertainties associated with the SC-GHG estimates. First, the current scientific and economic understanding of discounting approaches suggests discount rates appropriate for intergenerational analysis in the context of climate change are likely to be less than 3 percent, near 2 percent or lower.[37] Second, the IAMs used to produce these interim estimates do not include all of the important physical, ecological, and economic impacts of climate change recognized in the climate change literature and the science underlying their ''damage functions''—*i.e.,* the core parts of the IAMs that map global mean temperature changes and other physical impacts of climate change into economic (both market and nonmarket) damages—lags behind the most recent research. For example, limitations include the incomplete treatment of catastrophic and non-catastrophic impacts in the integrated assessment models, their incomplete treatment of adaptation and technological change, the incomplete way in which inter-regional and intersectoral linkages are modeled, uncertainty in the extrapolation of damages to high temperatures, and inadequate representation of the relationship between the discount rate and uncertainty in economic growth over long time horizons. Likewise, the socioeconomic and emissions scenarios used as inputs to the models do not reflect new information from the last decade of scenario generation or the full range of projections. The modeling limitations do not all work in the same direction in terms of their influence on the SC-CO_2 estimates. However, as discussed in the February 2021 TSD, the IWG has recommended that, taken together, the limitations suggest that the interim SC-GHG estimates used in this rule likely underestimate the damages from GHG emissions. DOE concurs with this assessment.

DOE's derivations of the SC-GHGs (*i.e.,* SC-CO_2, SC-N_2O, and SC-CH_4) values used for this rule are discussed in the following sections, and the results of DOE's analyses estimating the benefits and disbenefits of the changes in emissions of these pollutants are presented in section V.A. of this document.

a. Social Cost of Carbon

The SC-CO_2 values used for this rule were generated using the values presented in the 2021 update from the IWG's February 2021 TSD. Table IV.8 shows the updated sets of SC-CO_2 estimates from the latest interagency update in 5-year increments from 2020 to 2050. The full set of annual values used is presented in the SNOPR TSD. For purposes of capturing the uncertainties involved in regulatory impact analysis, DOE has determined it is appropriate include all four sets of SC-CO_2 values, as recommended by the IWG.[38]

[37] Interagency Working Group on Social Cost of Greenhouse Gases (IWG). 2021. Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990. February. United States Government. Available at: *<https://www.whitehouse.gov/briefing-room/blog/2021/02/26/a-return-to-science-evidence-based-estimates-of-the-benefits-of-reducing-climate-pollution/.*

[38] For example, the February 2021 TSD discusses how the understanding of discounting approaches suggests that discount rates appropriate for intergenerational analysis in the context of climate change may be lower than 3 percent.

TABLE IV.8—ANNUAL SC-CO_2 VALUES FROM 2021 INTERAGENCY UPDATE, 2020–2050

[2020$ per metric ton CO_2]

Year	Discount rate			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
2020	14	51	76	152
2025	17	56	83	169
2030	19	62	89	187
2035	22	67	96	206
2040	25	73	103	225
2045	28	79	110	242
2050	32	85	116	260

In calculating the potential climate benefits and disbenefits resulting from changes in CO_2 emissions, DOE used the values from the 2021 interagency report, adjusted to 2021$ using the implicit price deflator for gross domestic product (''GDP'') from the Bureau of Economic Analysis. DOE derived values from 2051 to 2070 based on estimates published by EPA.[39] These estimates are based on methods, assumptions, and parameters identical to the 2020–2050 estimates published by the IWG. If further analysis of monetized climate benefits beyond 2070 becomes available prior to the publication of the final rule, DOE will include that analysis in the final rule.

DOE multiplied the CO_2 emissions change estimated for each year by the SC-CO_2 value for that year in each of the four cases. To calculate a present value of the stream of monetized climate impacts, DOE discounted the values in each of the four cases using the specific discount rate that had been used to obtain the SC-CO_2 values in each case.

b. Social Cost of Methane and Nitrous Oxide

The SC-CH_4 and SC-N_2O values used for this rule were generated using the values presented in the February 2021 TSD.[40] Table IV.9 shows the updated sets of SC-CH_4 and SC-N_2O estimates from the latest interagency update in 5-year increments from 2020 to 2050. To capture the uncertainties involved in regulatory impact analysis, DOE has determined it is appropriate to include all four sets of SC-CH_4 and SC-N_2O values, as recommended by the IWG.

TABLE IV.9—ANNUAL SC-CH_4 AND SC-N_2O VALUES FROM 2021 INTERAGENCY UPDATE, 2020–2050

[2020$ per metric ton]

Year	SC-CH_4				SC-N_2O			
	Discount rate and statistic				Discount rate and statistic			
	5%	3%	2.5%	3%	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile	Average	Average	Average	95th percentile
2020	670	1,500	2,000	3,900	5,800	18,000	27,000	48,000
2025	800	1,700	2,200	4,500	6,800	21,000	30,000	54,000
2030	940	2,000	2,500	5,200	7,800	23,000	33,000	60,000
2035	1,100	2,200	2,800	6,000	9,000	25,000	36,000	67,000
2040	1,300	2,500	3,100	6,700	10,000	28,000	39,000	74,000
2045	1,500	2,800	3,500	7,500	12,000	30,000	42,000	81,000
2050	1,700	3,100	3,800	8,200	13,000	33,000	45,000	88,000

DOE multiplied the CH_4 and N_2O emissions change estimated for each year by the SC-CH_4 and SC-N_2O estimates for that year in each of the cases. To calculate a present value of the stream of estimated monetized impacts, DOE discounted the values in each of the cases using the specific discount rate that had been used to obtain the SC-CH_4 and SC-N_2O estimates in each case.

2. Monetization of Other Emissions Impacts

For the SNOPR, DOE estimated the monetized value of NO_X and SO_2 emissions changes from electricity generation using benefit-per-ton estimates for that sector from the EPA's Benefits Mapping and Analysis Program.[41] DOE used EPA's values for $PM_{2.5}$-related benefits associated with NO_X and SO_2 and for ozone-related benefits associated with NO_X for 2025, 2030, and 2040, calculated with discount rates of 3 percent and 7 percent. DOE used linear interpolation to define values for the years not given in the 2025 to 2040 period; for years beyond 2050 the values are held constant.

DOE also estimated the monetized value of NO_X and SO_2 emissions

[39] *See* EPA, *Revised 2023 and Later Model Year Light-Duty Vehicle GHG Emissions Standards: Regulatory Impact Analysis*, Washington, DC, December 2021. Available at: *www.epa.gov/system/files/documents/2021–12/420r21028.pdf* (last accessed January 13, 2022).

[40] See Interagency Working Group on Social Cost of Greenhouse Gases, *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide. Interim Estimates Under Executive Order 13990,* Washington, DC, February 2021. Available at: *www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostofCarbonMethaneNitrousOxide.pdf* (last accessed March 17, 2021).

[41] *Estimating the Benefit per Ton of Reducing $PM_{2.5}$ Precursors from 21 Sectors. www.epa.gov/benmap/estimating-benefit-ton-reducing-pm25-precursors-21-sectors.*

changes from site use of natural gas in buildings impacted by this rule using benefit-per-ton estimates from the EPA's Benefits Mapping and Analysis Program. Although none of the sectors covered by EPA refers specifically to residential and commercial buildings, the sector called ''area sources'' would be a reasonable proxy for Federal buildings.[42] The EPA document provides high and low estimates for 2025 and 2030 at 3- and 7-percent discount rates.[43] DOE used the same linear interpolation and extrapolation as it did with the values for electricity generation.

DOE multiplied the emissions changes (in tons) in each year by the associated $/ton values, and then discounted each series using discount rates of 3 percent and 7 percent as appropriate.

We request comment on how to address the monetization of climate and health benefits and disbenefits from this proposal.

D. Conclusion

Table IV.10 provides DOE's estimate of cumulative emissions changes expected to result from this rulemaking. DOE acknowledges exchanging on-site fossil fuel generated energy for reliance on the electric grid, which may still be generating energy with fossil fuels, doesn't necessarily lead to an immediate reduction in emissions of GHGs and SO_2. However, it does prepare federal buildings for a green energy future. By ensuring that federal buildings are designed—either from the ground up, or when being renovated—to rely on the electric grid, the rule ensures that long-term, as the grid integrates more renewable energies, emissions will be reduced.

TABLE IV.10—CUMULATIVE EMISSIONS CHANGES IN 2025–2084

Pollutant	Total
Primary (plant) Emissions Changes	
CO_2 (million metric tons)	−0.3
Hg (tons)	−0.01
NO_X (thousand tons)	0.54
SO_2 (thousand tons)	−1.0
CH_4 (thousand tons)	−0.1
N_2O (thousand tons)	−0.02
Upstream Emissions Changes	
CO_2 (million metric tons)	0.1
Hg (tons)	−0.00002
NO_X (thousand tons)	1.3
SO_2 (thousand tons)	−0.01
CH_4 (thousand tons)	10.5
N_2O (thousand tons)	−0.0004
Total Emissions Changes	
CO_2 (million metric tons)	−0.2
Hg (tons)	−0.01
NO_X (thousand tons)	1.9
SO_2 (thousand tons)	−1.0
CH_4 (thousand tons)	10.4
N_2O (thousand tons)	−0.021

Negative values refer to an increase in emissions.

Table IV.11 presents the present value of monetized climate disbenefits associated with the CO_2 emissions changes using the full set of SC-CO_2 estimates described previously.

[42] ''Area sources'' represents all emission sources for which states do not have exact (point) locations in their emissions inventories. Because exact locations would tend to be associated with larger sources, ''area sources'' would be fairly representative of small, dispersed sources like homes, businesses and office buildings.

[43] ''Area sources'' are a category in the 2018 document from EPA, but are not used in the 2021 document cited previously. See: *www.epa.gov/sites/default/files/2018-02/documents/sourceapportionmentbpttsd_2018.pdf.*

TABLE IV.11—PRESENT VALUE OF MONETIZED CLIMATE DISBENEFITS FROM CHANGES IN CO_2 EMISSIONS FOR CLEAN ENERGY RULE CONSTRUCTION IMPACTS 2025–2054 WITH A 30-YEAR LIFETIME

	SC-CO_2 Case			
	Discount rate and statistics			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
	Million 2021$			
Total	−2.3	−9.4	−14.3	−28.3

Note: Negative numbers represent an increase cost or disbenefit. Climate benefits and disbenefits associated with CO_2 emissions changes occur over 2025–2070. DOE expects additional climate impacts to accrue from CO_2 emissions changes post 2070, but a lack of available SC-CO_2 estimates for years beyond 2070 prevents DOE from monetizing these additional impacts in this analysis.

Table IV.12 presents the monetized climate benefits associated with the estimated CH_4 emissions reduction, and Table IV.13 presents the monetized climate disbenefits associated with the estimated changes in N_2O emissions.

TABLE IV.12—PRESENT VALUE OF MONETIZED CLIMATE BENEFITS FROM CHANGES IN METHANE EMISSIONS FOR CLEAN ENERGY RULE CONSTRUCTION IMPACTS 2025–2054 WITH A 30-YEAR LIFETIME

	SC-CH_4 Case			
	Discount rate and statistics			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
	Million 2021$			
Total	4.0	12.4	17.4	32.7

Note: Climate benefits and disbenefits associated with CH_4 emissions changes occur over 2025–2070. DOE expects additional climate impacts to accrue from CH_4 emissions changes post 2070, but a lack of available SC-CH_4 estimates for years beyond 2070 prevents DOE from monetizing these additional impacts in this analysis.

TABLE IV.13—PRESENT VALUE OF MONETIZED CLIMATE DISBENEFITS FROM CHANGES IN NITROUS OXIDE EMISSIONS FOR CLEAN ENERGY RULE CONSTRUCTION IMPACTS 2025–2054 WITH A 30-YEAR LIFETIME

	SC-N_2O Case			
	Discount rate and statistics			
	5%	3%	2.5%	3%
	Average	Average	Average	95th percentile
	Million 2021$			
Total	−0.1	−0.3	−0.4	−0.7

Note: Negative numbers represent an increase cost or disbenefit. Climate benefits and disbenefits associated with N_2O emissions changes occur over 2025–2070. DOE expects additional climate impacts to accrue from N_2O emissions changes post 2070, but a lack of available SC-N_2O estimates for years beyond 2070 prevents DOE from monetizing these additional impacts in this analysis.

DOE is well aware that scientific and economic knowledge about the contribution of CO_2 and other GHG emissions to changes in the future global climate and the potential resulting damages to the global and U.S. economy continues to evolve rapidly. DOE, together with other Federal agencies, will continue to review methodologies for estimating the monetary value of changes in CO_2 and other GHG emissions. This ongoing review will consider the comments on this subject that are part of the public record for this and other rulemakings, as well as other methodological assumptions and issues.

DOE also estimated the monetary value of the health benefits and disbenefits associated with changes in NO_X and SO_2 emissions anticipated to result from this rule. The dollar-per-ton values that DOE used are discussed in section V.C of this document. Table IV.14 presents the present value for NO_X emissions reduction calculated using 7-percent and 3-percent discount rates, and Table IV.15 presents similar results for SO_2 emissions increases. The results in these tables reflect application of EPA's low dollar-per-ton values, which DOE used to be conservative.

TABLE IV.14—PRESENT VALUE OF NO_X EMISSIONS REDUCTION

	3% Discount rate (low)	7% Discount rate (low)	3% Discount rate (high)	7% Discount rate (high)
	Million 2021$			
Total	20.2	6.6	31.0	10.9

TABLE IV.15—PRESENT VALUE OF SO_2 EMISSIONS INCREASE

	3% Discount rate (low)	7% Discount rate (low)	3% Discount rate (high)	7% Discount rate (high)
	Million 2021$			
Total	−54.1	−22.5	−57.8	−23.9

Note: Negative numbers represent an increase cost or disbenefit.

The Federal building energy standards in this proposed rule are projected to result in an estimated national increased energy use of 0.029 quad. The increase is for the full fuel cycle which is essentially accounting for source energy impacts. The actual breakdown is .001 upstream energy savings and an increase of 0.030 primary energy use (energy use impacts at the power plants) for a grand total of an increase in .029 quads of full fuel cycle energy. Additionally, the Federal building energy standards are projected to result in an estimated national CO_2 emissions increase of 0.2 Mt (million metric tons) according to AEO 2022 emission projection values accounting for electricity procured from the grid. It should be noted that this is a CO_2 emissions increase only and does not account for the additional emission impacts from other GHGs such as N_2O and CH_4. When combining CO_2 increases with savings in Methane (CH_4) and minor increases in N_2O into a CO_2 equivalent metric, there results in an overall net savings of CO_2e emissions of approximately 0.07 MMT (million metric tons) CO_2e.

Notably, the recent enactment of the Inflation Reduction Act of 2022 (Pub. L. 117–169) and the Infrastructure Investment and Jobs Act (Pub. L. 117–58) will drive power sector emissions reductions in both the near-term and the short-term. With these laws in place, U.S. economy-wide greenhouse gas emissions are already projected to be 40 percent below 2005 levels in 2030, with the power sector representing the largest source of these reductions. In contrast to the base case presented in this rulemaking, there are alternative scenarios for projecting the future emissions associated with grid electricity that better align with these new policy drivers. These scenarios, discussed in section V.A of this document, have a large effect on the net emissions impacts of the proposed rulemakings and present larger environmental and overall net benefits. With these policy drivers now in place, reduced power sector emissions below 40% would only further add to the benefits of this proposed rulemaking in the future in terms of emissions benefits. These scenarios do not present comprehensive profiles for all additional climate factors beyond CO_2 emissions (such as NO_X, Hg, N_2O, CH_4, and SO_2), and have been presented only in the corresponding TSD for reference.

A more detailed discussion of the basis for these tentative conclusions is contained in the remainder of this document and the accompanying TSD. Further discussion on the costs and benefits can be found in section V.A of this document.

E. Reference Resources

DOE has prepared a list of resources to help Federal agencies address the reduction of fossil fuel-generated energy consumption. These resources come in many forms such as design guidance, case studies and in a variety of media such as printed documents or websites. The resources for energy efficiency improvement will also provide guidance for fossil fuel-generated energy consumption reductions.

- U.S. Department of Energy, Federal Energy Management Program. (*https://www.energy.gov/eere/femp/federal-energy-management-program*). FEMP provides access to numerous resources and tools that can help Federal agencies improve the energy efficiency of new and existing buildings.
- U.S. Department of Energy, Building Technologies Program. Database of high-performance buildings. (*https://buildingdata.energy.gov/*).
- U.S. Department of Energy, Better Buildings Program. Decarbonization Resource Hub. (*https://betterbuildingssolutioncenter.energy.gov/carbon-hub*).
- New York State Energy Research and Development Authority (NYSERDA). Building Decarbonization Insights. (*https://www.nyserda.ny.gov/All-Programs/Empire-Building-Challenge/Building-Decarbonization-Insights*)
- New Buildings Institute. Buildings Database. (*https://newbuildings.org/resource/getting-to-zero-database/*).

V. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866 and 13563

Executive Order (''E.O.'') 12866, ''Regulatory Planning and Review,'' as supplemented and reaffirmed by E.O. 13563, ''Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 21, 2011), requires agencies, to the extent permitted by law, to (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or

marketable permits, or providing information upon which choices can be made by the public. DOE emphasizes as well that E.O. 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, OIRA has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. For the reasons stated in the preamble, this proposed regulatory action is consistent with these principles.

Section 6(a) of E.O. 12866 also requires agencies to submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (''OIRA'') for review. OIRA has determined that this proposed regulatory action constitutes a ''significant regulatory action'' under section 3(f) of E.O. 12866. Accordingly, pursuant to section 6(a)(3)(C) of E.O. 12866, DOE has provided to OIRA an assessment, including the underlying analysis, of benefits and costs anticipated from the proposed regulatory action, together with, to the extent feasible, a quantification of those costs; and an assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, and an explanation why the planned regulatory action is preferable to the identified potential alternatives. These assessments are summarized in the tables that follows, as well as elsewhere in this preamble. Further detail can be found in the technical support document for this proposed rulemaking.

DOE's analyses indicate that the proposed regulation would save a significant amount of site energy; however, switching from gas loads burned on-site to electric loads produced off-site, at national average level emission rates, would result in an increase of CO_2, N_2O, Hg, and SO_2 emissions with a decrease in NO_X and CH_4 emissions. Electrifying the end-use equipment results in emissions that become dependent upon the electricity generation mix delivered to the building. Relative to the case without the proposed amended standards, Clean Energy Rule compliant buildings constructed in the 30-year period that begins in the anticipated year of compliance with the proposed amended standards (2025–2034) will result in—an increased lifetime energy use of 0.029 quadrillion British thermal units (''Btu''), or quads.[44]

The cumulative net present value (''NPV'') of the proposed standards for Clean Energy Rule compliant buildings ranges from −$15.6 million (at a 7-percent discount rate) to −$85.3 Million (at a 3-percent discount rate). This NPV expresses the estimated total value of future operating-cost savings minus the estimated increased product costs for a Clean Energy Rule compliant building constructed in 2025–2054.

In addition, the proposed standards for Clean Energy Rule compliant buildings are projected to impact emissions of multiple greenhouse gases and other pollutants. DOE estimates that the proposed standards would result in cumulative emissions (over the same period as for energy savings) impacts of an increase of 0.2 million metric tons (''Mt'')[45] of carbon dioxide (''CO_2''), an increase of 1.0 thousand tons of sulfur dioxide (''SO_2''), a decrease of 1.9 thousand tons of nitrogen oxides (''NO_X''), a decrease of 10.4 thousand tons of methane (''CH_4''), an increase of 0.021 thousand tons of nitrous oxide (''N_2O''), and an increase of 0.01 tons of mercury (''Hg'').[46]

DOE estimates the monetized net climate benefits from a change in emissions of greenhouse gases using four different estimates of the social cost of CO_2 (''SC-CO_2''), the social cost of methane (''SC-CH_4''), and the social cost of nitrous oxide (''SC-N_2O''). Together these represent the social cost of greenhouse gases (''SC-GHG''). DOE used interim SC-GHG values developed by an Interagency Working Group on the Social Cost of Greenhouse Gases (''IWG'').[47] The derivation of these values is discussed in section IV. of this document. For presentational purposes, the net climate benefits (Including both the climate benefits and disbenefits) associated with the average SC-GHG at a 3-percent discount rate is $2.8 million, primarily driven by savings in CH_4. DOE does not have a single central SC-GHG point estimate and it emphasizes the importance and value of considering the benefits calculated using all four SC-GHG estimates.[48]

DOE also estimates health disbenefits from changes in SO_2 and NO_X emissions.[49] DOE estimates the present value of the health disbenefits would be $15.9 million using a 7-percent discount rate, and $33.9 million using a 3-percent discount rate which is driven by SO_2 emission increases outweighing NO_X emissions decreases.[50] DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health effects and (for NO_X) ozone precursor health benefits, but will continue to assess the ability to monetize other effects such as health effects from reductions in direct $PM_{2.5}$ emissions.

Table V.1 summarizes the economic benefits and costs expected to result from the proposed standards. In the table, total benefits for both the 3-percent and 7-percent discount rate cases include monetized climate benefits based on the average SC-GHG estimate under 3-percent discount rate (thus the climate benefits number stays the same). DOE does not have a single central SC-GHG point estimate and it emphasizes the importance and value of considering the benefits calculated using all four SC-GHG estimates. The estimated total net benefits using each of the four cases are presented in section IV of this document.

[44] The quantity refers to full-fuel-cycle (''FFC'') energy savings. FFC energy savings includes the energy consumed in extracting, processing, and transporting primary fuels (*i.e.,* coal, natural gas, petroleum fuels), and, thus, presents a more complete picture of the impacts of energy efficiency standards. For more information on the FFC metric, see section on emission within this document.

[45] A metric ton is equivalent to 1.1 short tons. Results for emissions other than CO_2 are presented in short tons.

[46] DOE calculated emissions changes relative to the no-new-standards case, which reflects key assumptions in the *Annual Energy Outlook [2022]* (''*AEO[2022*'']). *AEO2022* represents current federal and state legislation and final implementation of regulations as of the time of its preparation. See section IV.K of this document for further discussion of *AEO2022* assumptions that effect air pollutant emissions.

[47] See Interagency Working Group on Social Cost of Greenhouse Gases, *Technical Support Document: Social Cost of Carbon, Methane, and Nitrous Oxide. Interim Estimates Under Executive Order 13990,* Washington, DC, February 2021, *available at www.whitehouse.gov/wp-content/uploads/2021/02/TechnicalSupportDocument_SocialCostof CarbonMethaneNitrousOxide.pdf?source=email.*

[48] On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

[49] DOE estimated the monetized value of NO_X and SO_2 emissions changes associated with the Clean Energy Rule using benefit per ton estimates from the scientific literature. See section IV.L.2 of this document for further discussion.

[50] DOE estimates the economic value of these emissions changes resulting from the considered rule for the purpose of complying with the requirements of Executive Order 12866.

TABLE V.1—SUMMARY OF MONETIZED ECONOMIC BENEFITS AND COSTS

[Million 2021$] [2025–2054 plus 30-year lifetime]

	Million 2021$	
	3% Discount rate	7% Discount rate
Operating Cost Savings	−195.5	−89.5
Climate Benefits *	2.8	2.8
Health Benefits **	−33.9	−15.9
Total Benefits †	−226.7	−102.7
Incremental Product Costs ††	−139.4	−85.5
Net Benefits	−87.3	−17.3

Note: This table presents the costs and benefits associated with Federal new commercial and multi-family high-rise buildings built and operated in 2025–2084. These results include benefits which accrue after 2054 from the buildings constructed in 2025–2054. Climate benefits and disbenefits associated with GHG emissions changes occur over 2025–2070. DOE expects additional climate impacts to accrue from GHG emissions changes post 2070, but a lack of available SC-CO_2, SC-CH_4, and SC-N_2O estimates for emissions years beyond 2070 prevents DOE from monetizing these additional impacts in this analysis.

* Climate benefits are calculated using four different estimates of the social cost of carbon (SC-CO_2), methane (SC-CH_4), and nitrous oxide (SC-N_2O) (model average at 2.5 percent, 3 percent, and 5 percent discount rates; 95th percentile at 3 percent discount rate). Together these represent the social cost of greenhouse gases (SC-GHG). For presentational purposes of this table, the climate benefits associated with the average SC-GHG at a 3 percent discount rate are shown but the Department does not have a single central SC-GHG point estimate. See section IV.C of this document for more details. On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

** Health disbenefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. See section IV.C of this document for more details.

† Total and net benefits include those consumer, climate, and health benefits that can be quantified and monetized. For presentation purposes, total and net benefits for both the 3-percent and 7-percent cases are presented using the average SC-GHG with 3-percent discount rate, but the Department does not have a single central SC-GHG point estimate. DOE emphasizes the importance and value of considering the benefits calculated using all four SC-GHG estimates.

‡ Costs include incremental equipment costs as well as installation costs.

The benefits and costs of the proposed standards can also be expressed in terms of annualized values. The monetary values for the total annualized net benefits are (1) the reduced product purchase prices and installation costs, minus (2) the increase in operating costs, plus (3) the monetized value of changes in GHG, and NO_X, and SO_2 emissions, all annualized.[51] The benefits and disbenefits associated with changes in emissions as a result of the proposed standards are also calculated based on the lifetime of a Clean Energy Rule compliant building constructed in 2025–2054.

Estimates of annualized benefits and costs of the proposed standards are shown in. The results show as the primary estimate utilize a 7-percent discount rate for operating benefits, costs, and health benefits and disbenefits (from changes to NO_X and SO_2 emissions), and a 3-percent discount rate case for climate benefits (from GHG emissions) are as follows:

- Capital cost impacts of the standards proposed in this case are estimated to be $7.89 million per year in decreased equipment costs.
- Annual operating disbenefits are estimated to be $8.26 million per year in increased equipment operating costs, primarily driven by the higher relative cost of electricity compared to natural gas.
- Net climate benefits total $0.15 million per year, primarily driven by savings from CH_4.
- Net health disbenefits total $1.47 million per year, primarily driven by increased SO_2 emissions overshadowing NO_X emissions savings.
- Overall net monetized disbenefits would amount to a cost of $1.70 million per year.

Using a 3-percent discount rate for all benefits, disbenefits and costs the annualized results are as follows:

- Capital cost impacts of the standards proposed in this case are estimated to be $7.55 million per year in decreased equipment costs.
- Annual operating disbenefits are estimated to be $10.58 million per year in increased equipment operating costs, driven by the higher relative cost of electricity compared to natural gas.
- Net Climate benefits total $0.15 million per year, primarily driven by savings from CH_4.
- Net health disbenefits total $1.84 million per year, primarily driven by increased SO_2 emissions overshadowing NO_X emissions savings.
- Overall net monetized disbenefits would amount to a cost of $4.73 million per year.

[51] To convert the time-series of costs and benefits into annualized values, DOE calculated a present value in $2021, the year used for discounting the NPV of total costs and savings. For the benefits, DOE calculated a present value associated with each year's shipments in the year in which the shipments occur (*e.g.,* 2030), and then discounted the present value from each year to 2022. Using the present value, DOE then calculated the fixed annual payment over a 30-year period, starting in the compliance year, that yields the same present value.

TABLE V.2—ANNUALIZED MONETIZED BENEFITS AND COSTS OF PROPOSED REGULATION
[Million 2021$]

Category	Million 2021$/year	
	3% Discount rate	7% Discount rate
Operating Cost Impacts	−10.58	−8.26
Climate Benefits*	0.15	0.15
Health Benefits**	−1.84	−1.47
Total Benefits†	−12.27	−9.58
Incremental Product Costs††	−7.55	−7.89
Net Benefits	−4.73	−1.70

Note: This table presents the costs and benefits associated with the Clean Energy Rule impacted buildings in 2025–2084. These results include benefits which accrue after 2054 from the buildings constructed in 2025–2054.

*Climate benefits are calculated using four different estimates of the SC-GHG (see section IV.D of this document). For presentational purposes of this table, the climate benefits associated with the average SC-GHG at a 3 percent discount rate are shown, but the Department does not have a single central SC-GHG point estimate. On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and presents monetized benefits where appropriate and permissible under law.

**Health disbenefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions.

†Total benefits for both the 3-percent and 7-percent cases are presented using the average SC-GHG with 3-percent discount rate, but the Department does not have a single central SC-GHG point estimate. DOE emphasizes the importance and value of considering the benefits calculated using all four SC-GHG estimates.

††Costs include incremental equipment costs as well as installation costs.

DOE's analysis of the national impacts of the proposed standards is described in sections IV.A, and IV.B of this document.

Table V.3 presents DOE's evaluation of the economic impacts of the proposed regulations, as measured by the average life-cycle cost (''LCC'').[52] The average LCC savings are −$30.1 Million and there is no traditional PBP as the incremental capital cost of the proposed regulation is negative but the incremental operating cost is positive (see section IV of this document).

TABLE V.3—IMPACTS OF PROPOSED REGULATION

Clean energy rule compliant building policy	Average LCC savings (million 2021$)
3% Discount Rate	−56.13
7% Discount Rate	−4.077

DOE's analysis is sensitive to how emission factors per unit of grid electricity purchased change over time. The base case presented in this rulemaking utilizes emission factors obtained through EIA's Annual Energy Outlook for 2022 (AEO 2022). This is consistent with the methodology used in other rulemakings (including the efficiency portions for the analysis behind 10 CFR parts 433 and 435) and representative of an expected or ''business as usual'' case. However, AEO 2022 does not account for goals or plans to accelerate grid decarbonization, such as President Biden's goal to achieve 100% carbon pollution-free electricity by 2035. Such accelerated clean grid scenarios can significantly impact the overall emissions profile of the rule allowing for more climate benefits sooner in the lifecycle of the expected projects.

To demonstrate this proposed rulemaking's sensitivity to purchased electricity emission factor ''cleanliness'' projections, DOE analyzed an additional case where the future grid emission factors were assumed to follow a ''95% reduction by 2035'' (95 by 2035) profile as defined in the National Renewable Energy Lab's ''2021 Standard Scenarios Report: A U.S. Electricity Sector Outlook'' report presented in the technical support document for this rulemaking. This case represents a change in national electricity generation which assumes national power sector CO_2 emissions reach 95% below 2005 levels by 2035 and are eliminated on a net basis by 2050. This aggressive case results in only three years of annual increases in CO_2e gas emissions and results in cumulative savings of CO_2e emissions just after 5 years. Results for the 95 by 2035 case are presented in Table V.4 and Table V.5 of this document. Additional details on the sensitivity to emission factor progression and an additional case run based on the EIA Corporate Goal data are presented in the technical support document and environmental assessment supporting this rule. As noted previously, these alternative cases are presented to show the emissions and climate impacts of this rule in accelerated clean grid scenarios that may flow from recent legislation and Administration priorities, but that are

[52] The average LCC refer to buildings that are affected by a standard and are measured relative to the efficiency distribution in the no-new-standards case, which depicts the market in the compliance year in the absence of new or amended standards (see section E. Impacts of the Rule of this document). The simple PBP, which is designed to compare specific building performance levels, is measured relative to the baseline compliance case (see section V.A of this document).

not represented in the base case using AEO 2022 (the ''business as usual'' case).

TABLE V.4—SUMMARY OF MONETIZED ECONOMIC BENEFITS AND COSTS (MILLION 2021$) (2025–2054 PLUS 30-YEAR LIFETIME) FOR 95 BY 35 EMISSIONS REDUCTIONS CASE

	Million 2021$	
	3% Discount rate	7% Discount rate
Operating Cost Savings	−195.5	−89.5
Climate Benefits*	92.9	92.9
Health Benefits**	46.6	15.8
Total Benefits†	−56.0	19.2
Incremental Product Costs††	−139.4	−85.5
Net Benefits	83.4	104.6

Note: This table presents the costs and benefits associated with Federal new commercial and multi-family high-rise buildings built in 2025–2084. These results include benefits which accrue after 2054 from the buildings constructed in 2025–2054.

*Climate benefits are calculated using four different estimates of the social cost of carbon (SC-CO_2), methane (SC-CH_4), and nitrous oxide (SC-N_2O) (model average at 2.5 percent, 3 percent, and 5 percent discount rates; 95th percentile at 3 percent discount rate). Together these represent the social cost of greenhouse gases (SC-GHG). For presentational purposes of this table, the climate benefits associated with the average SC-GHG at a 3 percent discount rate are shown but the Department does not have a single central SC-GHG point estimate. See section IV.C of this document for more details. On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

**Health disbenefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions. See section IV.C of this document for more details.

†Total and net benefits include those consumer, climate, and health benefits that can be quantified and monetized. For presentation purposes, total and net benefits for both the 3-percent and 7-percent cases are presented using the average SC-GHG with 3-percent discount rate, but the Department does not have a single central SC-GHG point estimate. DOE emphasizes the importance and value of considering the benefits calculated using all four SC-GHG estimates.

††Costs include incremental equipment costs as well as installation costs.

TABLE V.5—ANNUALIZED MONETIZED BENEFITS AND COSTS OF PROPOSED REGULATION (MILLION 2021$) FOR 95 BY 35 EMISSIONS REDUCTIONS CASE

Category	Million 2021$/year	
	3% Discount rate	7% Discount rate
Operating Cost Impacts	−10.58	−8.26
Climate Benefits*	5.03	5.03
Health Benefits**	2.52	1.46
Total Benefits†	−3.03	−1.77
Incremental Product Costs††	−7.55	−7.89
Net Benefits	4.51	6.11

Note: This table presents the costs and benefits associated with Clean Energy Rule impacted buildings in 2025–2084. These results include benefits which accrue after 2054 from the buildings constructed in 2025–2054.

*Climate benefits are calculated using four different estimates of the SC-GHG (see section IV.D of this document). For presentational purposes of this table, the climate benefits associated with the average SC-GHG at a 3 percent discount rate are shown, but the Department does not have a single central SC-GHG point estimate. On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the Federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the Federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and presents monetized benefits where appropriate and permissible under law.

**Health disbenefits are calculated using benefit-per-ton values for NO_X and SO_2. DOE is currently only monetizing (for SO_2 and NO_X) $PM_{2.5}$ precursor health benefits and (for NO_X) ozone precursor health benefits but will continue to assess the ability to monetize other effects such as health benefits from reductions in direct $PM_{2.5}$ emissions.

†Total benefits for both the 3-percent and 7-percent cases are presented using the average SC-GHG with 3-percent discount rate, but the Department does not have a single central SC-GHG point estimate. DOE emphasizes the importance and value of considering the benefits calculated using all four SC-GHG estimates.

††Costs include incremental equipment costs as well as installation costs.

DOE's analysis of the impacts of the proposed regulation on federal agencies is described in section V.A, Cost Effectiveness, of this document.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (''IRFA'') for any rule that by law must be proposed for public comment, unless the agency certifies

that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by E.O. 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website (*www.energy.gov/gc/office-general-counsel*).

This proposed rule applies only to the fossil fuel-generated energy consumption of new Federal buildings and Federal buildings undergoing major renovation. As such, the only entities directly regulated by this rulemaking would be Federal agencies. DOE does not believe that there will be any impacts on small entities such as small businesses, small organizations, or small governmental jurisdictions.

On the basis of the foregoing, DOE certifies that this rule will not have a significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared a regulatory flexibility analysis for this rulemaking. DOE's certification and supporting statement of factual basis will be provided to the Chief Counsel for Advocacy of the Small Business Administration pursuant to 5 U.S.C. 605(b).

C. Review Under the Paperwork Reduction Act

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

D. Review Under the National Environmental Policy Act of 1969

DOE prepared a draft Environmental Assessment (EA) (DOE/EA–1778) entitled, ''Environmental Assessment for Final Rulemaking, 10 CFR parts 433 and 435, Fossil Fuel-Generated Energy Consumption Reduction for New Federal Buildings and Major Renovations of Federal Buildings,'' pursuant to the Council on Environmental Quality's (CEQ) Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act (NEPA) (40 CFR parts 1500–1508), NEPA, as amended (42 U.S.C. 4321 *et seq.*), and DOE's NEPA Implementing Procedures (10 CFR part 1021).

The draft EA addresses the possible environmental effects attributable to the implementation of this proposed rule. The rule, by its fundamental intent, will have a positive impact on the environment. The anticipated impacts of this proposed rulemaking are an overall decrease in CO_2 equivalent gases (despite modest increases in base CO_2 and N_2O emissions, CH_4 emission reductions result in net savings) with an additional decrease in NO_X emission and an increase in SO_2 emissions resulting from reduced fossil fuel-generated energy consumption in new Federal buildings and major renovations of Federal buildings but increased electric purchases from the grid.

To identify the potential environmental impacts that may result from implementing the proposed rule on Federal buildings, DOE compared the requirements of the proposed rule shifting all scope 1 stationary combustion on site fossil fuel usage to electric with the ''no-action alternative''.

Accordingly, DOE concludes in the draft EA that new Federal buildings designed and constructed to be compliant with the Clean Energy Rule will not have a significant environmental impact compared to Federal buildings designed and constructed to Standard 90.1–2019 because the site energy impacts are very sensitive to and offset by upstream emissions associated with electricity purchased from the grid. This change in energy usage translates to varied emissions impacts of carbon dioxide (''CO_2''), nitrogen oxides (''NO_X''), mercury (''Hg''), and methane (''CH_4'') over the 30-year period examined in the EA. As reported in the EA, Cumulative emission changes for 30 years of construction and operation for Federal buildings built during the analysis period (2025 through 2054) were estimated to be an increase of 174,730 metric tons of CO_2, an increase of 907.4 tons of SO_2, a decrease of 1,597.67 tons of NO_X, a decrease of 8,917.46 tons of CH_4, and an increase of 17.76 tons of N_2O.

E. Review Under Executive Order 13132

E.O. 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this proposed rule and has tentatively determined that it 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. Therefore, no further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

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

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (''UMRA'') requires each Federal agency to assess the effects of Federal regulatory actions on State,

local, and Tribal governments and the private sector. Public Law 104–4, section 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *www.energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf.*

This proposed rulemaking contains neither an intergovernmental mandate nor a mandate that may result in the expenditure of $100 million or more in any year by State, local and Tribal governments, in the aggregate, or by the private sector so these requirements under the UMRA do not apply.

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

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

I. Review Under Executive Order 12630

Pursuant to E.O. 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (Mar. 15, 1988), DOE has determined that this proposed rule would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

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

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for Federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). Pursuant to OMB Memorandum M–19–15, Improving Implementation of the Information Quality Act (April 24, 2019), DOE published updated guidelines which are available at *www.energy.gov/sites/prod/files/2019/12/f70/DOE%20Final%20Updated%20IQA%20Guidelines%20Dec%202019.pdf.* DOE has reviewed this SNOPR under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

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

This proposed rulemaking would not have a significant adverse effect on the supply, distribution, or use of energy. Moreover, as the rulemaking would result in increased building energy efficiency, it would not have a significant adverse effect on energy. For these reasons, the rulemaking is not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

L. Information Quality

On December 16, 2004, OMB, in consultation with the Office of Science and Technology Policy (''OSTP''), issued its Final Information Quality Bulletin for Peer Review (''the Bulletin''). 70 FR 2664 (Jan. 14, 2005). The Bulletin establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal Government, including influential scientific information related to agency regulatory actions. The purpose of the bulletin is to enhance the quality and credibility of the Government's scientific information. Under the Bulletin, EIA's CBECS and RECS are ''influential scientific information,'' which the Bulletin defines as ''scientific information that the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.'' 70 FR 2664, 2667 (January 14, 2005). The Academy recommendations have been peer reviewed pursuant to section II.2 of the Bulletin. Both surveys are peer reviewed internally within EIA and other DOE offices before they are published. In addition, both surveys are subject to public comment that EIA addresses before finalizing CBECS and RECS.

M. Description of Materials Incorporated by Reference

In this final rule, DOE incorporates by reference ANSI/ASHRAE/IES Standard 90.1–2019, Energy Standard for Buildings Except Low-Rise Residential Buildings, (I–P Edition), 2019. This standard provides minimum requirements for energy efficient designs for buildings except for low-rise residential buildings. Copies of this standard are available from ASHRAE, Inc., 180 Peachtree Corners, GA 30092, (404) 636–8400, *www.ashrae.org.* ASHRAE provides a free, online, read-only version of Standard 90.1–2019 available at *www.ashrae.org/technical-resources/standards-and-guidelines.* Users must scroll down to locate and click on Standard 90.1–2019 (IP).

The Director of the Federal Register previously approved ANSI/ASHRAE/IES 90.1–2004, 2007, 2010, and 2013, Energy Standard for Buildings Except Low-Rise Residential Buildings for incorporation by reference in 10 CFR part 433.

In this final rule, DOE incorporates by reference the ICC 2021 International Energy Conservation Code, (IECC), Redline Version, copyright 2021. This U.S. standard provides minimum requirements for energy-efficient

designs for low-rise residential buildings. Copies of this standard are available from the International Code Council, 4051 West Flossmoor Road, Country Club Hills, IL 60478, 1–888–422–7233, *www.iccsafe.org.*

The Director of the Federal Register previously approved ICC International Energy Conservation Code (IECC) 2005, 2009, and 2015 Editions, for incorporation by reference in 10 CFR part 435.

VI. Public Participation

A. Attendance at the Public Meeting

The time, date, and location of the public meeting are listed in the **DATES** and **ADDRESSES** sections at the beginning of this document. This meeting will be held via webinar. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants can be found at the following link: *https://doe.webex.com/weblink/register/ra441feed3edc105af1383fa6e41e1e39.* Participants are responsible for ensuring their systems are compatible with the webinar software.

Please note that foreign nationals attending the meeting are subject to advance security screening procedures which require advance notice prior to attendance at the public meeting. If a foreign national wishes to participate in the public meeting, please inform DOE of this fact as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email (*Regina.Washington@ee.doe.gov*) so that the necessary procedures can be completed.

B. Procedure for Submitting Prepared General Statements for Distribution

Any person who has plans to present a prepared general statement may request that copies of his or her statement be made available at the public meeting. Such persons may submit requests, along with an advance electronic copy of their statement in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format, to the appropriate address shown in the **ADDRESSES** section at the beginning of this document. The request and advance copy of statements must be received at least one week before the public meeting and are to be emailed. Please include a telephone number to enable DOE staff to make follow-up contact, if needed.

C. Conduct of the Public Meeting

DOE will designate a DOE official to preside at the public meeting and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA. (42 U.S.C. 6306) A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the public meeting. There shall not be discussion of proprietary information, costs or prices, market share, or other commercial matters regulated by U.S. anti-trust laws. After the public meeting, interested parties may submit further comments on the proceedings, as well as on any aspect of the rulemaking, until the end of the comment period.

The public meeting will be conducted in an informal, conference style. DOE will present a general overview of the topics addressed in this rulemaking, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this rulemaking. Each participant will be allowed to make a general statement (within time limits determined by DOE), before the discussion of specific topics. DOE will allow, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this rulemaking. The official conducting the public meeting will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the previous procedures that may be needed for the proper conduct of the public meeting.

A transcript of the public meeting will be included in the docket, which can be viewed as described in the *Docket* section at the beginning of this document and will be accessible on the DOE website. In addition, any person may buy a copy of the transcript from the transcribing reporter.

D. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule before or after the public meeting, but no later than the date provided in the **DATES** section at the beginning of this proposed rule. Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this document.

Submitting comments via *www.regulations.gov.* The *www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (''CBI'')). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email. Comments and documents submitted via email also will be posted to *www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying

documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. No telefacsimiles (''faxes'') will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, that are written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: one copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

VII. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this supplemental notice of proposed rulemaking.

List of Subjects

10 CFR Part 433

Buildings and facilities, Energy conservation, Engineers, Federal buildings and facilities, Fossil fuel reductions, Housing, Incorporation by reference, Multi-family residential buildings.

10 CFR Part 435

Buildings and facilities, Energy conservation, Engineers, Federal buildings and facilities, Fossil fuel reductions, Housing, Incorporation by reference.

Signing Authority

This document of the Department of Energy was signed on December 6, 2022, by Mary Sotos, Director of the Federal Energy Management Program, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on December 9, 2022.

Treena V. Garrett,

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

For the reasons set forth in the preamble, DOE proposes to amend parts 433 and 435 of chapter II of title 10 of the Code of Federal Regulations as set forth below:

PART 433—ENERGY EFFICIENCY STANDARDS FOR THE DESIGN AND CONSTRUCTION OF NEW FEDERAL COMMERCIAL AND MULTI–FAMILY HIGH–RISE RESIDENTIAL BUILDINGS

■ 1. The authority citation for part 433 continues to read as follows:

Authority: 42 U.S.C. 6831–6832, 6834–6835; 42 U.S.C. 7101 *et seq.*

■ 2. Amend § 433.1 by adding paragraph (b) to read as follows:

§ 433.1 Purpose and scope.

* * * * *

(b) This part also establishes a maximum allowable fossil fuel-generated energy consumption standard for new Federal buildings that are commercial or multi-family high-rise residential buildings and major renovations to Federal buildings that are commercial or multi-family high-rise residential buildings, for which design for construction began on or after [*Date one year after date of publication in the* ***Federal Register***].

* * * * *

■ 3. Amend § 433.2 by:

■ a. Adding in alphabetical order the definitions of ''Construction cost,'' ''Design for renovation'', ''EISA-subject building or project'', ''Federal building,'' ''Fiscal year (FY),'' ''Major renovation,'' ''Major renovation cost,'' ''Major renovation of all Scope 1 fossil fuel-using systems in a building,'' ''Major renovation of a Scope 1 fossil fuel-using building system or Scope 1 fossil fuel-using component,'' and ''Multi-family high-rise residential building,''.

■ b. Revising the definition of ''Proposed building''; and

■ c. Adding in alphabetical order the definition of ''Scope 1 fossil fuel-generated energy consumption'', ''Shift adjustment multiplier'' and ''Technical impracticability''.

The additions and revision read as follows:

§ 433.2 Definitions.

* * * * *

Construction cost means all costs associated with design and construction of a Federal building. It includes the cost of design, permitting, construction (materials and labor), and building commissioning. It does not include legal or administrative fees, or the cost of acquiring the land.

* * * * *

Design for renovation means the stage when the energy efficiency and sustainability details (such as insulation levels, HVAC systems, water-using systems, etc.) are either explicitly determined or implicitly included in a renovation project cost specification.

EISA-subject building or project means, for purposes of this rule, any new Federal building or renovation project that is subject to the cost thresholds and reporting requirements in Section 433 of EISA 2007 ((42 U.S.C. 6834(a)(3)(D)(i))). The cost threshold referenced in Section 433 of EISA is $2.5 million in 2007 dollars. GSA provides a table of annual updates to this cost threshold at *https://www.gsa.gov/real-estate/design-and-construction/annual-prospectus-thresholds.* GSA also provides a second cost threshold for renovations of leased buildings that is ½ of the cost threshold for renovation of Federally owned buildings.

* * * * *

Federal building as defined in 42 U.S.C. 6832 means any building to be constructed by, or for the use of, any Federal agency. Such term shall include buildings built for the purpose of being

leased by a Federal agency, and privatized military housing.

Fiscal year (FY) begins on October 1 of the year prior to the specified calendar year and ends on September 30 of the specified calendar year.

* * * * *

Major renovation means either major renovation of all Scope 1 fossil fuel-generated/consuming systems in a Federal building or major renovation of one or more Scope 1 fossil fuel-using building systems or components, as defined in this section.

Major renovation cost means:

(1) Preliminary planning, engineering, architectural, legal, fiscal, and economic investigations and studies, surveys, designs, plans, working drawings, specifications, procedures, and other similar actions necessary for the alteration of a public building; and (2) Repairing, remodeling, improving, or extending, or other changes in, a public building as per 40 U.S.C. 3301(a)(1).

Major renovation of all Scope 1 fossil fuel-using systems in a building means construction on an existing Federal building that is so extensive that it replaces all Scope 1 fossil fuel-using systems in the building. This term includes, but is not limited to, comprehensive replacement or restoration of most or all major systems, interior work (such as ceilings, partitions, doors, floor finishes, etc.), or building elements and features.

Major renovation of a Scope 1 fossil fuel-using building system or Scope 1 fossil fuel-using component means changes to a Federal building that provide significant opportunities for energy efficiency or reduction in fossil fuel-related energy consumption. This includes, but is not limited to, replacement of the HVAC system, hot water system, or cooking system, or other fossil fuel-using systems or components of the building that have a major impact on fossil fuel usage.

Multi-family high-rise residential building means a residential Federal building that contains 3 or more dwelling units and that is designed to be 4 or more stories above grade.

* * * * *

Proposed building means the design for construction of a new Federal commercial or multi-family high-rise residential building, proposed for construction, or a major renovation to a Federal commercial or multi-family high-rise residential building.

* * * * *

Scope 1 fossil fuel-generated energy consumption means, for purposes of this proposed rule, the on-site stationary combustion of fossil fuels that contribute to Scope 1 emissions for generation of electricity, heat, cooling, or steam as defined by ''Federal Greenhouse Gas Accounting and Reporting Guidance'' (Council on Environmental Quality, January 17, 2016), including but not limited to, combustion of fuels in stationary sources (*e.g.,* boilers, furnaces, turbines, and emergency generators). This term does not include mobile sources, fugitive emissions, or process emissions as defined by ''Federal Greenhouse Gas Accounting and Reporting Guidance'' (Council on Environmental Quality, January 17, 2016).

Shift adjustment multiplier means that agencies can apply a multiplication factor to their Maximum Allowable Fossil Fuel-Generated Energy Consumption by Building Category target based upon the weekly hours of active operation of the building. The weekly hours of operation to use as a basis for the shift adjustment multiplier lookup should be based upon the time in which in the building is actively occupied and operating per its intended use type and should include unoccupied hours or other times of limited use (such as night-time setback hours).

Technical impracticability means achieving the Scope 1 fossil fuel-generated energy consumption targets would (1) not be feasible from an engineering design or execution standpoint due to existing physical or site constraints that prohibit modification or addition of elements or spaces (2) significantly obstruct building operations and the functional needs of a building, specifically for industrial process loads, critical national security functions, mission critical information systems as defined in NIST SP 800–60 Vol. 2 Rev. 1, and research operations, or (3) significantly degrade energy resiliency and energy security of building operations as defined in 10 U.S.C. 101(e)(6) and 10 U.S.C. 101(e)(7) respectively. Upon determination that complying with the Clean Energy Rule is technically impracticable, the building is still required to reduce fossil fuel consumption to the maximum extent practicable. Technical impracticability may include technology availability and cost considerations but may not be based solely on cost considerations.

■ 4. Amend § 433.3 by revising paragraph (b)(5) to read as follows:

§ 433.3 Materials incorporated by reference.

* * * * *

(b) * * *

(5) ANSI/ASHRAE/IES 90.1–2019, (''ASHRAE 90.1–2019''), Energy Standard for Buildings Except Low-Rise Residential Buildings, I–P Edition, copyright 2019, IBR approved for §§ 433.2, 433.100, 433.101, 433.201 and appendix A to this subpart.

■ 5. Subpart B is added to part 433 to read as follows:

Subpart B—Reduction in Scope 1 Fossil Fuel-Generated Energy Consumption

Sec.

§ 433.200 Scope 1 Fossil fuel-generated energy consumption requirement.

(a) *New EISA-Subject buildings.* (1) New Federal buildings that are commercial or multi-family high-rise residential buildings, for which design for construction began on or after December 21, 2023, must be designed to meet the requirements of paragraph (c) of this section if the cost of the building is at least $2,500,000 (in 2007 dollars, adjusted for inflation). *See* GSA Annual Prospectus Thresholds at *www.gsa.gov/real-estate/design-construction/gsa-annual-prospectus-thresholds.*

(2) Reserved.

(b) *Major renovations of EISA-Subject buildings.* (1) Major renovations to Federal buildings that are commercial or multi-family high-rise residential buildings, for which design for construction began on or after December 21, 2023, must be designed to meet the requirements of paragraph (c) or (d) of this section, as applicable, if:

(i) The renovation is a major renovation to a public building as defined in 40 U.S.C. 3301 and for which transmittal of a prospectus to Congress is required under 40 U.S.C. 3307; or

(ii) The cost of the major renovation of a Federally owned building is at least $2,500,000 (in 2007 dollars, adjusted for inflation). The cost of a major renovation for a Federally leased building is at least $1,250,000 (in 2007 dollars). *See* GSA Annual Prospectus Thresholds at *www.gsa.gov/real-estate/design-construction/gsa-annual-prospectus-thresholds.*

(2) This subpart only applies to major renovations that meet the major renovation of all scope 1 fossil fuel-using systems in a Federal building or the major renovation of a scope 1 fossil fuel-using building system or scope 1

fossil fuel-using component definition in § 433.2.

(3) For leased buildings, this subpart applies to major renovations only if the building was originally built for the use of any Federal agency, including being leased by a Federal agency.

(4) This subpart applies only to the portions of the proposed building or proposed building systems that are being renovated and to the extent that the scope of the renovations permits compliance with the applicable requirements of this subpart. Unaltered portions of the proposed building or proposed building systems are not required to comply with this subpart.

(c) *Federal buildings that are of the type included in Appendix A of this subpart.*

(1) *New Construction and Major Renovations of all Scope 1 Fossil Fuel-Using Systems in EISA-Subject Buildings.*

(i) Design for construction began during fiscal year 2024 through fiscal year 2029. For new construction or major renovations of all Scope 1 fossil-fuel using systems in a Federal building for which design for construction or renovation, as applicable, began during fiscal year 2024 through 2029, the Scope 1 fossil fuel-generated energy consumption of the proposed building, based on the building design and calculated according to § 433.201(a), must not exceed the value identified in Tables A–1a to A–2a (if targets based on emissions are used) or Tables A–1b to A–2b (if targets based on kBtu of fossil fuel usage are used) of appendix A of this subpart for the associated building type, climate zone, and fiscal year in which design for construction began.

(A) Federal agencies may apply a shift adjustment multiplier to the values in Tables A–1a to A–2a or Tables A–1b to A–2b based on the following baseline hours of operation assumed in Tables A–1a to A–2a or Tables A–1b to A–2b.

(B) To calculate the shift adjustment multiplier, agencies shall estimate the number of shifts for their new building and multiply by the appropriate factor shown below in Table VII.1 of this section for their building type. The Scope 1 fossil fuel-generated energy consumption target for the building would be the value in either Tables A–1a to A–2a or Tables A–1b to A–2b multiplied by the multiplier calculated in the previous sentence.

TABLE VII.1—SHIFT ADJUSTMENT MULTIPLIER BY HOURS OF OPERATION AND BUILDING TYPE

Building activity/type	Weekly hours of operation		
	50 or less	51 to 167	168
Admin/professional office	1	1	1.4
Bank/other financial	1	1	1.4
Government office	1	1	1.4
Medical office (non-diagnostic)	1	1	1.4
Mixed-use office	1	1	1.4
Other office	1	1	1.4
Laboratory	1	1	1.4
Distribution/shipping center	0.7	1.4	2.1
Nonrefrigerated warehouse	0.7	1.4	2.1
Convenience store	1	1	1.4
Convenience store with gas	1	1	1.4
Grocery store/food market	1	1	1.4
Other food sales	1	1	1.4
Fire station/police station	0.8	0.8	1.1
Other public order and safety	0.8	0.8	1.1
Medical office (diagnostic)	1	1	1.5
Clinic/other outpatient health	1	1	1.5
Refrigerated warehouse	1	1	1
Religious worship	0.9	1.7	1.7
Entertainment/culture	0.8	1.5	1.5
Library	0.8	1.5	1.5
Recreation	0.8	1.5	1.5
Social/meeting	0.8	1.5	1.5
Other public assembly	0.8	1.5	1.5
College/university	0.8	1.3	1.3
Elementary/middle school	0.8	1.3	1.3
High school	0.8	1.3	1.3
Preschool/daycare	0.8	1.3	1.3
Other classroom education	0.8	1.3	1.3
Fast food	0.4	1.1	2.1
Restaurant/cafeteria	0.4	1.1	2.1
Other food service	0.4	1.1	2.1
Hospital/inpatient health	1	1	1
Nursing home/assisted living	1	1	1
Dormitory/fraternity/sorority	1	1	1
Hotel	1	1	1
Motel or inn	1	1	1
Other lodging	1	1	1
Vehicle dealership/showroom	0.8	1.2	1.8
Retail store	0.8	1.2	1.8
Other retail	0.8	1.2	1.8
Post office/postal center	0.7	1.5	1.5
Repair shop	0.7	1.5	1.5
Vehicle service/repair shop	0.7	1.5	1.5
Vehicle storage/maintenance	0.7	1.5	1.5
Other service	0.7	1.5	1.5

TABLE VII.1—SHIFT ADJUSTMENT MULTIPLIER BY HOURS OF OPERATION AND BUILDING TYPE—Continued

Building activity/type	Weekly hours of operation		
	50 or less	51 to 167	168
Strip shopping mall	1	1	1
Enclosed mall	1	1	1
Bar/Pub/Lounge	1	1	1.4
Courthouse/Probation Office	1	1	1.4

(ii) Design for construction began during or after fiscal year 2030. For new construction or major renovations of all fossil fuel-using systems in an EISA-Subject building for which design for construction or renovation, as applicable, began during or after fiscal year 2030, the Scope 1 fossil fuel-generated energy consumption of the proposed building, based on building design and calculated according to § 433.201(a), must be zero.

(2) *Major Renovations of a Federal Building System or Component within an EISA-Subject Building.* System level renovations shall follow the renovation requirements in section 4.2.1.3 of the applicable building baseline energy efficiency standards listed in § 433.100 substituting the ''design for construction'' with ''design for renovation'' for the relevant date and shall replace all equipment that is included in the renovation with all electric or non-fossil fuel using ENERGY STAR or Federal Energy Management Program (FEMP) designated products as defined in § 436.42. For component level renovations, Agencies shall replace all equipment that is part of the renovation with all electric or non-fossil fuel using ENERGY STAR or FEMP designated products as defined in § 436.42.

(3) *Mixed-use buildings.* (i) For Federal buildings subject to the requirements of paragraph (c)(1) of this section that combine two or more building types identified in Tables 1a to 2a or Tables 1b to 2b of appendix A of this subpart, the maximum allowable fossil fuel-generated energy consumption of the proposed building is equal to the averaged applicable building type values in Tables A–1a to A–2a or Tables A–1b to A–2b weighted by floor area of the two or more building types. The equation which follows shall be used for mixed use buildings.

Equation 1: Scope 1 Fossil fuel-generated energy consumption for a mixed-use building = the sum across all building uses of (the fraction of total floor building floor area for building use i times the allowable fossil fuel-generated energy consumption for building use i)

Equation 1 may be rewritten as:

Scope 1 Fossil Fuel-Generated Energy Consumption for a Mixed Use Building = $\Sigma^{n}_{i=1}$ *(Fraction of Total Building Floor Area for Building Use i times Allowable Scope 1 Fossil Fuel-Generated Energy Consumption for Building Use).*

(ii) For example, if a proposed building for which design for construction began in FY2026 that is to be built in climate zone 4a has a total of 200 square feet—100 square feet of which qualifies as College/University and 100 square feet of which qualifies as Laboratory—the maximum allowable Scope 1 fossil fuel-generated energy consumption is equal to:

[(100 sqft. × 3 kBtu/yr.-sqft.) + (100 sqft × 10 kBtu/yr.-sqft.)]/200 sqft. = 6.5 kBtu/yr.-sqft.

(d) *Federal buildings that are of the type not included in Appendix A of this subpart—*

(1) *Process load buildings.* For building types that are not included in any of the building types listed in Tables A–1a to A–2a or A–1b to A–2b of appendix A of this subpart, or for building types in these tables that contain significant process loads that are not likely to be found in the Commercial Buildings Energy Consumption Survey (CBECS) and qualify for exemption per § 433.202, Federal agencies must select the applicable building type, climate zone, and fiscal year in which design for construction began from Tables 1a to 2a or 1b to 2b of appendix A of this subpart that most closely corresponds to the proposed building without the process load. The estimated Scope 1 fossil fuel-generated energy consumption of the process load must be added to the maximum allowable Scope 1 fossil fuel-generated energy consumption of the applicable building type for the appropriate fiscal year and climate zone to calculate the maximum allowable Scope 1 fossil fuel-generated energy consumption for the building. The same estimated Scope 1 fossil fuel-generated energy consumption of the process load that is added to the maximum allowable Scope 1 fossil fuel-generated energy consumption of the applicable building must also be used in determining the Scope 1 fossil fuel-generated energy consumption of the proposed building.

(2) *Mixed-use buildings.* For buildings that combine two or more building types with process loads or, alternatively, that combine one or more building types with process loads with one or more building types in Tables A–1a to A–2a or A–1b to A–2b of appendix A of this subpart, the maximum allowable Scope 1 fossil fuel-generated energy consumption of the proposed building is equal to the averaged process load building values determined under paragraph (d)(1) of this section and the applicable building type values in Tables A–1a to A–2a or A–1b to A–2b of appendix A of this subpart, weighted by floor area.

§ 433.201 Scope 1 Fossil fuel-generated energy consumption determination.

(a) The fossil fuel − generated energy consumption of a proposed building is calculated as follows:

Equation 2: Fossil fuel-generated energy consumption = Direct Scope 1 Fossil Fuel-Generated Consumption of Proposed Building/Floor Area

Where:

Direct Scope 1 Fossil Fuel-Generated Energy Consumption of Proposed Building equals the total Scope 1 fossil fuel-generated energy consumption of the proposed building calculated in accordance with the Performance Rating Method in Appendix G of ASHRAE 90.1–2019 (incorporated by reference; see § 433.3) and measured in thousands of British thermal units per year (kBtu/yr), except that this term does not include fossil fuel consumption for emergency electricity generation. Agencies must include all on-site fossil fuel use or Scope 1 emissions associated with non-emergency generation from backup generators (such as those for peak shaving or peak shifting). Any energy generation or Scope 1 emissions associated with biomass fuels are excluded. Any emissions associated with natural gas for alternatively fueled vehicles (''AFVs'') (or any other alternative fuel defined at 42 U.S.C. 13211 that is provided at a Federal

building) is excluded. Buildings with manufacturing or industrial process loads should be accounted for in the analysis for the building's fossil fuel consumption and GHG emissions but are not subject to the phase down targets.

Floor Area is the area enclosed by the exterior walls of a building, both finished and unfinished, including indoor parking facilities, basements, hallways, lobbies, stairways, and elevator shafts.

§ 433.202 Petition for downward adjustment.

(a) *New Federal buildings and major renovations of all Scope 1 fossil fuel-using systems in an EISA-subject building.* (1) Upon petition by a Federal agency the Director of FEMP may adjust the applicable maximum allowable Scope 1 fossil fuel-generated energy consumption standard with respect to a specific building, upon written certification from the head of the agency designing the building, that the requested adjustment is the largest feasible reduction in Scope 1 fossil fuel energy consumption that can practicably be achieved in light of the specified functional needs for that building, as demonstrated by:

(i) A statement sealed by the design engineer that the proposed building was designed in accordance with the applicable energy efficiency requirement to the maximum extent practicable and that each fossil fuel consuming product included in the proposed building that is of a product category covered by the ENERGY STAR program or FEMP for designated products is an ENERGY STAR product or a product meeting the FEMP designation criteria, as applicable;

(ii) A description of the systems, technologies, and practices that were evaluated and unable to meet the required fossil fuel reduction including a justification of why achieving the Scope 1 fossil fuel-generated energy consumption targets would be technically impracticable: and

(iii) Any other information the agency determines would help explain its request;

(2) The head of the agency designing the building, must also include the following information in the petition:

(i) A general description of the building, including but not limited to location, use type, floor area, stories, expected number of occupants and occupant schedule, project type, project cost, and functional needs, mission critical activity, research, and national security operations as applicable;

(ii) The maximum allowable Scope 1 fossil fuel energy consumption for the building from § 433.200(c) or (d);

(iii) The estimated Scope 1 fossil fuel energy consumption of the proposed building;

(iv) A description of the proposed building's energy-related features, including but not limited to:

(A) HVAC system type and configuration;

(B) HVAC equipment sizes and efficiencies;

(C) Ventilation systems (including outdoor air volume, controls technique, heat recovery systems, and economizers, if applicable);

(D) Service water heating system configuration and equipment (including solar hot water, wastewater heat recovery, and controls for circulating hot water systems, if applicable);

(E) Estimated industrial process loads; and

(F) Any other on-site fossil fuel consuming equipment.

(3) Petitions for downward adjustment should be submitted to *ff-petition@ee.doe.gov,* or to: U.S. Department of Energy, FEMP, Director, Fossil Fuel Reduction Petitions, EE–5F, 1000 Independence Ave. SW, Washington, DC 20585–0121.

(4) The Director of FEMP will make a best effort to notify the requesting agency in writing whether the petition for downward adjustment to the numeric reduction requirement is approved or rejected, in 45 calendar days of submittal, provided that the petition is complete. If the Director rejects the petition or establishes a value other than that presented in the petition, the Director will forward its reasons for rejection to the petitioning agency.

(b) *Major renovations of a Scope 1 fossil fuel-using building system or Scope 1 fossil fuel-using component.* (1) Upon petition by a Federal agency, the Director of FEMP may adjust the applicable requirements for the Federal agency to reduce Scope 1 on-site fossil fuel-generated energy consumption standard with respect to a specific renovation, upon written certification from the head of the agency designing the renovation, that the requested adjustment is the largest feasible reduction in Scope 1 fossil fuel energy consumption that can practicably be achieved in light of the specified functional needs for that building, as demonstrated by:

(i) A statement Sealed by the design engineer that the proposed renovation incorporates commercially available systems and/or components that provide a level of energy efficiency that is life-cycle cost effective as defined in this part and reduces consumption of Scope 1 fossil fuel energy to the maximum extent practicable and that each fossil fuel consuming product included in the proposed building that is of a product category covered by the ENERGY STAR program or FEMP for designated products is an ENERGY STAR product or a product meeting the FEMP designation criteria, as applicable.

(ii) A description of the systems, technologies, and practices that were evaluated and unable to meet the required fossil fuel reduction including a justification of why achieving the Scope 1 fossil fuel-generated energy consumption targets would be technically impracticable: and

(iii) Any other information the agency determines would help explain its request.

(2) The head of the agency making the design decisions for the building, must also include the following information in the petition:

(i) A general description of the building, including but not limited to location, use type, floor area, stories, estimated number of occupants and occupant schedule, project type, project cost, and functional needs, mission critical activity, research, and national security operations, as applicable;

(ii) The maximum allowable Scope 1 fossil fuel energy consumption for the building from § 433.200(c) or (d);

(iii) The estimated Scope 1 fossil fuel energy consumption of the building;

(iv) A description of system(s) or component(s) that are being renovated, including but not limited to:

(A) HVAC system or component type and configuration;

(B) HVAC equipment sizes and efficiencies;

(C) Ventilation systems or components (including outdoor air volume, controls technique, heat recovery systems, and economizers, if applicable);

(D) Service water heating system or component configuration and equipment (including solar hot water, wastewater heat recovery, and controls for circulating hot water systems, if applicable);

(E) Estimated process loads; and

(F) Any other on-site fossil fuel consuming equipment.

(3) Petitions for downward adjustment should be submitted to *ff-petition@ee.doe.gov,* or to: U.S. Department of Energy, FEMP, Director, Fossil Fuel Reduction Petitions, EE–5F, 1000 Independence Ave. SW, Washington, DC 20585–0121.

(4) The Director will make a best effort to notify the requesting agency in writing whether the petition for downward adjustment to the numeric reduction requirement is approved or

rejected, in 45 calendar days of submittal for major renovations of a buildings system, and 20 calendar days for major renovations of a component, granted the petition is complete. If the Director rejects the petition, the Director will forward its reasons for rejection to the petitioning agency.

(c) *Exclusions.* The General Services Administration (GSA) may not submit petitions under paragraphs (a) and (b) of this section. Agencies that are tenants of GSA buildings for which the agency, not GSA, has significant design control may submit petitions in accordance with this section.

Appendix A to Subpart B of Part 433—Maximum Allowable Fossil Fuel-Generated Energy Consumption

(a) For purposes of the tables in this appendix, the climate zones for each county in the United States are those listed in Normative Appendix B Building Envelope Climate Criteria, Table B–1 U.S. Climate Zones, ASHRAE 90.1–2019 (incorporated by reference; see § 433.3).

(b) For purpose of appendix A, the following definitions apply:

Education means a category of buildings used for academic or technical classroom instruction, such as elementary, middle, or high schools, and classroom buildings on college or university campuses. Buildings on education campuses for which the main use is not as a classroom are included in the category relating to their use. For example, administration buildings are part of ''Office,'' dormitories are ''Lodging,'' and libraries are ''Public Assembly.''

Food sales means a category of buildings used for retail or wholesale of food. For example, grocery stores are ''Food Sales.''

Food service means a category of buildings used for preparation and sale of food and beverages for consumption. For example, restaurants are ''Food Service.''

Health care (Inpatient) means a category of buildings used as diagnostic and treatment facilities for inpatient care.

Health care (Outpatient) means a category of buildings used as diagnostic and treatment facilities for outpatient care. Medical offices are included here if they use any type of diagnostic medical equipment (if they do not, they are categorized as an office building).

Laboratory means a category of buildings equipped for scientific experimentation or research as well as other technical, analytical, and administrative activities.

Lodging means a category of buildings used to offer multiple accommodations for short-term or long-term residents, including skilled nursing and other residential care buildings.

Mercantile (Enclosed and Strip Malls) means a category of shopping malls comprised of multiple connected establishments.

Multi-Family High-Rise Residential Buildings means a category of residential buildings that contain 3 or more dwelling units and that is designed to be 4 or more stories above grade.

Office means a category of buildings used for general office space, professional office, or administrative offices. Medical offices are included here if they do not use any type of diagnostic medical equipment (if they do, they are categorized as an outpatient health care building).

Public assembly means a category of public or private buildings, or spaces therein, in which people gather for social or recreational activities.

Public order and safety means a category of buildings used for the preservation of law and order or public safety.

Religious worship means a category of buildings in which people gather for religious activities, (such as chapels, churches, mosques, synagogues, and temples).

Retail (Other Than Mall) means a category of buildings used for the sale and display of goods other than food.

Service means a category of buildings in which some type of service is provided, other than food service or retail sales of goods.

Warehouse and storage means a category of buildings used to store goods, manufactured products, merchandise, raw materials, or personal belongings (such as self-storage).

TABLE A–1a—FY2020–FY2024 MAXIMUM ALLOWABLE FOSSIL FUEL-GENERATED ENERGY CONSUMPTION BY BUILDING CATEGORY, BUILDING TYPE AND CLIMATE ZONE, COMMERCIAL BUILDINGS AND MULTI-FAMILY HIGH-RISE RESIDENTIAL BUILDINGS

[CO_2e/yr-sqft]

Building category	Climate zone:	0A	0B	1A	1B	2A	2B	3A	3B	3C	4A	4B	4C	5A	5B	5C	6A	6B	7	8
	Building type	Fossil fuel-generated energy use intensity (CO_2e/yr-sqft)																		
Education	College/university	0.21	0.22	0.23	0.28	0.35	0.33	0.47	0.42	0.47	0.61	0.59	0.60	0.76	0.72	0.64	0.89	0.89	1.04	1.39
Education	Elementary/middle school	0.33	0.34	0.36	0.44	0.54	0.51	0.73	0.65	0.73	0.95	0.92	0.94	1.19	1.13	1.01	1.38	1.39	1.63	2.17
Education	High school	0.02	0.02	0.06	0.17	0.34	0.29	0.62	0.50	0.62	0.96	0.90	0.94	1.33	1.22	1.04	1.62	1.63	1.99	2.82
Education	Other classroom education	0.13	0.13	0.14	0.16	0.20	0.19	0.27	0.25	0.27	0.36	0.35	0.35	0.45	0.42	0.38	0.52	0.52	0.61	0.82
Education	Preschool/daycare	0.30	0.31	0.33	0.40	0.49	0.46	0.66	0.59	0.66	0.87	0.83	0.85	1.08	1.02	0.92	1.26	1.26	1.48	1.97
Enclosed Mall	Enclosed mall	0.35	0.35	0.38	0.46	0.57	0.54	0.76	0.68	0.76	1.00	0.96	0.99	1.25	1.18	1.06	1.45	1.46	1.71	2.27
Food Sales	Convenience store	0.33	0.34	0.36	0.43	0.54	0.51	0.73	0.65	0.73	0.95	0.91	0.94	1.19	1.12	1.00	1.38	1.39	1.62	2.16
Food Sales	Convenience store with gas station	0.24	0.24	0.26	0.31	0.39	0.36	0.52	0.46	0.52	0.68	0.65	0.67	0.85	0.80	0.72	0.98	0.99	1.16	1.54
Food Sales	Grocery store/food market	0.35	0.36	0.38	0.46	0.58	0.54	0.77	0.69	0.78	1.01	0.97	1.00	1.27	1.20	1.07	1.47	1.48	1.73	2.30
Food Sales	Other food sales	1.09	1.11	1.18	1.43	1.78	1.68	2.38	2.13	2.39	3.12	3.00	3.08	3.91	3.69	3.30	4.54	4.56	5.33	7.11
Food Service	Fast food	2.06	2.09	2.23	2.70	3.37	3.16	4.50	4.02	4.51	5.90	5.67	5.82	7.39	6.97	6.24	8.56	8.60	10.06	13.41
Food Service	Other food service	0.27	0.27	0.29	0.35	0.44	0.41	0.59	0.52	0.59	0.77	0.74	0.76	0.96	0.91	0.81	1.11	1.12	1.31	1.74
Food Service	Restaurant/cafeteria	1.47	1.49	1.59	1.92	2.40	2.25	3.21	2.87	3.21	4.20	4.04	4.15	5.26	4.96	4.44	6.10	6.13	7.17	9.56
Inpatient Health Care	Hospital/inpatient health	1.06	1.08	1.13	1.31	1.56	1.48	1.99	1.81	2.00	2.53	2.44	2.50	3.10	2.93	2.66	3.54	3.56	4.12	5.40
Laboratory	Laboratory	0.79	0.80	0.85	1.03	1.28	1.21	1.72	1.53	1.72	2.25	2.16	2.22	2.82	2.66	2.38	3.26	3.28	3.83	5.11
Lodging	Dormitory/fraternity/sorority	0.51	0.51	0.55	0.66	0.83	0.78	1.10	0.99	1.11	1.45	1.39	1.43	1.81	1.71	1.53	2.10	2.11	2.47	3.29
Lodging	Hotel	0.46	0.47	0.50	0.60	0.75	0.71	1.00	0.90	1.01	1.32	1.26	1.30	1.65	1.55	1.39	1.91	1.92	2.24	2.99
Lodging	Motel or inn	0.60	0.61	0.65	0.78	0.98	0.92	1.31	1.17	1.31	1.71	1.65	1.69	2.14	2.02	1.81	2.49	2.50	2.92	3.90
Lodging	Other lodging	0.23	0.24	0.25	0.30	0.38	0.36	0.51	0.45	0.51	0.66	0.64	0.65	0.83	0.78	0.70	0.96	0.97	1.13	1.51
Nursing	Nursing home/assisted living	0.82	0.83	0.88	1.07	1.33	1.25	1.78	1.60	1.79	2.34	2.25	2.31	2.93	2.76	2.47	3.39	3.41	3.99	5.32
Office	Administra tive/professional office	0.30	0.31	0.33	0.39	0.49	0.46	0.66	0.59	0.66	0.86	0.83	0.85	1.08	1.02	0.91	1.25	1.26	1.47	1.96
Office	Bank/other financial	0.18	0.19	0.20	0.24	0.30	0.28	0.40	0.36	0.40	0.53	0.50	0.52	0.66	0.62	0.56	0.76	0.77	0.90	1.19
Office	Government office	0.31	0.31	0.33	0.40	0.50	0.47	0.67	0.60	0.67	0.88	0.84	0.87	1.10	1.04	0.93	1.27	1.28	1.50	2.00
Office	Medical office (non-diagnostic)	0.34	0.35	0.37	0.45	0.56	0.52	0.74	0.66	0.74	0.97	0.94	0.96	1.22	1.15	1.03	1.41	1.42	1.66	2.21
Office	Mixed-use office	0.26	0.27	0.28	0.34	0.43	0.40	0.58	0.51	0.58	0.75	0.72	0.74	0.94	0.89	0.80	1.10	1.10	1.29	1.72
Office	Other office	0.40	0.40	0.43	0.52	0.65	0.61	0.86	0.77	0.87	1.13	1.09	1.12	1.42	1.34	1.20	1.64	1.65	1.93	2.58
Outpatient Health Care	Clinic/other outpatient health	0.25	0.25	0.27	0.33	0.41	0.38	0.55	0.49	0.55	0.71	0.69	0.71	0.90	0.84	0.76	1.04	1.04	1.22	1.63
Outpatient Health Care	Medical office (diagnostic)	0.27	0.27	0.29	0.35	0.44	0.41	0.58	0.52	0.59	0.77	0.74	0.76	0.96	0.90	0.81	1.11	1.12	1.31	1.74
Public Assembly	Entertainment/culture	0.20	0.20	0.21	0.25	0.32	0.30	0.43	0.38	0.43	0.56	0.54	0.55	0.70	0.66	0.59	0.81	0.81	0.95	1.27
Public Assembly	Library	0.23	0.24	0.25	0.30	0.38	0.36	0.51	0.45	0.51	0.67	0.64	0.66	0.83	0.79	0.70	0.97	0.97	1.14	1.51
Public Assembly	Other public assembly	0.23	0.24	0.25	0.31	0.38	0.36	0.51	0.46	0.51	0.67	0.64	0.66	0.84	0.79	0.71	0.97	0.97	1.14	1.52
Public Assembly	Recreation	0.24	0.24	0.26	0.31	0.39	0.37	0.53	0.47	0.53	0.69	0.66	0.68	0.86	0.81	0.73	1.00	1.00	1.17	1.57
Public Assembly	Social/meeting	0.30	0.30	0.32	0.39	0.49	0.46	0.65	0.58	0.65	0.85	0.82	0.84	1.06	1.00	0.90	1.23	1.24	1.45	1.93
Public Order & Safety	Fire station/police station	0.54	0.55	0.58	0.70	0.88	0.83	1.17	1.05	1.18	1.54	1.48	1.52	1.93	1.82	1.63	2.23	2.25	2.62	3.50
Public Order & Safety	Other public order and safety	0.26	0.27	0.29	0.35	0.43	0.40	0.58	0.52	0.58	0.75	0.73	0.74	0.95	0.89	0.80	1.10	1.10	1.29	1.72
Religious Worship	Religious worship	0.24	0.24	0.26	0.31	0.39	0.37	0.52	0.47	0.52	0.68	0.66	0.67	0.85	0.81	0.72	0.99	1.00	1.16	1.55
Retail (except malls)	Other retail	0.40	0.40	0.43	0.52	0.65	0.61	0.86	0.77	0.86	1.13	1.09	1.12	1.42	1.34	1.20	1.64	1.65	1.93	2.57
Retail (except malls)	Retail store	0.01	0.01	0.04	0.11	0.22	0.18	0.40	0.32	0.40	0.62	0.58	0.61	0.85	0.79	0.67	1.04	1.05	1.28	1.81
Retail (except malls)	Vehicle dealership/showroom	0.56	0.57	0.60	0.73	0.91	0.86	1.22	1.09	1.22	1.60	1.54	1.58	2.00	1.89	1.69	2.32	2.33	2.72	3.63
Service	Other service	0.58	0.59	0.63	0.76	0.95	0.89	1.27	1.13	1.27	1.66	1.60	1.64	2.08	1.96	1.76	2.41	2.42	2.83	3.78
Service	Post office/postal center	0.24	0.25	0.26	0.32	0.40	0.37	0.53	0.47	0.53	0.69	0.67	0.69	0.87	0.82	0.73	1.01	1.01	1.19	1.58
Service	Repair shop	0.18	0.18	0.20	0.24	0.30	0.28	0.40	0.35	0.40	0.52	0.50	0.51	0.65	0.61	0.55	0.75	0.76	0.89	1.18
Service	Vehicle service/repair shop	0.37	0.37	0.39	0.48	0.60	0.56	0.80	0.71	0.80	1.04	1.00	1.03	1.31	1.23	1.10	1.51	1.52	1.78	2.37
Service	Vehicle storage/maintenance	0.29	0.30	0.31	0.38	0.47	0.45	0.63	0.57	0.64	0.83	0.80	0.82	1.04	0.98	0.88	1.21	1.21	1.42	1.89
Strip Shopping Mall	Strip shopping mall	0.35	0.35	0.38	0.45	0.57	0.53	0.76	0.68	0.76	0.99	0.96	0.98	1.25	1.17	1.05	1.44	1.45	1.70	2.26
Warehouse	Distribution/shipping center	0.20	0.20	0.21	0.26	0.32	0.31	0.43	0.39	0.44	0.57	0.55	0.56	0.71	0.67	0.60	0.83	0.83	0.97	1.29
Warehouse	Non-refrigerated warehouse	0.19	0.19	0.20	0.25	0.31	0.29	0.41	0.37	0.41	0.54	0.52	0.53	0.68	0.64	0.57	0.78	0.79	0.92	1.23
Warehouse	Refrigerated warehouse	0.03	0.04	0.04	0.05	0.06	0.05	0.08	0.07	0.08	0.10	0.10	0.10	0.12	0.12	0.11	0.14	0.15	0.17	0.23

TABLE A–1b—FY2020–FY2024 MAXIMUM ALLOWABLE FOSSIL FUEL-GENERATED ENERGY CONSUMPTION BY BUILDING CATEGORY, BUILDING TYPE AND CLIMATE ZONE, COMMERCIAL BUILDINGS AND MULTI-FAMILY HIGH-RISE RESIDENTIAL BUILDINGS

[Source kBtu/yr-sqft]

Building category	Climate zone:	0A	0B	1A	1B	2A	2B	3A	3B	3C	4A	4B	4C	5A	5B	5C	6A	6B	7	8
	Building type	Fossil fuel-generated energy use intensity (site kBtu/yr-sqft)																		
Education	College/university	2	2	2	3	3	3	4	4	4	6	5	5	7	7	6	8	8	9	13
Education	Elementary/middle school	3	3	3	4	5	5	7	6	7	9	8	9	11	10	9	13	13	15	20
Education	High school	0	0	1	2	3	3	6	5	6	9	8	9	12	11	9	15	15	18	26
Education	Other classroom education	1	1	1	1	2	2	2	2	2	3	3	3	4	4	3	5	5	6	7
Education	Preschool/daycare	3	3	3	4	4	4	6	5	6	8	8	8	10	9	8	11	11	13	18
Enclosed Mall	Enclosed mall	3	3	3	4	5	5	7	6	7	9	9	9	11	11	10	13	13	15	21
Food Sales	Convenience store	3	3	3	4	5	5	7	6	7	9	8	9	11	10	9	13	13	15	20
Food Sales	Convenience store with gas station	2	2	2	3	4	3	5	4	5	6	6	6	8	7	7	9	9	10	14
Food Sales	Grocery store/food market	3	3	3	4	5	5	7	6	7	9	9	9	12	11	10	13	13	16	21
Food Sales	Other food sales	10	10	11	13	16	15	22	19	22	28	27	28	36	33	30	41	41	48	64
Food Service	Fast food	19	19	20	24	31	29	41	37	41	54	51	53	67	63	57	78	78	91	122
Food Service	Other food service	2	2	3	3	4	4	5	5	5	7	7	7	9	8	7	10	10	12	16
Food Service	Restaurant/cafeteria	13	14	14	17	22	20	29	26	29	38	37	38	48	45	40	55	56	65	87
Inpatient Health Care	Hospital/inpatient health	10	10	10	12	14	13	18	16	18	23	22	23	28	27	24	32	32	37	49
Laboratory	Laboratory	7	7	8	9	12	11	16	14	16	20	20	20	26	24	22	30	30	35	46
Lodging	Dormitory/fraternity/sorority	5	5	5	6	7	7	10	9	10	13	13	13	16	16	14	19	19	22	30
Lodging	Hotel	4	4	5	5	7	6	9	8	9	12	11	12	15	14	13	17	17	20	27
Lodging	Motel or inn	5	6	6	7	9	8	12	11	12	16	15	15	19	18	16	23	23	27	35
Lodging	Other lodging	2	2	2	3	3	3	5	4	5	6	6	6	8	7	6	9	9	10	14
Nursing	Nursing home/assisted living	7	8	8	10	12	11	16	14	16	21	20	21	27	25	22	31	31	36	48
Office	Administrative/professional office	3	3	3	4	4	4	6	5	6	8	8	8	10	9	8	11	11	13	18
Office	Bank/other financial	2	2	2	2	3	3	4	3	4	5	5	5	6	6	5	7	7	8	11
Office	Government office	3	3	3	4	5	4	6	5	6	8	8	8	10	9	8	12	12	14	18
Office	Medical office (non-diagnostic)	3	3	3	4	5	5	7	6	7	9	8	9	11	10	9	13	13	15	20
Office	Mixed-use office	2	2	3	3	4	4	5	5	5	7	7	7	9	8	7	10	10	12	16
Office	Other office	4	4	4	5	6	6	8	7	8	10	10	10	13	12	11	15	15	18	23
Outpatient Health Care	Clinic/other outpatient health	2	2	2	3	4	3	5	4	5	6	6	6	8	8	7	9	9	11	15
Outpatient Health Care	Medical office (diagnostic)	2	2	3	3	4	4	5	5	5	7	7	7	9	8	7	10	10	12	16
Public Assembly	Entertainment/culture	2	2	2	2	3	3	4	3	4	5	5	5	6	6	5	7	7	9	11
Public Assembly	Library	2	2	2	3	3	3	5	4	5	6	6	6	8	7	6	9	9	10	14
Public Assembly	Other public assembly	2	2	2	3	3	3	5	4	5	6	6	6	8	7	6	9	9	10	14
Public Assembly	Recreation	2	2	2	3	4	3	5	4	5	6	6	6	8	7	7	9	9	11	14
Public Assembly	Social/meeting	3	3	3	4	4	4	6	5	6	8	7	8	10	9	8	11	11	13	18
Public Order & Safety	Fire station/police station	5	5	5	6	8	7	11	10	11	14	13	14	17	16	15	20	20	24	32
Public Order & Safety	Other public order and safety	2	2	3	3	4	4	5	5	5	7	7	7	9	8	7	10	10	12	16
Religious Worship	Religious worship	2	2	2	3	4	3	5	4	5	6	6	6	8	7	7	9	9	11	14
Retail (except malls)	Other retail	4	4	4	5	6	6	8	7	8	10	10	10	13	12	11	15	15	17	23
Retail (except malls)	Retail store	0	0	0	1	2	2	4	3	4	6	5	5	8	7	6	9	9	12	16
Retail (except malls)	Vehicle dealership/showroom	5	5	5	7	8	8	11	10	11	14	14	14	18	17	15	21	21	25	33
Service	Other service	5	5	6	7	9	8	12	10	12	15	14	15	19	18	16	22	22	26	34
Service	Post office/postal center	2	2	2	3	4	3	5	4	5	6	6	6	8	7	7	9	9	11	14
Service	Repair shop	2	2	2	2	3	3	4	3	4	5	5	5	6	6	5	7	7	8	11
Service	Vehicle service/repair shop	3	3	4	4	5	5	7	6	7	9	9	9	12	11	10	14	14	16	22
Service	Vehicle storage/maintenance	3	3	3	3	4	4	6	5	6	8	7	7	9	9	8	11	11	13	17
Strip Shopping Mall	Strip shopping mall	3	3	3	4	5	5	7	6	7	9	9	9	11	11	10	13	13	15	21
Warehouse	Distribution/shipping center	2	2	2	2	3	3	4	4	4	5	5	5	6	6	5	7	8	9	12
Warehouse	Non-refrigerated warehouse	2	2	2	2	3	3	4	3	4	5	5	5	6	6	5	7	7	8	11
Warehouse	Refrigerated warehouse	0	0	0	0	1	0	1	1	1	1	1	1	1	1	1	1	1	2	2

TABLE A–2a—FY2025–FY2029 MAXIMUM ALLOWABLE FOSSIL FUEL-GENERATED ENERGY CONSUMPTION BY BUILDING CATEGORY, BUILDING TYPE AND CLIMATE ZONE, COMMERCIAL BUILDINGS AND MULTI-FAMILY HIGH-RISE RESIDENTIAL BUILDINGS

[CO_2e/yr-sqft]

Building category	Climate zone:	0A	0B	1A	1B	2A	2B	3A	3B	3C	4A	4B	4C	5A	5B	5C	6A	6B	7	8
	Building Type	Fossil fuel-generated energy use intensity (CO_2e/yr-sqft)																		
Education	College/university	0.11	0.11	0.12	0.14	0.17	0.16	0.23	0.21	0.23	0.30	0.29	0.30	0.38	0.36	0.32	0.44	0.44	0.52	0.69
Education	Elementary/middle school	0.17	0.17	0.18	0.22	0.27	0.26	0.36	0.33	0.36	0.48	0.46	0.47	0.60	0.56	0.50	0.69	0.70	0.81	1.08
Education	High school	0.01	0.01	0.03	0.09	0.17	0.14	0.31	0.25	0.31	0.48	0.45	0.47	0.66	0.61	0.52	0.81	0.81	0.99	1.41
Education	Other classroom education	0.06	0.06	0.07	0.08	0.10	0.10	0.14	0.12	0.14	0.18	0.17	0.18	0.22	0.21	0.19	0.26	0.26	0.31	0.41
Education	Preschool/daycare	0.15	0.15	0.16	0.20	0.25	0.23	0.33	0.30	0.33	0.43	0.42	0.43	0.54	0.51	0.46	0.63	0.63	0.74	0.98
Enclosed Mall	Enclosed mall	0.17	0.18	0.19	0.23	0.29	0.27	0.38	0.34	0.38	0.50	0.48	0.49	0.63	0.59	0.53	0.73	0.73	0.85	1.14
Food Sales	Convenience store	0.17	0.17	0.18	0.22	0.27	0.25	0.36	0.32	0.36	0.48	0.46	0.47	0.60	0.56	0.50	0.69	0.69	0.81	1.08
Food Sales	Convenience store with gas station	0.12	0.12	0.13	0.15	0.19	0.18	0.26	0.23	0.26	0.34	0.33	0.33	0.42	0.40	0.36	0.49	0.49	0.58	0.77
Food Sales	Grocery store/food market	0.18	0.18	0.19	0.23	0.29	0.27	0.39	0.35	0.39	0.51	0.49	0.50	0.63	0.60	0.54	0.74	0.74	0.86	1.15
Food Sales	Other food sales	0.55	0.55	0.59	0.71	0.89	0.84	1.19	1.07	1.19	1.56	1.50	1.54	1.96	1.85	1.65	2.27	2.28	2.66	3.55
Food Service	Fast food	1.03	1.05	1.11	1.35	1.68	1.58	2.25	2.01	2.26	2.95	2.83	2.91	3.69	3.48	3.12	4.28	4.30	5.03	6.71
Food Service	Other food service	0.13	0.14	0.14	0.18	0.22	0.21	0.29	0.26	0.29	0.38	0.37	0.38	0.48	0.45	0.41	0.56	0.56	0.65	0.87
Food Service	Restaurant/cafeteria	0.74	0.75	0.79	0.96	1.20	1.13	1.60	1.43	1.61	2.10	2.02	2.07	2.63	2.48	2.22	3.05	3.06	3.58	4.78
Inpatient Health Care	Hospital/inpatient health	0.53	0.54	0.56	0.65	0.78	0.74	1.00	0.91	1.00	1.26	1.22	1.25	1.55	1.47	1.33	1.77	1.78	2.06	2.70
Laboratory	Laboratory	0.39	0.40	0.42	0.51	0.64	0.60	0.86	0.77	0.86	1.12	1.08	1.11	1.41	1.33	1.19	1.63	1.64	1.92	2.56
Lodging	Dormitory/fraternity/sorority	0.25	0.26	0.27	0.33	0.41	0.39	0.55	0.49	0.55	0.72	0.70	0.71	0.91	0.85	0.76	1.05	1.06	1.23	1.65
Lodging	Hotel	0.23	0.23	0.25	0.30	0.38	0.35	0.50	0.45	0.50	0.66	0.63	0.65	0.82	0.78	0.70	0.96	0.96	1.12	1.50
Lodging	Motel or inn	0.30	0.30	0.32	0.39	0.49	0.46	0.65	0.58	0.66	0.86	0.82	0.84	1.07	1.01	0.91	1.24	1.25	1.46	1.95
Lodging	Other lodging	0.12	0.12	0.13	0.15	0.19	0.18	0.25	0.23	0.25	0.33	0.32	0.33	0.42	0.39	0.35	0.48	0.48	0.57	0.75
Nursing	Nursing home/assisted living	0.41	0.42	0.44	0.53	0.67	0.63	0.89	0.80	0.89	1.17	1.12	1.15	1.46	1.38	1.24	1.70	1.71	1.99	2.66
Office	Administrative/professional office	0.15	0.15	0.16	0.20	0.25	0.23	0.33	0.29	0.33	0.43	0.41	0.43	0.54	0.51	0.46	0.63	0.63	0.74	0.98
Office	Bank/other financial	0.09	0.09	0.10	0.12	0.15	0.14	0.20	0.18	0.20	0.26	0.25	0.26	0.33	0.31	0.28	0.38	0.38	0.45	0.60
Office	Government office	0.15	0.16	0.17	0.20	0.25	0.24	0.33	0.30	0.34	0.44	0.42	0.43	0.55	0.52	0.46	0.64	0.64	0.75	1.00
Office	Medical office (non-diagnostic)	0.17	0.17	0.18	0.22	0.28	0.26	0.37	0.33	0.37	0.49	0.47	0.48	0.61	0.58	0.51	0.71	0.71	0.83	1.11
Office	Mixed-use office	0.13	0.13	0.14	0.17	0.22	0.20	0.29	0.26	0.29	0.38	0.36	0.37	0.47	0.45	0.40	0.55	0.55	0.64	0.86
Office	Other office	0.20	0.20	0.21	0.26	0.32	0.30	0.43	0.39	0.43	0.57	0.54	0.56	0.71	0.67	0.60	0.82	0.83	0.97	1.29
Outpatient Health Care	Clinic/other outpatient health	0.13	0.13	0.13	0.16	0.20	0.19	0.27	0.24	0.27	0.36	0.34	0.35	0.45	0.42	0.38	0.52	0.52	0.61	0.81
Outpatient Health Care	Medical office (diagnostic)	0.13	0.14	0.14	0.18	0.22	0.21	0.29	0.26	0.29	0.38	0.37	0.38	0.48	0.45	0.41	0.56	0.56	0.65	0.87
Public Assembly	Entertainment/culture	0.10	0.10	0.11	0.13	0.16	0.15	0.21	0.19	0.21	0.28	0.27	0.27	0.35	0.33	0.29	0.40	0.41	0.48	0.63
Public Assembly	Library	0.12	0.12	0.13	0.15	0.19	0.18	0.25	0.23	0.25	0.33	0.32	0.33	0.42	0.39	0.35	0.48	0.49	0.57	0.76
Public Assembly	Other public assembly	0.12	0.12	0.13	0.15	0.19	0.18	0.25	0.23	0.26	0.33	0.32	0.33	0.42	0.39	0.35	0.49	0.49	0.57	0.76
Public Assembly	Recreation	0.12	0.12	0.13	0.16	0.20	0.18	0.26	0.23	0.26	0.34	0.33	0.34	0.43	0.41	0.36	0.50	0.50	0.59	0.78
Public Assembly	Social/meeting	0.15	0.15	0.16	0.19	0.24	0.23	0.32	0.29	0.33	0.42	0.41	0.42	0.53	0.50	0.45	0.62	0.62	0.72	0.97
Public Order & Safety	Fire station/police station	0.27	0.27	0.29	0.35	0.44	0.41	0.59	0.53	0.59	0.77	0.74	0.76	0.96	0.91	0.81	1.12	1.12	1.31	1.75
Public Order & Safety	Other public order and safety	0.13	0.13	0.14	0.17	0.22	0.20	0.29	0.26	0.29	0.38	0.36	0.37	0.47	0.45	0.40	0.55	0.55	0.64	0.86
Religious Worship	Religious worship	0.12	0.12	0.13	0.16	0.19	0.18	0.26	0.23	0.26	0.34	0.33	0.34	0.43	0.40	0.36	0.50	0.50	0.58	0.78
Retail (except malls)	Other retail	0.20	0.20	0.21	0.26	0.32	0.30	0.43	0.39	0.43	0.57	0.54	0.56	0.71	0.67	0.60	0.82	0.82	0.96	1.29
Retail (except malls)	Retail store	0.01	0.01	0.02	0.06	0.11	0.09	0.20	0.16	0.20	0.31	0.29	0.30	0.43	0.39	0.34	0.52	0.52	0.64	0.90
Retail (except malls)	Vehicle dealership/showroom	0.28	0.28	0.30	0.37	0.46	0.43	0.61	0.55	0.61	0.80	0.77	0.79	1.00	0.94	0.84	1.16	1.17	1.36	1.82
Service	Other service	0.29	0.29	0.31	0.38	0.47	0.45	0.63	0.57	0.64	0.83	0.80	0.82	1.04	0.98	0.88	1.21	1.21	1.42	1.89
Service	Post office/postal center	0.12	0.12	0.13	0.16	0.20	0.19	0.27	0.24	0.27	0.35	0.33	0.34	0.44	0.41	0.37	0.50	0.51	0.59	0.79
Service	Repair shop	0.09	0.09	0.10	0.12	0.15	0.14	0.20	0.18	0.20	0.26	0.25	0.26	0.33	0.31	0.27	0.38	0.38	0.44	0.59
Service	Vehicle service/repair shop	0.18	0.19	0.20	0.24	0.30	0.28	0.40	0.36	0.40	0.52	0.50	0.51	0.65	0.62	0.55	0.76	0.76	0.89	1.19
Service	Vehicle storage/maintenance	0.15	0.15	0.16	0.19	0.24	0.22	0.32	0.28	0.32	0.42	0.40	0.41	0.52	0.49	0.44	0.60	0.61	0.71	0.95
Strip Shopping Mall	Strip shopping mall	0.17	0.18	0.19	0.23	0.28	0.27	0.38	0.34	0.38	0.50	0.48	0.49	0.62	0.59	0.53	0.72	0.73	0.85	1.13
Warehouse	Distribution/shipping center	0.10	0.10	0.11	0.13	0.16	0.15	0.22	0.19	0.22	0.28	0.27	0.28	0.36	0.34	0.30	0.41	0.41	0.49	0.65
Warehouse	Non-refrigerated warehouse	0.09	0.10	0.10	0.12	0.15	0.14	0.21	0.18	0.21	0.27	0.26	0.27	0.34	0.32	0.29	0.39	0.39	0.46	0.61
Warehouse	Refrigerated warehouse	0.02	0.02	0.02	0.02	0.03	0.03	0.04	0.03	0.04	0.05	0.05	0.05	0.06	0.06	0.05	0.07	0.07	0.08	0.11

TABLE A–2b—FY2025–FY2029 MAXIMUM ALLOWABLE FOSSIL FUEL-GENERATED ENERGY CONSUMPTION BY BUILDING CATEGORY, BUILDING TYPE AND CLIMATE ZONE, COMMERCIAL BUILDINGS AND MULTI-FAMILY HIGH-RISE RESIDENTIAL BUILDINGS

[Site kBtu/yr-sqft]

Building category	Climate zone:	0A	0B	1A	1B	2A	2B	3A	3B	3C	4A	4B	4C	5A	5B	5C	6A	6B	7	8
	Building Type	Fossil fuel-generated energy use intensity (site kBtu/yr-sqft)																		
Education	College/university	1	1	1	1	2	1	2	2	2	3	3	3	3	3	3	4	4	5	6
Education	Elementary/middle school	2	2	2	2	2	2	3	3	3	4	4	4	5	5	5	6	6	7	10
Education	High school	0	0	0	1	2	1	3	2	3	4	4	4	6	6	5	7	7	9	13
Education	Other classroom education	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	3	4
Education	Preschool/daycare	1	1	1	2	2	2	3	3	3	4	4	4	5	5	4	6	6	7	9
Enclosed Mall	Enclosed mall	2	2	2	2	3	2	3	3	3	5	4	4	6	5	5	7	7	8	10
Food Sales	Convenience store	2	2	2	2	2	2	3	3	3	4	4	4	5	5	5	6	6	7	10
Food Sales	Convenience store with gas station	1	1	1	1	2	2	2	2	2	3	3	3	4	4	3	4	4	5	7
Food Sales	Grocery store/food market	2	2	2	2	3	2	4	3	4	5	4	5	6	5	5	7	7	8	10
Food Sales	Other food sales	5	5	5	6	8	8	11	10	11	14	14	14	18	17	15	21	21	24	32
Food Service	Fast food	9	9	10	12	15	14	20	18	20	27	26	26	34	32	28	39	39	46	61
Food Service	Other food service	1	1	1	2	2	2	3	2	3	3	3	3	4	4	4	5	5	6	8
Food Service	Restaurant/cafeteria	7	7	7	9	11	10	15	13	15	19	18	19	24	23	20	28	28	33	43
Inpatient Health Care	Hospital/inpatient health	5	5	5	6	7	7	9	8	9	11	11	11	14	13	12	16	16	19	24
Laboratory	Laboratory	4	4	4	5	6	5	8	7	8	10	10	10	13	12	11	15	15	17	23
Lodging	Dormitory/fraternity/sorority	2	2	2	3	4	4	5	4	5	7	6	6	8	8	7	10	10	11	15
Lodging	Hotel	2	2	2	3	3	3	5	4	5	6	6	6	7	7	6	9	9	10	14
Lodging	Motel or inn	3	3	3	4	4	4	6	5	6	8	7	8	10	9	8	11	11	13	18
Lodging	Other lodging	1	1	1	1	2	2	2	2	2	3	3	3	4	4	3	4	4	5	7
Nursing	Nursing home/assisted living	4	4	4	5	6	6	8	7	8	11	10	10	13	13	11	15	15	18	24
Office	Administrative/professional office	1	1	1	2	2	2	3	3	3	4	4	4	5	5	4	6	6	7	9
Office	Bank/other financial	1	1	1	1	1	1	2	2	2	2	2	2	3	3	3	3	3	4	5
Office	Government office	1	1	2	2	2	2	3	3	3	4	4	4	5	5	4	6	6	7	9
Office	Medical office (non-diagnostic)	2	2	2	2	3	2	3	3	3	4	4	4	6	5	5	6	6	8	10
Office	Mixed-use office	1	1	1	2	2	2	3	2	3	3	3	3	4	4	4	5	5	6	8
Office	Other office	2	2	2	2	3	3	4	4	4	5	5	5	6	6	5	7	7	9	12
Outpatient Health Care	Clinic/other outpatient health	1	1	1	1	2	2	2	2	2	3	3	3	4	4	3	5	5	6	7
Outpatient Health Care	Medical office (diagnostic)	1	1	1	2	2	2	3	2	3	3	3	3	4	4	4	5	5	6	8
Public Assembly	Entertainment/culture	1	1	1	1	1	1	2	2	2	3	2	2	3	3	3	4	4	4	6
Public Assembly	Library	1	1	1	1	2	2	2	2	2	3	3	3	4	4	3	4	4	5	7
Public Assembly	Other public assembly	1	1	1	1	2	2	2	2	2	3	3	3	4	4	3	4	4	5	7
Public Assembly	Recreation	1	1	1	1	2	2	2	2	2	3	3	3	4	4	3	5	5	5	7
Public Assembly	Social/meeting	1	1	1	2	2	2	3	3	3	4	4	4	5	5	4	6	6	7	9
Public Order & Safety	Fire station/police station	2	2	3	3	4	4	5	5	5	7	7	7	9	8	7	10	10	12	16
Public Order & Safety	Other public order and safety	1	1	1	2	2	2	3	2	3	3	3	3	4	4	4	5	5	6	8
Religious Worship	Religious worship	1	1	1	1	2	2	2	2	2	3	3	3	4	4	3	4	5	5	7
Retail (except malls)	Other retail	2	2	2	2	3	3	4	3	4	5	5	5	6	6	5	7	7	9	12
Retail (except malls)	Retail store	0	0	0	1	1	1	2	1	2	3	3	3	4	4	3	5	5	6	8
Retail (except malls)	Vehicle dealership/showroom	3	3	3	3	4	4	6	5	6	7	7	7	9	9	8	11	11	12	16
Service	Other service	3	3	3	3	4	4	6	5	6	8	7	7	9	9	8	11	11	13	17
Service	Post office/postal center	1	1	1	1	2	2	2	2	2	3	3	3	4	4	3	5	5	5	7
Service	Repair shop	1	1	1	1	1	1	2	2	2	2	2	2	3	3	2	3	3	4	5
Service	Vehicle service/repair shop	2	2	2	2	3	3	4	3	4	5	5	5	6	6	5	7	7	8	11
Service	Vehicle storage/maintenance	1	1	1	2	2	2	3	3	3	4	4	4	5	4	4	5	6	6	9
Strip Shopping Mall	Strip shopping mall	2	2	2	2	3	2	3	3	3	5	4	4	6	5	5	7	7	8	10
Warehouse	Distribution/shipping center	1	1	1	1	1	1	2	2	2	3	2	3	3	3	3	4	4	4	6
Warehouse	Non-refrigerated warehouse	1	1	1	1	1	1	2	2	2	2	2	2	3	3	3	4	4	4	6
Warehouse	Refrigerated warehouse	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	1	1	1	1

PART 435—ENERGY EFFICIENCY STANDARDS FOR THE DESIGN AND CONSTRUCTION OF NEW FEDERAL LOW–RISE RESIDENTIAL BUILDINGS

■ 6. The authority citation for part 435 continues to read as follows:

Authority: 42 U.S.C. 6831–6832; 6834–6836; 42 U.S.C. 8253–54; 42 U.S.C. 7101 *et seq.*

■ 7. Amend § 435.1, by adding paragraph (b) to read as follows:

§ 435.1 Purpose and scope.

* * * * *

(b) This part also establishes a maximum allowable fossil fuel-generated energy consumption standard for new Federal buildings that are low-rise residential buildings and major renovations to Federal buildings that are low-rise residential buildings, for which design for construction began on or after December 21, 2023.

* * * * *

■ 8. Amend § 435.2 by:

■ a. Adding in alphabetical order, the definitions of ''Construction cost,'' ''Design for renovation'', ''EISA-subject building or project'', ''Federal building,'' ''Fiscal year (FY),'' ''Major renovation,'' ''Major renovation cost,'' ''Major renovation of all Scope fossil fuel-using systems in a building,'' and ''Major renovation of a Scope 1 fossil fuel-using building system or Scope 1 fossil fuel-using component'';

■ b. Revising the definitions of ''Proposed building''; and

■ c. Adding in alphabetical order, the definitions of ''Scope 1 fossil fuel-generated energy consumption'' and ''Shift adjustment multiplier'' and ''Technical impracticability''.

The additions and revision read as follows:

§ 435.2 Definitions.

* * * * *

Construction cost means all costs associated with design and construction of a Federal building. It includes the cost of design, permitting, construction (materials and labor), and building commissioning. It does not include legal or administrative fees, or the cost of acquiring the land.

* * * * *

Design for renovation means the stage when the energy efficiency and sustainability details (such as insulation levels, HVAC systems, water-using systems, etc.) are either explicitly determined or implicitly included in a renovation project cost specification.

* * * * *

EISA-subject building or project means, for purposes of this rule, any new building or renovation project that is subject to the cost thresholds and reporting requirements in Section 433 of EISA 2007 ((42 U.S.C. 6834(a)(3)(D)(i))). The cost threshold referenced in Section 433 of EISA is $2.5 million in 2007 dollars. GSA provides a table of annual updates to this cost threshold at *https://www.gsa.gov/real-estate/design-and-construction/annual-prospectus-thresholds.* GSA also provides a second cost threshold for renovations of leased buildings that is ½ of the cost threshold for renovation of Federally owned buildings.

* * * * *

Federal building as defined in 42 U.S.C. 6832 means any building to be constructed by, or for the use of, any Federal agency. Such term shall include buildings built for the purpose of being leased by a Federal agency, and privatized military housing.

Fiscal Year (FY) begins on October 1 of the year prior to the specified calendar year and ends on September 30 of the specified calendar year.

* * * * *

Major renovation means either major renovation of all Scope 1 fossil fuel-generated/consuming systems in a building or major renovation of one or more Scope 1 fossil fuel-using building systems or components, as defined in this section.

Major renovation cost means:

(1) Preliminary planning, engineering, architectural, legal, fiscal, and economic investigations and studies, surveys, designs, plans, working drawings, specifications, procedures, and other similar actions necessary for the alteration of a public building; and (2) Repairing, remodeling, improving, or extending, or other changes in, a public building as per 40 U.S.C. 3301(a)(1).

Major renovation of all Scope 1 fossil fuel-using systems in a building means construction on an existing building that is so extensive that it replaces all Scope 1 fossil fuel-using systems in the building. This term includes, but is not limited to, comprehensive replacement or restoration of most or all major systems, interior work (such as ceilings, partitions, doors, floor finishes, etc.), or building elements and features.

Major renovation of a Scope 1 fossil fuel-using building system or Scope 1 fossil fuel-using component means changes to a building that provide significant opportunities for energy efficiency or reduction in fossil fuel-related energy consumption. This includes, but is not limited to, replacement of the HVAC system, hot water system, or cooking system, or other fossil fuel-using systems or components of the building that have a major impact on fossil fuel usage.

* * * * *

Proposed building means the design for construction of a new Federal low-rise residential building, or major renovation to a Federal low-rise residential building, proposed for construction.

Scope 1 fossil fuel-generated energy consumption means, for purposes of this rule, the on-site stationary combustion of fossil fuels that contribute to Scope 1 emissions for generation of electricity, heat, cooling, or steam as defined by ''Federal Greenhouse Gas Accounting and Reporting Guidance'' (Council on Environmental Quality, January 17, 2016). Emissions that result from combustion of fuels in stationary sources (*e.g.,* boilers, furnaces, turbines, and emergency generators). This term does not include mobile sources, fugitive emissions, or process emissions as defined by ''Federal Greenhouse Gas Accounting and Reporting Guidance'' (Council on Environmental Quality, January 17, 2016).

Shift adjustment multiplier means that agencies can apply a multiplication factor to their Maximum Allowable Fossil Fuel-Generated Energy Consumption by Building Category target based upon the weekly hours of active operation of the building. The weekly hours of operation to use as a basis for the shift adjustment multiplier lookup should be based upon the time in which in the building is actively occupied and operating per its intended use type and should include unoccupied hours or other times of limited use (such as night-time setback hours).

Technical impracticability means achieving the Scope 1 fossil fuel-generated energy consumption targets would—

(1) Not be feasible from an engineering design or execution standpoint due to existing physical or site constraints that prohibit modification or addition of elements or spaces,

(2) Significantly obstruct building operations and the functional needs of a building, specifically for industrial process loads, critical national security functions, mission critical information systems as defined in NIST SP 800–60 Vol. 2 Rev. 1, and research operations, or

(3) Significantly degrade energy resiliency and energy security of building operations as defined in 10 U.S.C. 101(e)(6) and 10 U.S.C. 101(e)(7) respectively. Upon determination that

complying with the Clean Energy Rule is technically impracticable, the building is still required to reduce fossil fuel consumption to the maximum extent practicable. Technical impracticability may include technology availability and cost considerations but may not be based solely on cost considerations.

■ 9. Amend § 435.3 by revising paragraph (b)(4) to read as follows:

§ 435.3 Materials incorporated by reference.

* * * * *

(b) * * *

(4) ICC 2021 International Energy Conservation Code (IECC), Redline Version, Copyright 2021, (''IECC 2021''), IBR approved for §§ 435.2, 435.5, 435.201, and appendix A to this subpart.

■ 10. Section 435.4 is revised to read as follows:

§ 435.4 Life-cycle cost-effective.

Except as specified in subparts A, B or C of this part, Federal agencies shall determine life-cycle cost-effectiveness by using the procedures set out in subpart A of 10 CFR part 436. A Federal agency may choose to use any of four methods, including life-cycle cost, net savings, savings-to-investment ratio, and adjusted internal rate of return using the discount rate published in the annual supplement to the Life Cycle Costing Manual for the FEMP (NIST 85–3273).

■ 11. Subpart B is added to part 435 to read as follows:

Subpart B—Reduction in Scope 1 Fossil Fuel-Generated Energy Consumption

Sec.

§ 435.200 Scope 1 Fossil fuel-generated energy consumption requirement.

(a) *New EISA-Subject buildings.* (1) New Federal buildings that are low-rise residential buildings, for which design for construction began on or after [Date one year after date of publication in the **Federal Register**], must be designed to meet the requirements of paragraph (c) of this section if the cost of the building is at least $2,500,000 (in 2007 dollars, adjusted for inflation). *See* GSA Annual Prospectus Thresholds at *www.gsa.gov/real-estate/design-construction/gsa-annual-prospectus-thresholds.*

(b) *Major renovations of EISA-Subject buildings.* (1) Major renovations to Federal buildings that are low-rise residential buildings, for which design for construction began on or after [*Date one year after date of publication in the* ***Federal Register***], must be designed to meet the requirements of paragraph (c) of this section if the cost of the major renovation is at least $2,500,000 (in 2007 dollars, adjusted for inflation).

(2) This subpart applies only to the portions of the proposed building or proposed building systems that are being renovated and to the extent that the scope of the renovation permits compliance with the applicable requirements in this subpart. Unaltered portions of the proposed building or proposed building systems are not required to comply with this subpart.

(3) For leased buildings, this subpart applies to major renovations only if the proposed building was originally built for the use of any Federal agency, including being leased by a Federal agency.

(c) *Federal buildings that are of the type included in Appendix A of this subpart*—(1) New Construction and Major Renovations of all Scope 1 Fossil Fuel-Using Systems in an EISA-Subject Building.

(i) Design for construction began during fiscal year 2024 through fiscal year 2029. For new construction or major renovations of all fossil fuel-using systems in an EISA-subject building, for which design for construction or renovation, as applicable, began during fiscal year 2024 through 2029, the Scope 1 fossil fuel-generated energy consumption of the proposed building, based on the building design and calculated according to § 435.201(a), must not exceed the value identified in Tables A–1a to A–2a (if targets based on Scope 1 emissions are used) or Tables A–1b to A–2b (if targets based on kBtu of fossil fuel usage are used) of Appendix A of this subpart for the associated building type, climate zone, and fiscal year in which design for construction began.

(A) Federal agencies may apply a shift adjustment multiplier to the values in Tables A–1a to A–2a or Tables A–1b to A–2b based on the following baseline hours of operation assumed in Tables A–1a to A–2a or Tables A–1b to A–2b.

(B) To calculate the shift adjustment multiplier, agencies shall estimate the number of shifts for their new building and multiply by the appropriate factor shown below in Table 1 for their building type. The Scope 1 fossil fuel-generated energy consumption target for the building would be the value in either Tables A–1a to A–2a or Tables A–1b to A–2b multiplied by the multiplier calculated in the previous sentence.

TABLE VII.2—SHIFT ADJUSTMENT MULTIPLIER BY HOURS OF OPERATION AND BUILDING TYPE

Building activity/type	Weekly hours of operation		
	50 or less	51 to 167	168
Admin/professional office	1	1	1.4
Bank/other financial	1	1	1.4
Government office	1	1	1.4
Medical office (non-diagnostic)	1	1	1.4
Mixed-use office	1	1	1.4
Other office	1	1	1.4
Laboratory	1	1	1.4
Distribution/shipping center	0.7	1.4	2.1
Nonrefrigerated warehouse	0.7	1.4	2.1
Convenience store	1	1	1.4
Convenience store with gas	1	1	1.4
Grocery store/food market	1	1	1.4
Other food sales	1	1	1.4
Fire station/police station	0.8	0.8	1.1
Other public order and safety	0.8	0.8	1.1
Medical office (diagnostic)	1	1	1.5
Clinic/other outpatient health	1	1	1.5

TABLE VII.2—SHIFT ADJUSTMENT MULTIPLIER BY HOURS OF OPERATION AND BUILDING TYPE—Continued

Building activity/type	Weekly hours of operation		
	50 or less	51 to 167	168
Refrigerated warehouse	1	1	1
Religious worship	0.9	1.7	1.7
Entertainment/culture	0.8	1.5	1.5
Library	0.8	1.5	1.5
Recreation	0.8	1.5	1.5
Social/meeting	0.8	1.5	1.5
Other public assembly	0.8	1.5	1.5
College/university	0.8	1.3	1.3
Elementary/middle school	0.8	1.3	1.3
High school	0.8	1.3	1.3
Preschool/daycare	0.8	1.3	1.3
Other classroom education	0.8	1.3	1.3
Fast food	0.4	1.1	2.1
Restaurant/cafeteria	0.4	1.1	2.1
Other food service	0.4	1.1	2.1
Hospital/inpatient health	1	1	1
Nursing home/assisted living	1	1	1
Dormitory/fraternity/sorority	1	1	1
Hotel	1	1	1
Motel or inn	1	1	1
Other lodging	1	1	1
Vehicle dealership/showroom	0.8	1.2	1.8
Retail store	0.8	1.2	1.8
Other retail	0.8	1.2	1.8
Post office/postal center	0.7	1.5	1.5
Repair shop	0.7	1.5	1.5
Vehicle service/repair shop	0.7	1.5	1.5
Vehicle storage/maintenance	0.7	1.5	1.5
Other service	0.7	1.5	1.5
Strip shopping mall	1	1	1
Enclosed mall	1	1	1
Bar/Pub/Lounge	1	1	1.4
Courthouse/Probation Office	1	1	1.4

(ii) Design for construction began during or after fiscal year 2030. For new construction and major renovations of all Scope 1 fossil fuel-using systems in an EISA-subject building, the Scope 1 fossil fuel-generated energy consumption of the proposed building, based on building design and calculated according to § 435.201(a), must be zero.

(2) Major Renovations of a Scope 1 Fossil Fuel-Using Building System or Scope 1 fossil fuel-using Component within an EISA-Subject Building shall follow the renovation requirements in section 4.2.1.3 of the applicable building baseline energy efficiency standards listed in § 435.4 substituting the term ''design for construction'' with ''design for renovation'' for the relevant date, and shall replace all equipment that is included in the renovation with all electric or non-fossil fuel using ENERGY STAR or FEMP designated products as defined in § 436.42. For component level renovations, Agencies shall replace all equipment that is part of the renovation with all electric or non-fossil fuel using ENERGY STAR or FEMP designated products as defined in § 436.42.

(d) *EISA-Subject buildings that are of the type not included in Appendix A of this subpart*—(1) *Process load buildings.* For building types that are not included in any of the building types listed in Tables A–1a to A–2a or A–1b to A–2b of appendix A of this subpart, or for building types in these tables that contain significant process loads, Federal agencies must select the applicable building type, climate zone, and fiscal year in which design for construction began from Tables A–1a to A–2a or A–1b to A–2b of appendix A of this subpart that most closely corresponds to the proposed building without the process load. The estimated Scope 1 fossil fuel-generated energy consumption of the process load must be added to the maximum allowable Scope 1 fossil fuel-generated energy consumption of the applicable building type for the appropriate fiscal year and climate zone to calculate the maximum allowable Scope 1 fossil fuel-generated energy consumption for the building. The same estimated Scope 1 fossil fuel-generated energy consumption of the process load that is added to the maximum allowable Scope 1 fossil fuel-generated energy consumption of the applicable building must also be used in determining the Scope 1 fossil fuel-generated energy consumption of the proposed building.

(2) *Mixed-use buildings.* For buildings that combine two or more building types with process loads or, alternatively, that combine one or more building types with process loads with one or more building types in Tables A–1a to A–2a or A–1b to A–2b of appendix A of this subpart, the maximum allowable Scope 1 fossil fuel-generated energy consumption of the proposed building is equal to the averaged process load building values determined under paragraph (d)(1) of this section and the applicable building type values in Tables A–1a to A–2a or A–1b to A–2b of appendix A of this subpart, weighted by floor area. Equation 1 shall be used for mixed use buildings.

Equation 1: Scope 1 Fossil fuel generated energy consumption for a mixed-use building = the sum across all building uses of (the fraction of total floor building floor area for building use i times the allowable fossil fuel-generated energy consumption for building use i)

Equation 2 may be rewritten as:

Scope 1 Fossil Fuel-Generated Energy Consumption for a Mixed Use Building = $\Sigma^{n}_{i=1}$ *(Fraction of Total Building Floor Area for Building Use i times Allowable Scope 1 Fossil Fuel-Generated Energy Consumption for Building Use).*

§ 435.201 Scope 1 Fossil fuel-generated energy consumption determination.

(a) The Scope 1 fossil fuel-generated energy consumption of a proposed design is calculated as follows:

Equation: Scope 1 Fossil Fuel-Generated Energy Consumption = Direct Fossil Fuel Consumption of Proposed Building/Floor Area

Where:

Direct Scope 1 Fossil Fuel-Generated Energy Consumption of Proposed Building equals the total site Scope 1 fossil fuel-generated energy consumption of the proposed building calculated in accordance with the Simulated Performance Alternative in Section 405 of the IECC 2021 (incorporated by reference; see § 435.3), and measured in thousands of British thermal units per year (kBtu/yr), except that this term does not include fossil fuel consumption for emergency electricity generation. Agencies must include all on-site fossil fuel use or Scope 1 emissions associated with non-emergency generation from backup generators (such as those for peak shaving or peak shifting). Any energy generation or Scope 1 emissions associated with biomass fuels are excluded. Any emissions associated with natural gas for alternatively fueled vehicles (''AFVs'') (or any other alternative fuel defined at 42 U.S.C. 13211 that is provided at a Federal building) is excluded. Buildings with manufacturing or industrial process loads should be accounted for in the analysis for the building's fossil fuel consumption and GHG emissions but are not subject to the phase down targets.

Floor Area is the floor area of the structure that is enclosed by exterior walls, including finished or unfinished basements, finished or heated space in attics, and garages if they have an uninsulated wall in common with the house. Not included are crawl spaces, and sheds and other buildings that are not attached to the house.

§ 435.202 Petition for downward adjustment.

(a) *New Federal buildings and major renovations of all Scope 1 fossil fuel-using systems in an EISA-subject building.* (1) Upon petition by a Federal agency the Director of FEMP may adjust the applicable maximum allowable Scope 1 fossil fuel energy consumption standard with respect to a specific building, upon written certification from the head of the agency designing the building, that the requested adjustment is the largest feasible reduction in Scope 1 fossil fuel energy consumption that can practicably be achieved in light of the specified functional needs for that building, as demonstrated by:

(i) A statement sealed by the design engineer that the proposed building was designed in accordance with the applicable energy efficiency requirements to the maximum extent practicable and that each fossil fuel consuming product included in the proposed building that is of a product category covered by the ENERGY STAR program or FEMP for designated products is an ENERGY STAR product or a product meeting the FEMP designation criteria, as applicable;

(ii) A description of the systems, technologies, and practices that were evaluated and unable to meet the required fossil fuel reduction including a justification of why achieving the Scope 1 fossil fuel-generated energy consumption targets would be technically impracticable: and

(iii) Any other information the agency determines would help explain its request;

(2) The head of the agency designing the building, must also include the following information in the petition:

(i) A general description of the building, including but not limited to location, use type, floor area, stories, expected number of occupants and occupant schedule, project type, project cost, and functional needs, mission critical activity, research, and national security operations as applicable;

(ii) The maximum allowable Scope 1 fossil fuel energy consumption for the building from paragraphs (c) or (d) of this section;

(iii) The estimated Scope 1 fossil fuel energy consumption of the proposed building;

(iv) A description of the proposed building's energy-related features, including but not limited to:

(A) HVAC system type and configuration;

(B) HVAC equipment sizes and efficiencies;

(C) Ventilation systems (including outdoor air volume, controls technique, heat recovery systems, and economizers, if applicable);

(D) Service water heating system configuration and equipment (including solar hot water, wastewater heat recovery, and controls for circulating hot water systems, if applicable);

(E) Estimated industrial process loads; and

(F) Any other on-site fossil fuel consuming equipment.

(3) Petitions for downward adjustment should be submitted to *ff-petition@ee.doe.gov,* or to: U.S. Department of Energy, FEMP, Director, Fossil Fuel Reduction Petitions, EE–5F, 1000 Independence Ave. SW, Washington, DC 20585–0121.

(4) The Director will make a best effort to notify the requesting agency in writing whether the petition for downward adjustment to the numeric reduction requirement is approved or rejected, in 45 calendar days of submittal, granted the petition is complete. If the Director rejects the petition or establishes a value other than that presented in the petition, the Director will forward its reasons for rejection to the petitioning agency.

(b) *Major renovations of a Scope 1 fossil fuel-using building system or Scope 1 fossil fuel-using component.* (1) Upon petition by a Federal agency, the Director of FEMP may adjust the applicable requirements for the Federal agency to reduce Scope 1 on-site fossil fuel-generated energy consumption standard with respect to a specific renovation, upon written certification from the head of the agency designing the renovation, that the requested adjustment is the largest feasible reduction in Scope 1 fossil fuel energy consumption that can practicably be achieved in light of the specified functional needs for that building, as demonstrated by:

(i) A statement Sealed by the design engineer that the proposed renovation incorporates commercially available systems and/or components that provide a level of energy efficiency that is life-cycle cost effective as defined in this part and reduces consumption of Scope 1 fossil fuel energy consumption to the maximum extent practicable and that each fossil fuel consuming product included in the proposed building that is of a product category covered by the ENERGY STAR program or FEMP for designated products is an ENERGY STAR product or a product meeting the FEMP designation criteria, as applicable.

(ii) A description of the systems, technologies, and practices that were evaluated and unable to meet the required fossil fuel reduction including a justification of why achieving the Scope 1 fossil fuel-generated energy consumption targets would be technically impracticable: and

(iii) Any other information the agency determines would help explain its request.

(2) The head of the agency making the design decisions for the building, must

also include the following information in the petition:

(i) A general description of the building, including but not limited to location, use type, floor area, stories, estimated number of occupants and occupant schedule, project type, project cost, and functional needs, mission critical activity, research, and national security operations as applicable;

(ii) The maximum allowable Scope 1 fossil fuel energy consumption for the building from § 435.200(c) or (d);

(iii) The estimated Scope 1 fossil fuel energy consumption of the building;

(iv) A description of system(s) or component(s) that are being renovated, including but not limited to:

(A) HVAC system or component type and configuration;

(B) HVAC equipment sizes and efficiencies;

(C) Ventilation systems or components (including outdoor air volume, controls technique, heat recovery systems, and economizers, if applicable);

(D) Service water heating system or component configuration and equipment (including solar hot water, wastewater heat recovery, and controls for circulating hot water systems, if applicable);

(E) Estimated process loads; and

(F) Any other on-site fossil fuel consuming equipment.

(3) Petitions for downward adjustment should be submitted to *ff-petition@ee.doe.gov,* or to: U.S. Department of Energy, FEMP, Director, Fossil Fuel Reduction Petitions, EE–5F, 1000 Independence Ave. SW, Washington, DC 20585–0121.

(4) The Director will make a best effort to notify the requesting agency in writing whether the petition for downward adjustment to the numeric reduction requirement is approved or rejected, in 45 calendar days of submittal for major renovations of a buildings system, and 20 calendar days for major renovations of a component, granted the petition is complete. If the Director rejects the petition, the Director will forward its reasons for rejection to the petitioning agency.

(c) *Exclusions.* The General Services Administration (GSA) may not submit petitions under paragraphs (a) and (b) of this section. Agencies that are tenants of GSA buildings for which the agency, not GSA, has significant design control may submit petitions in accordance with this section.

Appendix A to Subpart B of Part 435 Maximum Allowable Scope 1 Fossil Fuel Generated Energy Consumption

(a) For purposes of the tables in this appendix, the climate zones for each county in the United States are those listed in Figure 301.1 of IECC 2021 (incorporated by reference; see § 435.3).

(b) For purpose of appendix A, the following definitions apply:

Mobile Home means a dwelling unit built to the Federal Manufactured Home Construction and Safety Standards in 24 CFR part 3280, that is built on a permanent chassis and moved to a site. It may be placed on a permanent or temporary foundation and may contain one or more rooms.

Multi-Family in 2–4 Unit Buildings means a category of structures that is divided into living quarters for two, three, or four families or households in which one household lives above or beside another. This category also includes houses originally intended for occupancy by one family (or for some other use) that have since been converted to separate dwellings for two to four families.

Multi-Family in 5 or More Unit Buildings means a category of structures that contain living quarters for five or more households or families and in which one household lives above or beside another.

Single-Family Attached means a building with two or more connected dwelling units, generally with a shared wall, each providing living space for one household or family. Attached houses are considered single-family houses as long as they are not divided into more than one dwelling unit and they have independent outside entrances. A single-family house is contained within walls extending from the basement (or the ground floor if there is no basement) to the roof. Townhouses, row houses, and duplexes are considered single-family attached dwelling units, as long as there is no dwelling unit above or below another.

Single-Family Detached means a separate, unconnected dwelling unit, not sharing a wall with any other building or dwelling unit, which provides living space for one household or family. A single-family house is contained within walls extending from the basement (or the ground floor if there is no basement) to the roof. This includes modular homes but does not include mobile homes.

TABLE A–1a—FY2020–FY2024 MAXIMUM ALLOWABLE FOSSIL FUEL-GENERATED ENERGY CONSUMPTION BY BUILDING CATEGORY, BUILDING TYPE AND CLIMATE ZONE, RESIDENTIAL BUILDINGS

[CO_2e/yr-sqft]

Building category	Climate zone:	0A	0B	1A	1B	2A	2B	3A	3B	3C	4A	4B	4C	5A	5B	5C	6A	6B	7	8
	Building activity/type	Fossil fuel-generated energy use intensity (CO_2e/yr-sqft)																		
Residential	Mobile	0.66	0.67	0.68	0.73	0.80	0.78	0.92	0.76	0.87	0.92	1.07	1.05	1.06	1.23	1.19	1.11	1.36	1.36	1.51
Residential	Single-family detached	0.40	0.41	0.41	0.45	0.50	0.48	0.58	0.47	0.55	0.58	0.69	0.67	0.68	0.79	0.76	0.71	0.88	0.88	0.99
Residential	Single-family attached	0.76	0.76	0.77	0.78	0.80	0.79	0.83	0.79	0.82	0.83	0.87	0.87	0.87	0.92	0.90	0.88	0.95	0.95	0.99
Residential	Multi-family (in 2–4-unit building)	0.56	0.57	0.61	0.74	0.93	0.87	1.25	0.83	1.11	1.25	1.64	1.58	1.62	2.06	1.95	1.74	2.40	2.41	2.82
Residential	Multi-family (in 5+ unit building)	0.24	0.25	0.29	0.42	0.61	0.55	0.93	0.51	0.80	0.93	1.32	1.26	1.30	1.74	1.63	1.42	2.08	2.09	2.50

TABLE A–1b—FY2020–FY2024 MAXIMUM ALLOWABLE FOSSIL FUEL-GENERATED ENERGY CONSUMPTION BY BUILDING CATEGORY, BUILDING TYPE AND CLIMATE ZONE, RESIDENTIAL BUILDINGS

[Source kBtu/yr-sqft]

Building category	Climate zone:	0A	0B	1A	1B	2A	2B	3A	3B	3C	4A	4B	4C	5A	5B	5C	6A	6B	7	8
	Building Activity/Type	Fossil fuel-generated energy use intensity (site kBtu/yr-sqft)																		
Residential	Mobile	6	6	6	7	7	7	8	7	8	8	10	10	10	11	11	10	12	12	14
Residential	Single-family detached	4	4	4	4	5	4	5	4	5	5	6	6	6	7	7	6	8	8	9
Residential	Single-family attached	7	7	7	7	7	7	8	7	7	8	8	8	8	8	8	8	9	9	9
Residential	Multi-family (in 2–4-unit building)	5	5	6	7	8	8	11	8	10	11	15	14	15	19	18	16	22	22	26
Residential	Multi-family (in 5+ unit building)	2	2	3	4	6	5	8	5	7	8	12	11	12	16	15	13	19	19	23

TABLE A–2a—FY2025–FY2029 MAXIMUM ALLOWABLE FOSSIL FUEL-GENERATED ENERGY CONSUMPTION BY BUILDING CATEGORY, BUILDING TYPE AND CLIMATE ZONE, RESIDENTIAL BUILDINGS

[CO_2e/yr-sqft]

Building category	Climate zone:	0A	0B	1A	1B	2A	2B	3A	3B	3C	4A	4B	4C	5A	5B	5C	6A	6B	7	8
	Building Activity/Type	Fossil fuel-generated energy use intensity (CO_2e/yr-sqft)																		
Residential	Mobile	0.33	0.34	0.37	0.40	0.39	0.46	0.38	0.44	0.46	0.54	0.52	0.53	0.62	0.59	0.55	0.68	0.68	0.76	0.33
Residential	Single-family detached	0.20	0.21	0.22	0.25	0.24	0.29	0.24	0.27	0.29	0.34	0.33	0.34	0.40	0.38	0.35	0.44	0.44	0.50	0.20
Residential	Single-family attached	0.38	0.38	0.39	0.40	0.40	0.42	0.39	0.41	0.42	0.44	0.43	0.44	0.46	0.45	0.44	0.47	0.48	0.50	0.38
Residential	Multi-family (in 2–4-unit building)	0.28	0.30	0.37	0.46	0.44	0.62	0.41	0.56	0.63	0.82	0.79	0.81	1.03	0.97	0.87	1.20	1.20	1.41	0.28
Residential	Multi-family (in 5+ unit building)	0.13	0.14	0.21	0.30	0.28	0.46	0.25	0.40	0.47	0.66	0.63	0.65	0.87	0.81	0.71	1.04	1.04	1.25	0.13

TABLE A–2b–FY2025–FY2029 MAXIMUM ALLOWABLE FOSSIL FUEL-GENERATED ENERGY CONSUMPTION BY BUILDING CATEGORY, BUILDING TYPE AND CLIMATE ZONE, RESIDENTIAL BUILDINGS

[Source kBtu/yr-sqft]

Building category	Climate zone:	0A	0B	1A	1B	2A	2B	3A	3B	3C	4A	4B	4C	5A	5B	5C	6A	6B	7	8
	Building Activity/Type	Fossil fuel-generated energy use intensity (site kBtu/yr-sqft)																		
Residential	Mobile	3	3	3	3	4	4	4	3	4	4	5	5	5	6	5	5	6	6	7
Residential	Single-family detached	2	2	2	2	2	2	3	2	2	3	3	3	3	4	3	3	4	4	4
Residential	Single-family attached	3	3	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	5
Residential	Multi-family (in 2–4-unit building)	3	3	3	3	4	4	6	4	5	6	7	7	7	9	9	8	11	11	13
Residential	Multi-family (in 5+ unit building)	1	1	1	2	3	3	4	2	4	4	6	6	6	8	7	6	9	9	11

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Part V

Department of Health and Human Services

Office of the Secretary

45 CFR Parts 160 and 162

Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160 and 162

[CMS–0053–P]

RIN 0938–AT38

Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard

AGENCY: Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This rule would implement requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, enacted on March 30, 2010—collectively, the Affordable Care Act. Specifically, this proposed rule would adopt standards for ''health care attachments'' transactions, which would support both health care claims and prior authorization transactions, and a standard for electronic signatures to be used in conjunction with health care attachments transactions. To better support the use of the proposed standards for attachments transactions with prior authorization transactions, this rule also proposes to adopt a modification to the standard for the referral certification and authorization transaction (X12 278) to move from Version 5010 to Version 6020.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 21, 2023.

ADDRESSES: In commenting, please refer to file code CMS–0053–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of 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–0053–P, P.O. Box 8013, Baltimore, MD 21244–1850.

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–0053–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Daniel Kalwa, (410) 786–1352. Geanelle G. Herring, (410) 786–4466. Christopher Wilson, (410) 786–3178.

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. Executive Summary

A. Purpose

This rule proposes to adopt a set of standards for the electronic exchange of clinical and administrative data to support prior authorizations and health care claims adjudication. In determining the necessity of a health care service as part of making a coverage decision, health plans often require additional information that cannot adequately be conveyed in the specified fields or data elements of the adopted prior authorization request or health care claims transaction. If adopted as proposed, this proposed rule would support electronic transmissions of this type of information, which should have the effect of decreasing the use of time and resource-consuming manual processes such as mail or fax often used today to transmit this information. This would facilitate prior authorization decisions and claims processing, reduce burden on providers and plans, and result in more timely delivery of patient health care services.

a. Need for the Regulatory Action

This rule would adopt a set of standards for the electronic exchange of clinical and administrative data to support prior authorizations and claims adjudication. Despite widespread deployment of electronic health records (EHRs), and industry experience with Health Insurance Portability and Accountability Act of 1996 (HIPAA) standards that continues to advance since HIPAA's advent, transmitting health care attachments is still primarily a manual process and, at this time, there are no adopted HIPAA standards, implementation guides, or operating rules for health care attachments or electronic signatures. If adopted, this proposed rule would support electronic transmissions of this type of information rather than the use of manual processes such as mail and fax that still predominate in the health care industry.

We believe that the health care industry has long anticipated the adoption of a set of HIPAA standards for the electronic exchange of clinical and administrative data to support electronic health care transactions, such as prior authorization of services and claims adjudication, and the standards we are proposing to adopt are an important step in reducing provider burden.

B. Summary of the Major Provisions

This rule would implement requirements of the Administrative Simplification subtitle of HIPAA and the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, enacted on March 30, 2010—collectively, the Affordable Care Act. Specifically, this proposed rule would adopt standards for ''health care attachments'' transactions, which would support health care claims and prior authorization transactions, and a standard for electronic signatures to be used in conjunction with health care attachments transactions. This rule also proposes modifying the referral certification and authorization transaction standard to move from the X12 278, Version 5010, to the X12 278, Version 6020.

C. Summary of Costs and Benefits

Based on industry research by the Council for Affordable Quality

Healthcare (CAQH), the 2019 CAQH report indicates that a fully electronic system for prior authorization with health care attachments could result in as much as $454 million in annual savings to the health care industry. Similar savings can be expected for the industry by switching to health care attachments for claims. The 2019 CAQH report further estimates that the industry could expect as much as $374 million in savings per year with the full adoption of health care attachments for claims. This results in total anticipated industry savings of $828 million per year for prior authorization and claims.

II. Background

A. Legislative Authority for Administrative Simplification

This background discussion presents a history of statutory provisions and regulations that are relevant for the purposes of this proposed rule.

1. Standards Adoption and Modification Under the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Congress addressed the need for a consistent framework for electronic transactions and other administrative simplification issues in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191, enacted on August 21, 1996). Through subtitle F of title II of HIPAA, Congress added to title XI of the Social Security Act (the Act) a new Part C, titled ''Administrative Simplification,'' which required the Secretary of the Department of Health and Human Services (the Secretary) to adopt standards for certain transactions to enable health information to be exchanged more efficiently and to achieve greater uniformity in the transmission of health information. For purposes of this and later discussion in this proposed rule, we sometimes refer to this statute as the ''original'' HIPAA provisions.

Section 1172(a) of the Act indicates that any standard adopted under HIPAA shall apply, in whole or in part, to the following persons, referred to as ''covered entities'': (1) a health plan; (2) a health care clearinghouse; and (3) a health care provider who transmits any health information in electronic form in connection with a [HIPAA transaction]. Generally, section 1172 of the Act indicates that any standard adopted under HIPAA is to be developed, adopted, or modified by a standard setting organization (SSO). In adopting a standard, the Secretary must rely upon recommendations of the National Committee on Vital and Health Statistics (NCVHS), in consultation with the organizations referred to in section 1172(c)(3)(B) of the Act, and appropriate federal and state agencies and private organizations.

Section 1172(b) of the Act indicates that a standard adopted under HIPAA must be consistent with the objective of reducing the administrative costs of providing and paying for health care. The transaction standards adopted under HIPAA enable financial and administrative electronic data interchange (EDI) using a common structure, as opposed to the many varied, often proprietary, transaction formats on which industry had previously relied and that, due to lack of uniformity, engendered administrative burden. Section 1173(g)(1) of the Act, which was added by section 1104(b) of the Affordable Care Act, further addresses the goal of uniformity by requiring the Secretary to adopt a single set of operating rules for each transaction during the implementation of the electronic standards. These operating rules are required to be consensus-based and reflect the business rules that affect health plans and health care providers and the manner in which they operate.

Section 1173(a) of the Act indicates that the Secretary must adopt standards for financial and administrative transactions, and data elements for those transactions, to enable health information to be exchanged electronically. The original HIPAA provisions require the Secretary to adopt standards for the following transactions: health claims or equivalent encounter information; health claims attachments; enrollment and disenrollment in a health plan; eligibility for a health plan; health care payment and remittance advice; health plan premium payments; first report of injury; health claim status; and referral certification and authorization. The Affordable Care Act added the requirement that the Secretary adopt a standard for electronic funds transfers. Additionally, section 1173(a)(1)(B) of the Act requires the Secretary to adopt standards for any other financial and administrative transactions the Secretary determines appropriate.

Section 1173(c) through (f) of the Act indicates the Secretary must adopt standards for code sets for appropriate data elements for each listed health care transaction; security standards for health care information; standards for electronic signatures in coordination with the Secretary of Commerce, compliance with which will be deemed to satisfy both state and federal statutory requirements for written signatures for the listed transactions; and standards for the transmission of appropriate standard data elements needed for the coordination of benefits, sequential processing of claims, and other data elements for individuals who have more than one health plan.

Section 1174 of the Act requires the Secretary to review the adopted standards and adopt modifications to them, which include additions to the standards, as appropriate, but not more frequently than once every 12 months. Section 1174(b)(2)(B)(ii) of the Act requires that modifications must be completed in a manner that minimizes disruption and cost of compliance.

Section 1175 of the Act prohibits health plans from refusing to conduct a transaction as a standard transaction.[1] It also prohibits health plans from delaying the transaction, or adversely affecting or attempting to adversely affect, a person or the transaction itself on the ground that the transaction is in standard format. It establishes a timetable for covered entities to comply with any standard, implementation specification, or modification as follows: for an initial standard or implementation specification, no later than 24 months (or 36 months for small health plans) following its adoption; for modifications, as the Secretary determines appropriate, but no earlier than 180 days after the modification is adopted.

Sections 1176 and 1177 of the Act establish civil money penalties (CMPs) and criminal penalties to which covered entities may be subject for violations of HIPAA Administrative Simplification rules. HHS administers the CMPs under section 1176 of the Act and the U.S. Department of Justice administers the criminal penalties under section 1177 of the Act. Section 1176(b) of the Act sets out limitations on the Secretary's authority and provides the Secretary certain discretion with respect to imposing CMPs. For example, this section provides that no CMPs may be imposed with respect to an act if a penalty has been imposed under section 1177 of the Act with respect to such act. This section also generally precludes the Secretary from imposing a CMP for a violation corrected during the 30-day period beginning when an individual knew or, by exercising reasonable diligence, would have known that the failure to comply occurred.

The original HIPAA provisions are discussed in greater detail in the August 17, 2000 final rule titled ''Health

[1] Defined at 45 CFR 162.103.

Insurance Reform: Standards for Electronic Transactions'' final rule (65 FR 50312, hereinafter referred to as the Transactions and Code Sets final rule), and the December 28, 2000, final rule titled ''Standards for Privacy of Individually Identifiable Health Information'' (65 FR 82462). We refer the reader to those documents for further information.

2. Amendments to HIPAA Administrative Simplification by the Affordable Care Act

Section 1104(c)(3) of the Affordable Care Act reiterated the original HIPAA requirement to adopt a health claims attachment standard, and directed the Secretary to promulgate a final rule to establish a transaction standard and a single set of associated operating rules. Section 1104(c)(3) of the Affordable Care Act requires that the adopted standard be ''consistent with the X12 Version 5010 transaction standards'' and indicates that the Secretary must adopt the standard and operating rules by January 1, 2014, to be effective no later than January 1, 2016, and that the Secretary may adopt the standard and operating rules on an interim final basis. This provision makes no allowance for an extended time for small health plans to achieve compliance.

B. Prior Rulemaking

In the Transactions and Code Sets final rule, we implemented some of the HIPAA Administrative Simplification requirements by adopting standards for electronic health care transactions developed by SSOs, and medical code sets to be used in those transactions. We adopted X12 Version 4010 standards for administrative transactions, and the National Council for Prescription Drug Programs (NCPDP) Telecommunication Version 5.1 standard for retail pharmacy transactions, which were specified at 45 CFR part 162, subparts K through R.

Since then, we have adopted a number of modifications to the HIPAA standards, most recently in a January 16, 2009 final rule (74 FR 3296) titled ''Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards'' (hereinafter referred to as the Modifications final rule). That rule, among other things, adopted updated versions of the standards, X12 Version 5010, and the NCPDP Telecommunication Standard Implementation Guide Version D.0 and equivalent Batch Standard Implementation Guide, Version 1, Release 2. We also adopted the NCPDP Implementation Guide for Batch Standard Version 3.0 standard for the Medicaid pharmacy subrogation transaction. Covered entities were required to comply with the Version 5010, Version D.0, and Version 3.0 standards on January 1, 2012, though with respect to the latter, small health plans were required to comply on January 1, 2013.

In the September 23, 2005 **Federal Register** (70 FR 55990), in a rule titled ''HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments; Proposed Rule,'' we proposed to adopt certain standards with respect to health care attachments. In that rule, rather than a standard with generalized applicability, we proposed to adopt health care claims attachment standards with respect to specific service areas that included ambulance services, clinical reports, emergency department, laboratory results, medications, and rehabilitation services. Due, however, to comments we received on our proposals, including comments related to the standards' lack of technical maturity and stakeholders' lack of readiness to implement electronic capture of clinical data, we did not finalize that rule. As a result, and despite the subsequent widespread deployment of electronic health records (EHRs) and greater industry experience with the HIPAA standards, transmitting health care attachments is still primarily a manual process and, at this time there are no adopted HIPAA standards, implementation guides, or operating rules for health care attachments or electronic signatures. Other specific details of prior rulemaking are discussed as appropriate in the context of the proposals in section II. of this proposed rule.

C. Standards and Code Sets Organizations

In this section, we discuss information about the organizations responsible for developing and maintaining the transaction standards and code sets that we are either proposing or discussing in this proposed rule. Information about each organization's balloting process—the process by which they vet and approve the products they develop and changes thereto—is available on their respective websites, links to which are provided in this section of this rule.

As we have discussed, the law requires any standard adopted under HIPAA to be developed, adopted, or modified by an SSO. Section 1171 of the Act provides that an SSO is an organization accredited by the American National Standards Institute (ANSI) that develops standards for information transactions, data elements, or any standard that is necessary to, or will facilitate the implementation of, Administrative Simplification. Per section 1172(c)(3) of the Act, a HIPAA SSO must develop, adopt, and modify standards in consultation with certain organizations—the National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), the Workgroup for Electronic Data Interchange (WEDI), and the American Dental Association (ADA). The two SSOs applicable to this proposed rule are the Accredited Standards Committee X12 (X12) and Health Level Seven International (HL7). Both SSOs maintain websites where the proposed implementation specifications may be obtained. One other organization, which is a health research institution and not an SSO, maintains a code set that is important to this rulemaking—the Regenstrief Institute, maintains a code set named Logical Observation Identifiers Names and Codes (LOINC).

1. X12 (*http://www.x12.org/*)

X12 develops and maintains standards for the electronic exchange of business-to-business transactions. An ANSI-accredited organization, X12 membership is open to all individuals and organizations. An X12 subcommittee known as Subcommittee N: Insurance (X12N) develops and maintains electronic standards specific to the insurance industry, including health care insurance. The subcommittee, which is comprised of volunteers, develops standards for electronic health care transactions for common administrative activities including: claims, remittance advice, claims status, enrollment, eligibility, authorizations and referrals, and electronic health care claims attachments. The X12N subcommittee is responsible for obtaining consensus on the standards from the entire organization, and produces draft documents that are made available for public review and comment, which the subcommittee addresses as necessary before voting on any proposal. Proposals must then be reviewed and ratified by a majority of the voting members of the X12N subcommittee and the executive committee of X12 itself.

2. Health Level Seven (HL7) (*www.HL7.org)*

HL7 is an ANSI-accredited SSO that develops and maintains standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. Its

domain is principally clinical data and its specific emphasis is on the interoperability between health care information systems. HL7, whose membership is open to all individuals and organizations, focuses its interface requirements on the entire health care organization rather than on a particular subset of the health care industry.

HL7 conducts a three-step process to establish standards. First, a technical committee develops standards through a voting process. All HL7 members are eligible to vote on standards, regardless of whether they are members of the committee that developed the standard. Non-members may also vote on a given ballot for a standard, though they must pay an administrative fee (that does not exceed the cost associated with an individual HL7 membership) associated with handling and processing. Second, HL7 technical committees vote on ''recommendations,'' which require a two-thirds majority for approval. Third, any recommended standards are submitted to the entire HL7 body for approval and, if approved, are submitted to ANSI for certification.

3. Regenstrief Institute (*LOINC.org*)

Regenstrief Institute (Regenstrief) is a health research institution that develops and maintains a proprietary code set, Logical Observation Identifiers Names and Codes (LOINC). LOINC is the code system, terminology, and vocabulary for identifying individual clinical results and other clinical information. Regenstrief worked closely with the HL7 Payer/Provider Information Exchange Workgroup, formerly known as the Attachments Work Group, to develop a set of LOINC codes to uniquely indicate the type and content of attachment information in electronic transmissions. Regenstrief maintains LOINC through its LOINC Committee, which is comprised of volunteer representatives from academia, industry, and government who serve as subject matter experts in their domains of expertise. That committee establishes overall naming conventions and policies for the development process.

D. Industry Standards, Code Sets, and Implementation Guides

1. Electronic Data Interchange (EDI) and Transaction Standards

HIPAA transactions involve the electronic transmission of information between two parties to carry out health care-related financial or administrative activities, such as health insurance claims submissions and prior authorization requests, and HHS-adopted standards for those transactions represent uniform requirements for EDI of those transmissions.

The benefit of HIPAA standards is that they use a common interchange structure, eliminating covered entities' need to have information technology (IT) systems that accommodate multiple proprietary, and potentially continually changing, data formats. By enabling covered entities to exchange medical, billing, and other information to process transactions in a more expedient and cost-effective manner by reducing handling and processing time and eliminating the risk of lost paper documents, HIPAA standards can reduce administrative burdens, lower operating costs, and improve overall data quality.

HIPAA transaction standards specify: (1) data interchange structures (message transmission formats); and (2) data content (all the data elements and code sets inherent to a transaction, and not related to the format of the transaction). Implementation specifications detail the nature, location, and content format of each piece of information transmitted in a transaction. Standardization of transactions also involves: specification of the data elements that are exchanged; uniform definitions of those specific data elements in each type of electronic transaction; identification of the specific codes or values that are valid for each data element; and specification of the business actions each party must take to ensure the exchange of administrative transactions occurs smoothly and reliably, regardless of the technology employed.

a. Implementation Guides—X12

As discussed previously, X12 develops and maintains standards for the electronic exchange of business-to-business transactions. The X12N subcommittee (X12N) publishes transmission standards that apply to many lines of business, not just health care. For example, the X12N 820 message format for premium payment may be used for automobile and casualty insurance, not just health insurance. X12 implementation specifications, referred to by the industry as ''implementation guides'' and written collaboratively by X12N workgroups, make these general standards functional for industry-specific uses. The specifications are based on X12 standards but contain detailed instructions for using the standard to meet a specific business need. X12's implementation specifications for HIPAA transaction standards adopted by the Secretary are known as ''Technical Reports Type 3'' (TR3); an example is the X12 standard adopted as the HIPAA standard for the health plan premium payments transaction, the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Payroll Deducted and Other Group Premium Payment for Insurance Products (820), February 2007, ASC X12N/005010X218).

Each X12N implementation guide has a unique version identification number (for example, 004010, 004050, or 005010), where the highest version number represents the most recent version. HHS adopted updated versions of the X12 standards in the Modifications final rule (74 FR 3296). We are proposing to adopt a Version 6020 standard for one of the HIPAA transactions, the rationale for which we discuss in section II. of this proposed rule.

b. Implementation Guides—HL7

HL7's Payer/Provider Information Exchange Workgroup develops standards for electronic health care attachments. The workgroup, which includes industry experts representing health care providers, health plans, and health technology vendors, is also responsible for creating and maintaining the implementation guides, which are sets of instructions and associated code tables that describe, list, or itemize the content, format, and code to be sent, and specify how such information is to be conveyed in an electronic health care attachment.

An HL7 standard that we are proposing to adopt in this proposed rule is the Clinical Document Architecture (CDA), which is an XML-based (a computer programming language) markup standard that specifies the encoding, structure, and semantics of clinical documents for purposes of transmitting attachment information. XML-coded files have the same characteristics and information as hard copy documents, so regardless of how data are sent within a transaction, they can be read and processed by both people and machines. Some health care attachments may not be conducive to XML formatting, such as medical imaging, video, or audio files. An important CDA feature is that it allows the entire body of an electronic document to be replaced by an image, for example, a scanned copy of a page or pages from a medical record. Although a header still supports automated document management, the clinical content can be conveyed by image or text document.

HL7 also produces the Consolidated CDA (C–CDA), an implementation guide that provides specifications for formatting document templates,

depending on whether they are structured or unstructured, enabling the CDA to create numerous specific document types (templates). The HL7 C–CDA implementation guide document templates are designed to be electronic versions of the most common types of paper document attachment information. Attachment information not included in a template may be created by using instructions included in the proposed unstructured document implementation guide; supported unstructured formats include MSWORD, PDF, Plain Text, RTF Text, HTML Text, GIF Image, TIF Image, JPEG Image, and PNG Image.

2. Code Sets

Transaction data content standardization involves identifying the specific codes or values for each data element. Health care EDI requires many types of code sets, including large medical data code sets and classification systems for medical diagnoses, procedures, and drugs, and smaller code sets to identify categories, such as type of facility, currency, or units, or a specific state within the United States. The American Medical Association's (AMA) Current Procedural Terminology (CPT–4), which identifies physician procedures, is an example of a health care code set. Federal agencies (the National Center for Health Statistics, the Centers for Medicare & Medicaid Services (CMS), and the U.S. Food and Drug Administration) and some private organizations (the AMA and the American Dental Association) have developed and maintain standards for large medical data code sets. These code sets are mandated for use in some federal and state programs, such as Medicare and Medicaid, and SSOs require or permit them for use in their standards. As we explain in section II. of this proposed rule, the X12 and HL7 standards we are proposing to adopt specify the use of the LOINC for HIPAA Attachments code set.

3. Implementation Guides as HIPAA Standards

Section 1172(d) of the Act directs the Secretary to establish specifications for implementing each of the adopted standards. As we explained previously, SSOs have developed various ''Implementation Guides'' by which to implement the same standards for different business purposes. We are proposing an approach we have taken with previous HIPAA rules that adopted a specific ''Implementation Guide'' as both the ''standard'' and the ''implementation specifications'' for each health care transaction.

In pursuing this approach, we were mindful that section 1104(c)(3) of the Affordable Care Act requires that the Secretary promulgate a final rule to establish a transaction standard and a single set of operating rules for health care attachments that is ''consistent with the X12 Version 5010 transaction standards.'' We interpret this requirement to mean that the proposed health care attachment implementation specifications must be compatible with X12 standards generally, meaning any standard we adopt for attachment information can be electronically transmitted by an X12 transmission standard in the same transaction. In this rule, we are proposing to adopt Version 6020 of the X12 standards. The Affordable Care Act was enacted in 2010, at which time we had recently adopted Version 5010 of the X12 standards. A decade later, and with X12 continuing to publish newer versions of its standards, we interpret the Affordable Care Act's mandate as referencing the then-current standards (the X12 Version 5010), but the Affordable Care Act did not specifically require a static standard in perpetuity, as that would be incongruent with the HIPAA standards paradigm.

In section II. of this proposed rule, we are proposing to adopt transaction standards that can be used together in a single electronic transmission. HL7 has noted that an extensive architecture already exists for information exchange based on the HIPAA transactions and code sets, which architecture is currently being used by the same stakeholders who would use the health care attachments transactions, so adoption of this architecture using X12 standards could have the least impact on covered entities.[2]

Independent of that concept, we are also aware that there are other types of standards being developed and piloted by SSOs. We solicit comment on this discussion and any alternative implementation specifications that may be considered consistent with X12 Version 5010.

E. NCVHS Recommendations to the Secretary

The NCVHS (*https://ncvhs.hhs.gov/*) is a statutory advisory committee responsible for providing HHS with recommendations on health information policy and standards. It does so by, among other things, convening regular forums for interaction with industry groups on key issues related to population health, standards, privacy and confidentiality, and data access and use. Pursuant to HIPAA, the NCVHS advises HHS on the adoption of standards, implementation specifications, code sets, identifiers, and operating rules for HIPAA transactions.

The NCVHS has held a number of hearings, and made several sets of recommendations to the Secretary (see *https://ncvhs.hhs.gov/reports/recommendation-letters/*) on claims attachments standards; we briefly summarize them here. The NCVHS Standards Subcommittee held a November 17, 2011 hearing on health claims attachments to gather information regarding updated industry practices, priorities, issues, and challenges. Participant testimony addressed the development status of standards and implementation specifications. Some organizations testified regarding their interest in serving as attachments operating rules authoring entities. By letter to HHS dated March 2, 2012, the Subcommittee told HHS it was premature to make formal recommendations regarding the adoption of any standard, implementation specification, or operating rule associated with health care attachments. On May 5, 2012, the NCVHS recommended that the Council for Affordable Quality Healthcare Committee (CAQH), a non-profit entity whose mission is to improve the efficiency, accuracy and effectiveness of industry-driven business transactions, be designated as the operating rules authoring entity.

CAQH established the Committee on Operating Rules for Information Exchange (CAQH CORE), an industry-wide collaboration committed to the development and adoption of health care operating rules for administrative transactions. CAQH CORE facilitates the adoption of health care operating rules that support standards, improve interoperability, and align administrative and clinical activities with market needs.

The Subcommittee held a second hearing on attachments on February 27, 2013, where it identified a trend toward convergence of administrative and clinical information. In a June 21, 2013 letter, the NCVHS recommended that, by January 1, 2016 (the date by which the Affordable Care Act required claims attachment standards to be effective), HHS adopt a number of initial attachments-related transaction standards, but advised HHS to take a comprehensive and incremental approach to considering attachment

[2] Transcript of NCVHS Subcommittee on Standards Hearing on Electronic Attachments Standards and Operating Rules, February 27, 2013: *https://ncvhs.hhs.gov/transcripts-minutes/transcript-of-the-february-27-2013-ncvhs-subcommittee-on-standards-hearing/.*

standards in order to promote innovation and flexibility. The NCVHS noted an industry consensus that adoption of standards should not be limited to ''claim attachments,'' but, rather, should be more inclusive of any kind of attachment with administrative or clinical information, and it recommended that attachments-related transaction standards should be applied to claims, eligibility, prior authorization, referrals, care management, post-payment audits, and any other administrative processes for which supplemental information is needed. Among other recommendations, the NCVHS advised HHS that attachment standards should support structured and unstructured data, and both solicited and unsolicited transmissions. It further advised that attachments standards should be defined for two types of transactions: (1) Query (the electronic solicitation of an attachment); and (2) Response (the electronic transmission of an attachment).

The NCVHS held another hearing on health care attachments on February 15, 2016, and on July 5, 2016 sent the Secretary a letter titled ''Recommendations for the Electronic Health Care Attachment Standard.'' This letter consolidated its previous recommendations on attachments and advised that updated versions of the available standards were ready for industry use and there was unanimous testimony that the health care industry was eager to see them adopted. Considering both the length of time that had elapsed since the previous proposed rule was published and the subsequent technology advances, the NCVHS recommended that HHS publish an expedited proposed rule adopting the recommended standards.

Finally, and most recently, on March 30, 2022, the NCVHS sent to the Secretary a letter titled ''Recommendations to Modernize Aspects of HIPAA and Other HIT Standards to Improve Patient Care and Achieve Burden Reduction.'' This letter continued to stress previous recommendations that urged the Secretary to adopt a standard for electronic attachments as soon as possible. The recommendation letter also states the following:

> We recognize that there is ongoing debate and no definitive industry consensus about the role of attachments (*i.e.,* documents) as opposed to data (*i.e.,* a string of data elements not structured within a document). While the vision with APIs [(Application Programming Interfaces)] based on FHIR® [(Fast Healthcare Interoperability Resources)] seems to be driving toward more of a data-driven transaction, we see more than sufficient industry demand for a document-based attachment standard, and we do not foresee any imminent demise of the utility of digital documents. We suggest short-term publication of an attachment rule, with consideration for emerging standards based on recent input from industry and other advisory group discussions. This could add immediate value for industry and could support future actions as HIPAA's procedural requirements may be updated to allow for non-document type digital attachment data.[3]

Based on the NCVHS's previous recommendations to the Secretary, and particularly in consideration of its most recent March 30, 2022 recommendation, we propose here a document-based attachments standard. We acknowledge that there is a growing base of evidence that may, in the future, support our proposing attachment standards relying on other technologies such as FHIR®, and we will continue to monitor and evaluate emerging technologies for their readiness to potentially propose in future rulemaking.

F. Other Industry Recommendations

1. Consensus-Based Organization Support

Industry consensus-based organizations have demonstrated the maturity of the NCVHS-recommended standards to support health care business needs and described the opportunities inherent in the adoption of health care attachments standards to integrate administrative and clinical data, such as in automating and streamlining workflows that, today, are primarily manual processes and sources of significant administrative burden.

WEDI (*https://www.wedi.org/*) is a public-private coalition formed by HHS in 1991 to serve as an advisory body on the use of health IT aimed at health care information exchange. WEDI, which section 1172(c)(3) of the Act identifies as an entity required to be consulted with respect to standards adoption, published a November 2017 white paper, in concert with X12 and HL7.[4] That white paper, described by WEDI as ''a single resource document for implementers to use to help them get started in their implementation planning for the request and receipt of electronic attachments,'' details the business and operational processes of exchanging additional information (attachments) using the HL7 standards for clinical information and the X12 transaction sets for requesting and transmitting the additional information. Its contents, which we have taken into account in this proposed rule, include all of the following:

- An overview of attachments.
- A discussion of resources needed to have a successful implementation of attachments standards.
- A review of current processes for requesting and responding to the need for attachment information.
- Examples of implementation approaches in the industry.
- A review of Electronic Attachment Business flows for Claims, Prior Authorizations and Notification.
- Business use cases and examples.
- Guidance on how to embed additional information within the applicable X12N transaction.

In May 2019, CAQH CORE issued a document titled ''Report on Attachments: A Bridge to a Fully Automated Future to Share Medical Documentation,'' [5] where it reported evidence from its 2018 environmental scan indicating a high degree of industry readiness and interest in the attachments standard. The report noted that ''the healthcare industry continues to wait for an electronic attachments standard that can simplify the exchange of necessary medical information and supplemental documentation'' and that ''health plans, providers and vendors lack the direction needed to support broad use of automation in the attachment workflow, or for industry to coalesce around the use of even a small number of electronic solutions,'' leading to largely manual, and often paper-based, processes, and ultimately underscoring the need to standardize electronic attachment exchange methods.

Shortly after, in July 2019, CAQH CORE released another report titled ''Moving Forward: Building Momentum for End-to-End Automation of the Prior Authorization Process.'' [6] There, CAQH CORE reported how, for even the HHS-adopted prior authorization transaction standards, health care industry uptake

[3] ''Recommendations to Modernize Aspects of HIPAA and Other HIT Standards to Improve Patient Care and Achieve Burden Reduction,'' available at *https://ncvhs.hhs.gov/wp-content/uploads/2022/04/Recommendation-Letter-HIT-Standards-Modernization-to-Improve-Patient-Care-March-30-2022.pdf* (March 2022)

[4] ''Guidance on Implementation of Standard Electronic Attachments for Healthcare Transactions,'' available at *https://www.wedi.org/2017/11/17/guidance-on-implementation-of-standard-electronic-attachments-for-healthcare-transactions/* (November 2017).

[5] ''CAQH CORE Report on Attachments: A Bridge to a Fully Automated Future to Share Medical Documentation,'' available at *https://www.caqh.org/sites/default/files/core/core-attachments-environmental-scan-report.pdf* (April 23, 2021).

[6] ''Moving Forward: Building Momentum for End-to-End Automation of the Prior Authorization Process,'' available at *https://www.caqh.org/sites/default/files/core/white-paper/CAQH-CORE-Automating-Prior-Authorization.pdf* (April 23, 2021).

lagged that of other transaction standards, and remained largely paper-based, due in large measure to a lack of infrastructure supporting electronic transmission of attachments that frequently serve as necessary supporting documentation in the prior authorization transaction.

2. Other Recent Public Comment Support

On June 11, 2019, CMS published a request for information (RFI) in the **Federal Register** titled ''Reducing Administrative Burden To Put Patients Over Paperwork'' (84 FR 27070). Particularly with respect to prior authorization, that RFI solicited public comment on ideas for regulatory, subregulatory, policy, practice, and procedural changes to reduce unnecessary administrative burdens for clinicians, providers, patients, and their families, with an aim to improve quality of care, lower costs, improve program integrity, and make the health care system more effective, simple, and accessible. To be clear, the RFI did not relate to, and was not for the purpose of, soliciting comments on HHS's efforts pertaining to HIPAA Administrative Simplification, but, nevertheless, many commenters, including organizations representing physician provider groups, insurance payers, health technology vendors, health care financial managers, and HIT standard advisory bodies, called for the release of an electronic attachments proposed rule to be accelerated, as well as guidance on other standards such as electronic signature protocols to achieve these goals. These commenters indicated that a HIPAA attachments transaction standard regulation could help reduce administrative burden in many clinical and administrative situations where documents need to be shared, and relieve providers of current burdensome, largely paper-based, processes.

In preparation for its August 25, 2020 Standards Committee Meeting, the NCVHS invited the public to provide feedback on the CAQH CORE operating rules for prior authorization transactions.[7] Commenters expressed their support for an attachments transaction standard regulation. In addition, commenters provided input on current standards development efforts underway to address prior authorization challenges, including recommendations for the Secretary to explore or allow the use of other standards or alternative approaches.

We solicit comments on other standards or alternative approaches in development, for example the use of FHIR Clinical Data Exchange (CDex) as discussed in an NCVHS recommendation letter,[8] including how they may be considered ''consistent with the X12 Version 5010 transaction standards.''

III. Provisions of the Proposed Rule

A. Overview

This rule proposes to adopt new standards and modify a currently adopted standard which we believe would meet a health care business need to integrate administrative and clinical data. These proposed actions would facilitate streamlined prior authorization processes that would help minimize clinical response times, reduce potential barriers to the transition to value-based payments, and significantly reduce administrative burden on provider and health plan organizations.[9] Consistent with NCVHS recommendations and collaborative industry organizations and stakeholders' input, we believe these industry consensus-based standards are sufficiently mature for adoption and that covered entities are ready to implement them.

Nearly every health plan has various requirements for health care providers to sometimes submit additional information beyond that contained in a HIPAA transaction. These requirements may be communicated to providers via contracts, manuals, or online databases of payment rules. This additional information may enable a health plan to make an administrative decision regarding whether a particular service is ''covered,'' or about the medical necessity of a service a provider has rendered or intends to render, or for other purposes. The information a health plan requires may, for example, include medical documentation to support health care claims payment, referral authorizations, enrollee eligibility inquiries, coordination of benefits, workers' compensation claims, post-payment claims auditing, and provider dispute resolution.[10]

A health care provider may transmit attachment information either in response to a health plan's specific request for the information (solicited), or, in certain situations, in the absence of a specific request (unsolicited). A ''solicited'' attachment transmission occurs where a health care provider transmits an attachment pursuant to a health plan's specific electronic request for attachment information. Conversely, a health care provider's transmitting to a health plan electronic attachment in the absence of a health plan's specific electronic request is known as an ''unsolicited'' transmission, and usually occurs pursuant to pre-established requirements for attachment information set forth in trading partner agreements or other guidance that specifies when additional information must be submitted to support certain diagnoses, items, services, or medications.

Although providers may transmit this additional information electronically via an attachment to a transaction, currently providers frequently transmit via manual processes that often involve paper mail, fax, and phone because there are no adopted HIPAA standards for health care attachments.

We are proposing standards herein to address these issues; in doing so, we need to define the term ''attachment information.''

B. Proposed Definition of Attachment Information

We propose to define ''attachment information'' at § 162.103 as documentation that enables the health plan to make a decision about health care that is not included in either of the following:

- A health care claims or equivalent encounter information transaction, as described in § 162.1101.
- A referral certification and authorization transaction, as described in § 162.1301(a) and the portion of § 162.1301(c) that pertains to authorization.

We use the term ''attachment information'' in our proposed definition of the health care attachments transaction at § 162.2001 to specify the information transmitted by a health care provider or requested by a health plan. We are proposing to separately define ''attachment information'' to prevent the transaction definition at § 162.2001 from becoming too unwieldy.

[7] *https://ncvhs.hhs.gov/wp-content/uploads/2020/10/Public-Comments-CAQH-CORE-Operating-Rules-for-Federal-Adoption-August-2020r.pdf*

[8] *https://ncvhs.hhs.gov/wp-content/uploads/2022/04/Recommendation-Letter-HIT-Standards-Modernization-to-Improve-Patient-Care-March-30-2022.pdf.*

[9] CAQH CORE Report on Attachments: ''A Bridge to a Fully Automated Future to Share Medical Documentation'', CAQH CORE, May 9, 2019: *https://www.caqh.org/about/press-release/caqh-core-study-reveals-five-opportunities-increase-electronic-exchange-medical.*

[10] Letter from NCVHS to the Secretary of HHS, March 2, 2012: *https://ncvhs.hhs.gov/wp-content/uploads/2014/05/120302lt1.pdf.*

The NCVHS recommended defining attachments as ''any *supplemental documentation needed* about a patient(s) to support a specific health care-related event (such as a claim, prior authorization, or referral) using a standardized format,'' and we have incorporated key aspects of their recommendation into our proposed definition of attachment information.[11] We have attempted to ensure that our proposed definition is broad and general enough to include all possible patient-related information that could be generated with respect to health care services, and have done this in several ways.

Documentation: First, we believe the word ''documentation,'' which the NCVHS recommended and that we include in our proposed definition, is adequately broad to indicate the wide scope of information the definition should cover.

Supplemental: Second, the NCVHS recommended the definition specify that the documentation be ''supplemental.'' In and of themselves, the health care claims and prior authorizations transactions, which the proposed health care attachments transactions would support, do not provide the documentation that would be furnished by a health care attachments transaction. To express that the documentation would be supplemental, our proposed definition indicates that we are referring to documentation ''that is not included'' in a health care claims transaction or prior authorization transaction, and we include specific references to the regulatory provisions defining the health care claims and prior authorization transactions. Should we propose to adopt health care attachments transaction standards to support additional transactions, we would likely propose to broaden our definition of attachment information to include regulatory references to them.

Needed: Third, the NCVHS recommended that the definition specify the supplemental documentation should be ''needed'' by a health plan to enable it to decide whether to pay a claim or authorize the provision of health care; our proposed definition accounts for this with the language ''enables the health plan to make a decision about health care.''

[11] NCVHS Letter to the Secretary of HHS on Recommendations for the Electronic Health Care Attachment Standard, July 5, 2016: *https://ncvhs.hhs.gov/wp-content/uploads/2018/03/2016-Ltr-Attachments-July-1-Final-Chair-CLEAN-for-Submission-Publication.pdf.*

C. Proposed Code Set, Transaction Definitions, and Standards

We are proposing to adopt certain industry consensus standards that, when used together, provide the functionality necessary for the transmission of electronic health care attachment information.[12] In this section, we describe proposed new requirements for: (1) a code set to be used for health care attachments transactions; (2) X12 standards for requesting and transmitting attachment information and HL7 standards for clinical information content; and (3) electronic signatures standards.

1. Code Set (LOINC for HIPAA Attachments)

Health plans and health care providers must have a clear and unambiguous way to specify attachment information—for example, a discharge summary, surgical operation note, or cardiovascular disease consult note—to be transmitted or requested in a health care attachments transaction.

The LOINC code set was developed for the following three principal purposes:

- To identify the specific kind of information that a health plan electronically requests of a health care provider and a health care provider electronically transmits to a health plan; for example, a discharge summary or a diagnostic imaging report.
- To specify certain optional modifier variables for attachment information, such as, for example, a time period for which the attachment information is requested.
- For structured attachment information, to identify specific HL7 Implementation Guide: LOINC Document Ontology document templates.

This rule proposes numerous implementation specifications containing specific instructions for how to utilize the LOINC for HIPAA Attachments with respect to those three purposes. Where an implementation specification requires the use of LOINC, it instructs users to utilize the codes valid at the time a transaction is initiated, similar to how other nonmedical data codes sets in HIPAA implementation specifications are treated. Regenstrief's website maintains online tools to help users search the LOINC database for specific LOINC codes or map local terms to LOINC codes (*https://loinc.org/attachments*). To improve ease of use, Regenstrief released and enhanced the search functionality to the SearchLoinc tool (*https://loinc.org/search-app/*). In addition, Regenstrief offers the LOINC Attachments Knowledge Base (*https://loinc.org/attachments*) to help users better find and utilize LOINC codes and resources such as mapping. Regenstrief maintains a twice-yearly release cycle, and covered entities would be expected to utilize the LOINC for Attachments codes, as specified by the relevant implementation specification. In our discussion of each implementation specification, we describe in more detail how each uses LOINC.

2. Electronic Health Care Attachments Transactions

In this section, we propose to adopt standards for requesting and transmitting attachment information (as we have proposed to define that term in § 162.103). We are proposing to adopt X12 standards with respect to the transmission of attachment information and HL7 standards with respect to the clinical content of attachments. Specifically, as detailed in the sections that follow, we are proposing to adopt three X12N Technical Report Type 3 (TR3) implementation specifications for requesting and transmitting attachment information, and three HL7 implementation guides for the clinical information embedded in those transactions. While CAQH CORE has developed operating rules for attachments, the NCVHS has yet to evaluate them and make a recommendation to the Secretary. Should the NCVHS recommend that the Secretary adopt those operating rules, we will consider adopting them.

a. Scope of Health Care Attachments Transactions

Section 1173(a) of the Act requires the Secretary to adopt standards for ''Health claims attachments,'' and section 1104(c)(3) of the Affordable Care Act reiterated that requirement, directing the Secretary to promulgate a final rule to adopt a transaction standard and a single set of associated operating rules. The attachments standards we are proposing satisfy the requirement to adopt a standard to support health care claims, but they also support prior authorization transactions. Hereafter we refer to ''health care attachments'' to refer to attachments for claims as well as prior authorization transactions

[12] For additional information about the business and operational processes involved in the exchange of these standards, we refer readers to the aforementioned November 2017 WEDI whitepaper and the HL7 CDA® R2 Attachment Implementation Guide: Exchange of C–CDA Based Documents, Release 1 Release 1 (Universal Realm) for more technical information. Both are available at: *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=464.*

instead of ''health claims attachments,'' which only includes the former.

Historically, the referral certification and authorization transaction has had among the lowest implementation rates of all the HIPAA transactions, likely attributable to the fact that we have not yet adopted standards for attachments. In a 2016 report, the CAQH CORE Index[13] noted that the uptake rate for such transactions being conducted fully electronically was only 18 percent, even 5 years after the adoption of Version 5010 of the X12 278 standard. The report also indicated that more than 50 percent of prior authorization transactions were conducted through proprietary web portals and automated phone calls as a means to conform to business processes due to the lack of an adopted health care attachments standard. Four years later, the 2020 CAQH Index reported only limited progress, with the uptake rate having increased to only 21 percent. As we have discussed, health plans frequently require attachment information before approving requests for prior authorization for health care services. Although section 1173(a)(1)(A) of the Act does not specifically require the Secretary to adopt attachments standards with respect to prior authorization transactions, section 1173(a)(1)(B) of the Act requires the Secretary to adopt standards for other appropriate financial and administrative transactions, consistent with the goals of improving the operation of the health care system and reducing administrative costs.

However, we are not proposing to adopt attachments standards for all health care transaction business needs. Not only would it be challenging to identify standard specifications and appropriate codes for the full array of different health care attachment types used today, but we also believe it is important that covered entities should consider gaining experience with a limited number of standard electronic attachment types so that technical and business issues can be identified to inform potential future rulemaking for other electronic attachments standards.

We request comment on alternative standards and approaches that can address the challenges described previously.

[13] CAQH CORE ''2016 CAQH INDEX® A Report of Healthcare Industry Adoption of Electronic Business Transactions and Cost Savings'' *https://www.caqh.org/sites/default/files/explorations/index/2016-caqh-index-report.pdf?token=qV_hI4H5.*

b. Proposed Definition of the Health Care Attachments Transaction

We are proposing to add a new Subpart T to 45 CFR part 162—Health Care Attachments. In Subpart T, in new § 162.2001, we are proposing to specify the electronic health care attachments transaction; specifically, we are proposing that any of three different types of transmissions would constitute a health care attachments transaction. For each type of transmission, we specify the entity type from which the transaction is being transmitted and to which it is being sent, the type of information being transmitted, and the purpose for the transaction. We note that the overarching purpose for all three types of transactions—to enable a health plan to make a decision about health care—is incorporated into the definition of attachment information, while for the two transmission types in § 162.2001(a), and as discussed later in this section, we further specify the purpose.

We are proposing the following three types of transmissions:

- In § 162.2001(a)(1) and (a)(2), a health care attachments transaction is either of two different types of transmissions, both of which are sent from a health care provider to a health plan and where the type of information being transmitted in both is attachment information.
- In § 162.2001(b), a health care attachments transaction is one type of transmission that is sent from a health plan to a health care provider, and where the type of information being transmitted is a request for attachment information.

The purpose for the transmission described in § 162.2001(a)(1) is to support a referral certification and authorization transaction, as described in § 162.1301(a), while the purpose for the transmission described in § 162.2001(a)(2) is to support a health care claims or equivalent encounter information transaction, as described in 162.1101. We are also proposing to make a conforming change to the definition of ''transaction'' in § 160.103, by replacing ''(10) Health claims attachments'' with ''(10) Health care attachments.''

3. Proposed Adoption of Electronic Health Care Attachments Transaction Standards

As noted earlier, the NCVHS has held a number of hearings and made several sets of recommendations to the Secretary on attachments standards.[14] By letter dated July 5, 2016, the NCVHS consolidated its earlier recommendations on attachments and advised that updated versions of the available standards were ready for industry use, noting that one of the most significant findings from its February 16, 2016 hearing was the general consensus across testifiers about the need for HHS to adopt the NCVHS-recommended standards.[15] The NCVHS noted that it considered a number of criteria and factors in evaluating standards, particularly whether candidates would meet the goals of administrative simplification. Among other recommendations, the NCVHS advised that attachments standards for queries, and both solicited and unsolicited responses, should support structured and unstructured data. The NCVHS concluded that its recommended standards meet the industry's business needs, improve administrative efficiency and reduce administrative burden, are flexible and agile to meet future technology developments and health system changes, and are mature, adoptable, and enforceable.

The NCVHS noted that its recommended standards represented a collaboration between X12 and HL7, with X12 providing for existing provider/payer EDI, and HL7 providing for the CDA. Specifically, the NCVHS recommended that HHS adopt the following standards for attachment-related transactions:

- For requesting attachments, the following standards:

++ For claim-related attachment requests, the ASC X12N 277 Health Care Claim Request for Additional Information.

++ For non-claim-related attachment requests, the ASC X12N 278 Health Care Service Review—Request for Review and Response—Response.

- For attachment message content and format in the transmission of attachment information, the following standards:

++ The HL7 CDA R2—Consolidated CDA Templates for Clinical Notes R2.1.

++ The HL7 Attachment Supplement Specification Request and Response Implementation Guide R1.

++ The Attachment Type Value Set: Logical Observation Identifier Names and Codes (LOINC) developed and maintained by the Regenstrief Institute, Inc.

[14] *https://ncvhs.hhs.gov/reports/recommendation-letters/.*

[15] See ''Recommendations for the Electronic Health Care Attachment Standard,'' *https://ncvhs.hhs.gov/wp-content/uploads/2018/03/2016-Ltr-Attachments-July-1-Final-Chair-CLEAN-for-Submission-Publication.pdf.*

++ The HL7 Implementation Guide for CDA Release 2: Additional CDA R2 Templates—Clinical Documents for Payers—Set 1.

• For the routing/envelope of attachment information, the following standards:

++ The ASC X12N 275 Additional Information to Support a Health Care Claim or Encounter.

++ The ASC X12N 275 Additional Information to Support a Health Care Services Review.

The health care attachments standards we are proposing are those recommended by the NCVHS, and discussed in its July 5, 2016 letter to the Secretary. Also, as previously discussed, section 1104(c)(3) of the Affordable Care Act requires that the adopted attachments standard be ''consistent with the X12 Version 5010 transaction standards,'' which we interpret as requiring that the proposed health care attachment implementation specifications be compatible with X12 standards generally, meaning any standard we adopt for attachment information can be electronically transmitted by an X12 transmission standard in the same transaction.

While the NCVHS did not recommend specific versions of the X12N attachments standards, we are proposing to adopt the X12N Versions 6020 for both the X12N 277 standard, that is, the X12N 277—Health Care Claim Request for Additional Information (006020X313), as well as for the X12N 278—Health Care Services Request for Review and Response Version (006020X315) standard for the referral certification and authorization transaction. We are proposing to adopt Version 6020 of these standards because they better harmonize with the X12N 275—Additional Information to Support a Health Care Claim or Encounter Version (006020X314) and the X12N 275—Additional Information to Support a Health Care Services Review Version (006020X316) standards we are proposing to adopt for a provider to transmit attachment information.

Although it may be possible to use different versions of the standards for health plan requests for, and provider transmissions of, attachment information, X12 recommended to the NCVHS that all parties to those transactions use Version 6020 of the standards as they are most compatible with each other.[16]

a. Proposed Adoption of X12N Standards for Health Care Attachments Transactions

(1) Proposed Adoption of Standards for Request From a Health Plan to a Health Care Provider for Attachment Information

(a) X12N 277—Health Care Claim Request for Additional Information (006020X313)

At § 162.2002(e)(1), we propose to adopt the X12N 277—Health Care Claim Request for Additional Information (006020X313) as the standard a health plan must use to electronically request attachment information from a health care provider to support a health care claim. We also propose to incorporate the same by reference in § 162.920.

The X12N 277 contains two noteworthy fields, which we discuss sequentially. The first is the health plan assigned claim control number, which allows for document reassociation. A health plan assigns a claim control number to associate its request with a provider's electronic health care claim. The health care provider then uses the health plan assigned claim control number in the X12 275 standard in the health care attachments transaction, discussed later in this proposed rule, that it transmits to the health plan, enabling the health plan to associate the attachment information with the previously submitted health care claim.

The other noteworthy X12N 277 field is for LOINC for HIPAA Attachments. The X12N 277 standard requires the use of the appropriate LOINC for HIPAA Attachments data element to identify the specific attachment information the health plan is requesting. The previously referenced 2017 WEDI whitepaper illustrates how the LOINC code is used in an X12 277 standard in the following hypothetical scenario: A provider performs a particular surgery for which there is no HCPCS code and sends the health plan a health care claim using a Not Otherwise Classified (NOC) procedure code. The health plan requires additional information about the procedure to adjudicate the claim, and sends the health care provider an X12N 277 Health Care Claim Request for Additional Information request using the appropriate LOINC for HIPAA Attachments code to specify the surgical operative note it needs.[17]

(b) X12N 278—Health Care Services Request for Review and Response (006020X315)

At § 162.2002(e)(2), we propose to adopt the X12N 278—Health Care Services Request for Review and Response (006020X315) as the standard a health plan must use to electronically request attachment information from a health care provider to support a prior authorization transaction. We also propose to incorporate the same by reference in § 162.920. The X12 278 standard is unique in that it is also used for a health care provider's request for prior authorization, as reflected at § 162.1302(b)(2)(ii). We are proposing to adopt Version 6020 of that standard, which would represent a modification to the currently adopted Version 5010 of the X12N 278. As we discussed previously, the NCVHS indicated that the updated version, that is, Version 6020, of the X12 278 is more compatible with the Version 6020 X12N 275 standard we are proposing for a health care provider's transmission of an attachment information transaction to a health plan in support of a prior authorization request. Version 6020 of the X12 278 also contains the same two noteworthy fields as the X12N 277, that is, the health plan assigned claim control number and the field for LOINC for HIPAA Attachments. In section II.D. of this proposed rule we discuss our proposed modification to update the current HIPAA standard, Version 5010 of the X12 278, to Version 6020.

(2) Proposed Adoption of Standards for Response From a Health Care Provider to a Health Plan for Attachment Information

(a) X12 275—Additional Information to Support a Health Care Claim or Encounter (006020X314)

We propose to adopt, at § 162.2002(d), the X12N 275—Additional Information to Support a Health Care Claim or Encounter (006020X314) as the standard a provider must use to electronically transmit attachment information to a health plan to support a health care claims or equivalent encounter information transaction. We also propose to incorporate the same by reference in § 162.920.

The X12N 275—Additional Information to Support a Health Care Claim or Encounter standard may be used with respect to both solicited and unsolicited attachment information. Using the previous example of a surgery for which there is not a HCPCS code, in the case where a health plan has solicited attachment information, the provider would reply to the X12N 277

[16] Transcript of NCVHS Subcommittee on Standards Hearing on Electronic Attachments Standards and Operating Rules, February 27, 2013: *https://ncvhs.hhs.gov/transcripts-minutes/transcript-of-the-february-27-2013-ncvhs-subcommittee-on-standards-hearing/.*

[17] Workgroup for Electronic Data Interchange (WEDI), ''Guidance on Implementation of Standard Electronic Attachments for Healthcare Transactions'' *https://www.wedi.org/2017/11/17/guidance-on-implementation-of-standard-electronic-attachments-for-healthcare-transactions/.*

request from the plan using the X12N 275 to convey the operative note as the attachment information. In the unsolicited scenario, the provider could concurrently transmit the X12N 275—Additional Information to Support a Health Care Claim or Encounter and a claim using the X12N 837 to enable the health plan to make a decision about the claim at the time of initial claim processing.

We note that the X12N 275—Additional Information to Support a Health Care Claim or Encounter claims attachment standard, as well as the X12N 275—Additional Information to Support a Health Care Services Review prior authorization standard (discussed in this section of this proposed rule), do not themselves contain claim or prior authorization attachment information. Rather, the standards serve as the electronic envelope for attachment information that is embedded in an HL7 standard. We describe in detail the specific HL7 standards for embedding attachment information in this section of the proposed rule, but the critical concept is that the health care attachment information is transported by the X12N 275 standard.

(b) X12N 275—Additional Information To Support a Health Care Services Review (006020X316)

We propose, at § 162.2002(c), to adopt the X12N 275—Additional Information to Support a Health Care Services Review (006020X316) as the standard a provider must use to electronically transmit attachment information to a health plan to support a health care provider's request for the review of health care to obtain an authorization for the health care; in other words, a prior authorization request. We also propose to incorporate the same by reference in § 162.920.

As we described in greater detail in our proposal to adopt the X12 275—Additional Information to Support a Health Care Claim or Encounter, this standard also can be sent in a solicited or unsolicited manner. Using our example of a surgery for which there is no HCPCS code, for solicited attachment information the provider would reply to the X12N 278 request from the health plan using the X12N 275 standard that conveys the operative note. In the unsolicited scenario, the provider could concurrently transmit the X12N 275 Additional Information to Support a Health Care Services Review and a prior authorization request using the X12N 278 to enable the health plan to make a decision about the prior authorization without additional requests for information.

B. Proposed Adoption of HL7 Implementation Guides for Health Care Attachment Information

The HL7 CDA standard is the only currently available SSO-created, NCVHS-recommended standard in the United States with published implementation specifications designed to support the HIPAA transactions. Other standards for the exchange of clinical information are being developed and piloted but, due in part to its readiness, we believe the HL7 CDA is the most appropriate standard for adoption at this time.

We are proposing to adopt the following three HL7 implementation guides as HIPAA standards for the attachment information included in health care attachments transactions:

- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 1—Introductory Material, June 2019 with Errata (hereafter Volume One or C–CDA Volume One or C–CDA 2.1)
- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 2—Templates and Supporting Material, June 2019 with Errata (hereafter Volume Two or C–CDA Volume Two or C–CDA 2.1)
- HL7 CDA R2 Attachment Implementation Guide: Exchange of C–CDA Based Documents, Release 1, March 2017 (hereafter the Attachment Implementation Guide)

Generally, the Attachment Implementation Guide specifies how to combine HL7 and X12 standards to transmit health care attachments transactions. For example, it contains instructions with respect to how to construct electronic health care attachments transactions, including how to attach and send the attachment information using the proposed X12N health care attachments standards. It also contains instructions for health plans to utilize the necessary LOINC codes for health plans to request health care attachments from a health care provider, and for providers to identify health care attachments document templates when transmitting them to a health plan. For the transmissions described in proposed § 162.2001, that is, transmissions of attachment information from a health care provider to a health plan for the specified purposes, and requests for attachment information from a health plan to a health care provider, we would require the use of the Attachment Implementation Guide at § 162.2002(a). We propose to incorporate this HL7 standard by reference in § 162.920 in a new paragraph (e) where we provide information about the availability of the HL7 standards we are proposing.

We are also proposing that for the transmissions of attachment information from a health care provider to a health plan for the specified purposes, as described in proposed § 162.2001(a), we would require the use of Volume One and Volume Two, and would include these requirements at § 162.2002(b)(1) and (b)(2), respectively. Collectively, these standards are instructions for the use of specific sections of the CDA, a larger set of clinical information standards developed by HL7, that provide specifications for users to create the HL7 document templates for the clinical information that would be used in the proposed health care attachments transactions.

Attachment information comes in two variants, ''structured'' and ''unstructured,'' and the proposed HL7 standards support both. A structured document is one that has a high degree of organization that is able to be interpreted by a computer, includes a header that contains metadata about the clinical information found in the body of the document, and a structured body. The clinical information contained in the document is subdivided into systematic sections and entries that can be identified and sorted by a computer using descriptive codes. HL7 Volume One and Volume Two instruct readers how to assemble the segments into a standardized set of document sections known as a document ''template,'' which is essentially a set of C–CDA components identified by a LOINC code, and include templates for the most common paper documents that serve as attachment information. An HL7 structured template is in a format that can be easily displayed in a human-readable format, while also enabling a computer to make an automated decision about a claim or a prior authorization request. Volume One and Volume Two also contain instructions for creating an unstructured document template for attachment information for which HL7 has not created a structured template. Unstructured documents still utilize an HL7 standard header that includes meta-data about the clinical information found in the document body, but the body does not contain tags that systematically identify the attachment information within. Examples of unstructured documents include medical imaging files, audio, video, and legacy attachment information such as scanned paper

documents. Unstructured content may also include attachment information that is not collected in a health care environment, but that a health plan may require for payment decisions, such as delivery receipts, home inspection reports, or patient-created diabetic logs.

The Attachment Implementation Guide also specifies how to construct a health care attachments transaction when Volume One or Volume Two do not provide a document template for particular attachment information. The Attachment Implementation Guide contains three criteria that any document template to be used as a health care attachment must meet if it is not already specified in one of the proposed implementation guides: (1) the template must be developed and published through the HL7 standards process; (2) the new template must be designated by HL7 as being compatible with a C–CDA 2.1 implementation specification and for use in the United States; and (3) a LOINC code for the template must be created by Regenstrief via its code creation process as previously described. This means that once a C–CDA 2.1 implementation guide-compatible document template has been created by HL7 and is assigned a LOINC code, which happens upon request of the HL7 Payer/Provider Information Exchange Workgroup once HL7 creates a new template, it may be used as attachment information in a health care attachments transaction. We invite comment on the proposed adoption of the HL7 standards—Volume One, Volume Two, and the Attachment Implementation Guide.

C. Electronic Signatures

Section 1173(e)(1) of the Act provides that the Secretary, in coordination with the Secretary of Commerce, must adopt standards specifying procedures for the electronic transmission and authentication of signatures for HIPAA transactions. Pursuant to that requirement, we proposed to adopt standards for electronic signatures in the August 12, 1998 proposed rule (63 FR 43242) titled ''Security and Electronic Signature Standards.'' That proposal, never finalized with respect to electronic signatures, would not have required the use of electronic signatures with any specific transaction. Rather, the proposed rule recognized that electronic signatures would require certain implementation features, including message integrity, nonrepudiation, and user authentication, and proposed that the standard for electronic signatures would be digital signatures—electronic stamps that contain information about both the user creating the signature and the document being signed—as the only technically mature means available that could provide for nonrepudiation in an open network environment. In comments on the proposed rule, industry overwhelmingly indicated that then-available technology was insufficient to enable the proposed provisions to be implemented. As such, in the February 20, 2003 final rule (68 FR 8334) titled, ''Health Insurance Reform: Security Standards'' (hereafter, February 2003 Security rule), we elected not to finalize the proposal, instead indicating that a final rule on electronic signature standards would be published at a later date. In the September 23, 2005 proposed rule titled HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments (70 FR 55990), we recognized that an electronic signature consensus standard still did not exist and that no federal standard governed the use of electronic signatures for private sector health care services. We sought industry input on how signatures should be handled when an attachment is requested and transmitted electronically.

Signatures play a vital role with respect to the documentation of health care, as a signature is often the only indicator available to health plans and health care providers that attachment information has been reviewed and approved by the service provider or other clinician with appropriate authority to supervise care. Health care entities recognize numerous legal and compliance best practices for clinician attestation of medical record documentation consistent with applicable federal and state laws and regulations, accreditation standards, payer requirements, documentation requirements for clinical services offered, and technology functionalities.[18]

Health care best practices, such as those of the National Committee for Quality Assurance (NCQA), generally direct that all entries in the medical record contain the author's identification.[19] A health care providers' signature (whether wet—in ink on paper documents—or electronic) on medical record documentation generally serves as the attestation that the appropriate provider representative has reviewed and approved the documentation. Health plans commonly require written and signed documentation as evidence of medical necessity for certain types of services. For example, in order for a laboratory to submit a claim for reimbursement of a laboratory test, a health plan may first require a physician visit and a signed physician order. When the laboratory later bills a health plan for the test, the plan may ask for evidence that it was ordered by an authorized health care provider; if the laboratory is unable to produce a signed order, it may not be reimbursed.

1. Proposed Definition of Electronic Signature

An electronic signature can be any of a number of types of marks or data that indicate a signatory's intent to sign. Examples of electronic signatures include an online check box indicating acceptance, a name entered by the signer in an online form, a signing device at a commercial checkout line on which a customer writes his or her signature, and an image of a signature that was written by hand and then scanned into an electronic image format.

We are proposing to define the term ''electronic signature'' as broadly as possible to ensure that it meets health care providers' and health plans' needs now and can also encompass future electronic signature technologies. However, we propose to narrowly specify the scope of the required use of electronic signatures, such that their required use would be limited to just attachment information transmitted electronically in electronic health care attachments transactions. Accordingly, the electronic signature standard we are proposing at § 162.2002(f) would pertain only to electronic signatures for attachment information transmitted by a health care provider in an electronic health care attachments transaction.

At § 162.103, we propose to define electronic signature as follows: Electronic signature means an electronic sound, symbol, or process, attached to or logically associated with attachment information and executed by a person with the intent to sign the attachment information.

[18] Electronic Signature, Attestation, and Authorship, AHIMA: *https://bok.ahima.org/PdfView?oid=107152.*

[19] ''Guidelines for Medical Record Documentation'', NCQA: *https://www.ncqa.org/wp-content/uploads/2018/07/20180110_Guidelines_Medical_Record_Documentation.pdf.*

2. Proposed Electronic Signature Standard

Electronic signatures vary in reliability and value based on the type of technology used, and any HIPAA electronic signature standard has to meet the needs of both health plans and health care providers that produce and use attachment information. Any standard that we adopt needs to support all of the current business functions and uses for signatures in the health plan payment decision process while providing assurance that attachment information is accurate and unaltered. The 1998 proposed rule that we mentioned previously, ''Security and Electronic Signature Standards,'' enumerated three implementation features necessary to achieve these goals: user authentication, message integrity, and non-repudiation (63 FR 43257). These core features, developed in conjunction with the Department of Commerce's National Institute of Standards and Technology and the health care industry, remain relevant to electronic signatures today. We discuss each in the following sections.

Authentication is the ability of a health plan to identify and verify the identity of the provider who signed a document, and is a vital signature characteristic because such verification serves to validate the attachment information. Just as a health plan might compare a physical signature to a signature card to authenticate a health care provider's identity, an electronic signature must provide a method of authentication. Some forms of electronic signatures do not allow for authentication; for example, a typed signature line in a word processing document that indicates it was signed by a physician does not have any unique traits that would permit authentication by a health plan.

Because some electronic signatures can be readily manipulated, there must also be a mechanism to ensure that signed attachment information remains unaltered since the time it was affixed; this feature is called message integrity. To maintain message integrity, there must be a way to electronically validate that the attachment information signed by the health care provider and sent to the health plan are identical. Without such a mechanism it would be possible, for example, to alter the amount or type of the medical item (such as, medication, durable medical equipment, a medical service, etc.) ordered by a physician after he or she had completed and signed the order.

Finally, an electronic signature standard must embody a feature known as nonrepudiation, which provides strong assurance of identity such that it is difficult for a signatory to later claim that the electronic representation is not valid or that he or she did not sign the document.[20] Nonrepudiation is a necessary feature of an electronic signature for health care attachments transactions because health plans will use attachment information to make administrative decisions about payment for health care services and may deny payment to a health care provider based on the information in electronically signed attachments.

An electronic signature standard must manifest each of these three features to suffice for attachment information in electronic health care attachments transactions. For example, were a signing system to incorporate authentication and nonrepudiation but lack a mechanism to ensure message integrity, a health plan could not be confident that the attachment information had not been altered since being signed. Or, were a signing system to incorporate nonrepudiation and message integrity but lack a mechanism for authentication, the health plan receiving the attachment information would be assured that the content had not been altered and that someone had signed, but it could never be certain of the actual signatory. In the previously discussed 1998 and 2005 proposed rules, HHS identified digital signature technology as the only electronic signature approach offering the features of authentication, message integrity, and nonrepudiation. We continue to believe that digital signature technology is the only electronic signature technology that supports all three features.

We considered proposing, as an electronic signature standard, the specifications for electronic signatures that are included in the HL7 implementation guides we are proposing here for electronic health care attachments transactions. But we decided not to pursue that route because the specifications included in those guides do not support authentication, message integrity, and nonrepudiation.

However, HL7 has also developed an implementation guide called the HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1 (hereafter Digital Signatures Guide), with supplemental specifications that add support for authentication, message integrity, and nonrepudiation to their other published implementation guides. The Digital Signatures Guide promotes these three features by utilizing digital signature technology to implement identity management using digital certificates, encryption requirements to support message integrity, and multiple signed elements to support nonrepudiation. As we previously noted, a digital signature is an electronic stamp that contains information about both the user creating the signature and the document that is being signed. Digital signatures are created using digital certificates to create a secure computer code that can be used later to authenticate the signer. At the same time, the certificate is used to create another computer code, usually referred to as a hash, which can be used by a computer to verify that the document has not been changed since it was originally signed; this is a mechanism to ensure the integrity of the signed document. In both cases, the codes are encrypted so the receiver knows that the codes themselves have also not been altered, enabling the receiver to be confident that the signature was applied by the authenticated individual.

We note that the Digital Signatures Guide does not include requirements for when a document must be signed and by whom. As previously discussed, requirements with respect to who may deliver health care and how it must be documented via signature vary greatly and are developed by health plans and outlined in their provider compliance manuals, trading partner agreements, and other contractual requirements between health plans and health care providers. We do not seek to regulate clinical best practices for documentation or interfere with health plans' business needs. Therefore, we are not proposing to specify when an electronic signature must be required, but, instead, we defer to the industry to continue to establish those expectations. We would also limit the scope of the required use of electronic signatures to just health care attachments transactions. Accordingly, we are proposing to require that, where a health care provider uses an electronic signature in a health care attachments transaction, the signature must conform to the implementation specifications in the Digital Signatures Guide. Specifically, we propose to adopt, at § 162.2002(f), the HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1 for electronic signatures for attachment information transmitted by a health care provider in an electronic health care attachments transactions

[20] Office of National Coordinator for Health Information Technology (ONC). Identity Management, December 6, 2017: *https://www.healthit.gov/sites/default/files/identitymanagementguidev5.13.pdf.*

specified in § 162.2001(a). We also propose to incorporate the same by reference in § 162.920.

We solicit comments on the proposed definition of electronic signature and the proposed HL7 Implementation Guide as the attachment information electronic signatures standard.

D. Proposed Modification to a HIPAA Standard

1. Modifications to Standards

Section 1174 of the Act requires the Secretary to review the adopted standards and adopt modifications to them as appropriate, but not more than once every 12 months. Modifications must be completed in a manner that minimizes disruption and cost of compliance. Per section 1175 of the Act, if the Secretary adopts a modification to a HIPAA standard or implementation specification, the compliance date for the modification may not be earlier than the 180th day following the date of the adoption of the modification. The Secretary must consider the time needed to comply due to the nature and extent of the modification when determining compliance dates, and may extend the time for compliance for small health plans if the Secretary deems it appropriate.

Section 162.910 sets out the standards maintenance process and defines the role of SSOs and Designated Standard Maintenance Organizations (DSMOs). An SSO is an organization accredited by the ANSI that develops and maintains standards for information transactions or data elements. The two SSOs applicable to this proposed rule are the Accredited Standards Committee X12 (X12) and Health Level Seven (HL7). On August 17, 2000, the Secretary designated six organizations (*see* Health Insurance Reform: Announcement of Designated Standard Maintenance Organizations Notice (65 FR 50373)) to maintain the health care transaction standards adopted by the Secretary, and to process requests for modifying an adopted standard or for adopting a new standard. The six organizations include X12, HL7, and NCPDP, along with the National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), and the Dental Content Committee (DCC) of the American Dental Association.

Section 162.910 also sets forth the procedures for the maintenance of existing standards and the adoption of modifications to existing standards and new standards. Under § 162.910(c), the Secretary considers recommendations for proposed modifications to existing standards or proposed new standards, only if the recommendations are developed through a process that provides for all of the following:

- Open public access.
- Coordination with other DSMOs.
- An appeal process for the requestor of the proposal or the DSMO that participated in the review and analysis if either were dissatisfied with the decision on the request.
- An expedited process to address HIPAA content needs identified within the industry.
- Submission of the recommendation to the NCVHS.

Any entity may submit change requests with a documented business case to support the recommendation to the DSMO, which receives and processes those change requests. The DSMO reviews the request and notifies the SSO of the recommendation for approval or rejection. Should the changes be recommended for approval, the DSMO also notifies the NCVHS and suggests that a recommendation for adoption be made to the Secretary of HHS. Information pertaining to the designation of a DSMO and its responsibilities can be found in the Transactions Rule and the Notice, which were both published on August 17, 2000 (65 FR 50365 and 50373).

The modification we are proposing in this rule was developed through a process that conforms with § 162.910. In February 2016, the NCVHS held hearings to review the Version 6020 X12N 278 implementation specifications as a standard for health care attachments transactions, which X12 recommended be adopted by HHS. Testimony from that hearing indicated the need for HHS to adopt the 6020 version of the X12N 278, which X12 testified resolves technical issues with Version 5010 of the X12N 278.[21] In its 2016 letter to the Secretary, the NCVHS recommended the adoption of the X12N 278 for health care attachments transactions, but did not recommend a specific version. Rather, the NCVHS recommended that the Secretary consider adopting the version expected to be in effect at the time the transactions standards are mandated.[22] Version 6020 of the X12N 278 is the most current version of the referral certification and authorization transaction standard.

2. Modification to Referral Certification and Authorization Transaction Standard

As just discussed, the NCVHS recommended that HHS adopt the referral certification and authorization transaction standard (ASC X12N 278) for non-claims-related attachment requests and responses. Although the NCVHS did not recommend a specific version of the standard, we are proposing to adopt Version 6020 of the X12N 278 because Version 6020 better harmonizes with the Additional Information to Support a Health Care Services Review Version—X12N 275–(006020X316) standard we are proposing to adopt for providers transmitting attachment information. As we also discussed, while it may be possible to use different versions of the standards for health plan requests for, and provider transmissions of, attachment information, X12 advised against it, recommending to the NCVHS [23] that all parties to those transactions use Version 6020 of the standards as they are most compatible with each other.

Adopting Version 6020 of the X12N 278 for referral certification and authorization transactions standard to replace Version 5010 of the X12N 278 would be a modification to a standard under HIPAA, similar to the previous modifications we adopted when we moved from Version 4010 to Version 5010 for the X12 standards. Version 6020 of the X12N 278 includes several changes, some of which are maintenance changes, and some of which represent more significant improvements over Version 5010. The two most significant changes each represent technical improvements and structural changes to the standard:

- One important change will better support referral certification and authorization transactions for dental services. Currently, health care providers are able to accurately report tooth status utilizing Version 5010 of the X12N 837 for health care claims, but Version 5010 of the X12N 278 cannot support reporting tooth status in health care referral certification and authorization transactions. Version 6020 of the X12N 278 expands support for reporting the status of individual teeth, which enables a health care provider to specifically indicate a missing tooth, extracted tooth, tooth to be extracted, or impacted tooth in a health care referral

[21] *https://ncvhs.hhs.gov/transcripts-minutes/transcript-of-the-february-16-2016-ncvhs-subcommittee-on-standards/.*

[22] *https://ncvhs.hhs.gov/wp-content/uploads/2018/03/2016-Ltr-Attachments-July-1-Final-Chair-CLEAN-for-Submission-Publication.pdf.*

[23] Transcript of NCVHS Subcommittee on Standards Hearing on Electronic Attachments Standards and Operating Rules, February 27, 2013: *https://ncvhs.hhs.gov/transcripts-minutes/transcript-of-the-february-27-2013-ncvhs-subcommittee-on-standards-hearing/.*

certification and authorization transaction. We expect this improvement in the X12N 278 to minimize or eliminate administrative delays attributable to providers having to convey relevant individual tooth information outside of the standard transactions process.

- Version 6020 revises and expands the drug authorization segment, which includes fields necessary to, for example, identify a drug, specify quantity of drug requested, specify drug dosage requested, and accommodate related procedure codes. Because Version 5010 does not enable entities to supply this additional information, health plans and providers must utilize cumbersome alternative methods to communicate drug information. Therefore, we also expect this improvement to minimize or eliminate administrative delays attributable to providers having to convey relevant drug information outside of the standard transactions process.

The referral certification and authorization transaction under § 162.1301 includes two transmission types from health care providers to health plans: prior authorization requests and referral certification requests. The X12N 278 standard is required for both types of transmission. As discussed, we are proposing that health care attachments transactions would apply to prior authorization transactions; we are not proposing that they apply to referral certification transactions. Although it would be technically feasible for us to propose to adopt Version 6020 only for prior authorization transmissions specified in § 162.1301(a) and retain Version 5010 for referral certification transmissions specified in § 162.1301(b), we are instead proposing Version 6020 for both transmission types because it includes improvements over Version 5010 that better support both transmission types, and we believe it would be more burdensome for covered entities to have to maintain both X12N 278 versions.

E. Proposed Compliance Dates

We are proposing to adopt new standards and a modification to a standard in this proposed rule. Section 1104(c)(3) of the Affordable Care Act, which requires the Secretary to adopt a transaction standard for health claims attachments, prescribes a 2-year compliance date for all covered entities and makes no special provision for small health plans, unlike the original HIPAA. In this rule, we are proposing that the same health care attachments standards would apply to both claims and prior authorization attachments transmissions. As the transmission standard for each type of attachment transaction transmission would be the same, we believe the compliance date for both types should also be the same. In addition, because we are proposing to treat the two attachments process together as one transaction in new Subpart T, adopting the same compliance timeframe for all covered entities would avoid the complications a bifurcated compliance timeframe—one for claims processes and another for prior authorization processes—would raise.

When the Secretary adopts a modification to a HIPAA standard, section 1175(b)(2) of the Act requires that the compliance date may not be earlier than the 180th day following the date of adoption. The Secretary must consider the time needed to comply due to the nature and extent of the modification when determining a compliance date, and may extend the time for small health plans to achieve compliance if the Secretary deems it appropriate. The adoption date of a standard or a modification is the effective date of the final rule in which the adoption or modification is established. The effective date is the date the rule amends the Code of Federal Regulations (CFR), which is typically 60 days after the date of publication in the **Federal Register**.

1. Proposed Compliance Date for Health Care Attachments and Electronic Signatures Standards

We are proposing to adopt the following seven standards for health care attachments transactions and electronic signatures:

- HL7 CDAR2: Attachment Implementation Guide: Exchange of C–CDA Based Documents, Release 1—March 2017.
- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 1—Introductory Material, June 2019 with Errata.
- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 2—Templates and Supporting Material, June 2019 with Errata.
- X12N 275 Additional Information to Support a Health Care Services Review (06020X316).
- X12N 275 Additional Information to Support a Health Care Claim or Encounter (06020X314).
- X12N 277—Health Care Claim Request for Additional Information (006020X313).
- HL7 Implementation Guide for CDA Release 2: Digital Signatures and Delegation of Rights, Release 1.

In accordance with section 1104(c)(3) of the Affordable Care Act, which sets a 2-year compliance date, and which makes no provision for an extended time for small health plans to achieve compliance, we are proposing that the compliance date for these standards would be 24 months after the effective date of the final rule for all covered entities. We would specify these compliance dates in § 162.2002.

2. Proposed Compliance Date for Modification

Section 1175(b)(2) of the Act requires the Secretary to determine an appropriate compliance date for the implementation of modified standards, such as the modification of the X12N 278 standard from Version 5010 to Version 6020, by taking into account the time needed to comply due to the nature and extent of the modification. The Act also requires that the compliance date be no earlier than the last day of the 180-day period beginning on the date the modification is adopted (the effective date of the final rule in which the modification is adopted). As discussed previously, we are proposing Version 6020 of the X12N 278 as the standard for referral certification and authorization transactions to be used by a health plan in conjunction with Version 6020 of the X12N 275, which a health care provider would use to electronically transmit attachment information to a health plan in support of a prior authorization request. As the X12N 278 will feature in the new health care attachments transaction, we believe it is important to align the compliance dates for the proposed modification to the X12N 278 standard and the health care attachments standards. Accordingly, we are proposing that covered entities would need to comply with Version 6020 of the standard 24 months after the effective date of the final rule. We would reflect this compliance date in § 162.1302 by: (1) revising paragraph (c) to specify only the standard identified in paragraph (b)(2)(i); and (2) adding new paragraph (d) to require covered entities to use, in paragraph (d)(1), Version 5010 X12N 278 for 24 months after the effective date of the final rule, and in paragraph (d)(2), Version 6020 X12N 278 on and after 24 months after the effective date of the final rule. We solicit comments on this proposed approach.

F. Proposed Incorporation by Reference

This proposed rule proposes to incorporate by reference: (1) X12 275—

Additional Information to Support a Health Care Claim or Encounter (006020X314); (2) X12N 275—Additional Information to Support a Health Care Services Review (006020X316); (3) X12N 277—Health Care Claim Request for Additional Information (006020X313); and (4) X12N 278—Health Care Services Request for Review and Response Version (006020X315) standard for the referral certification and authorization transaction implementation guides.

The X12 275—Additional Information to Support a Health Care Claim or Encounter implementation guide provides instructions to assist those who send additional supporting information or who receive additional supporting information to a health care claim or encounter. The implementation guide for X12N 275—Additional Information to Support a Health Care Services Review implementation guide contains the data elements used to communicate individual patient information requests and patient information (either solicited or unsolicited) between separate health care entities in a variety of settings to be consistent with confidentiality and use requirements. Instructions to collect patient information consisting of demographic, clinical and other supporting data are provided.

The X12N 277—Health Care Claim Request for Additional Information implementation guide contains the format and establishes the data contents of the Health Care Information Status Notification Transaction Set for use within the context of an Electronic Data Interchange (EDI) environment. This transaction set can be used by a health care payer or authorized agent to notify a provider, recipient, or authorized agent regarding the status of a health care claim or encounter or to request additional information from the provider regarding a health care claim or encounter, health care services review, or transactions related to the provisions of health care.

X12N 278—Health Care Services Request for Review and Response Version implementation guide contains the format. It establishes the data contents of the Health Care Services Review Information transaction set used within the context of an Electronic Data Interchange (EDI) environment. This transaction set can be used to transmit health care service information, such as subscriber, patient, demographic, diagnosis, or treatment data for the purpose of request for review, certification, notification, or reporting the outcome of a health care services review. Expected users of this transaction set are payors, plan sponsors, providers, utilization management, and other entities involved in health care services review.

This proposed rule proposes to incorporate by reference: (1) HL7 CDA R2 Attachment Implementation Guide: Exchange of C–CDA Based Documents, Release 1, March 2017; (2) HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 1—Introductory Material, June 2019 with Errata; and (3) HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 2—Templates and Supporting Material, June 2019 with Errata.

The HL7 CDA R2 Attachment Implementation Guide: Exchange of C–CDA Based Documents, Release 1, March 2017, defines the requirements for sending and receiving standards-based electronic attachments. It does so by applying additional constraints onto standards in common use for clinical documentation and by specifying requirements for sending and receiving systems for attachment requests and response messages. It defines the set of attachment documents as those that contain the minimum standard metadata to support basic document management functions, including identification of patients and providers, the type of document, date of creation, encounter information, and a globally unique document identifier.

HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 1—Introductory Material, June 2019 with Errata and HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 2—Templates and Supporting Material, June 2019 with Errata implementation guides contain a library of CDA templates, incorporating and harmonizing previous efforts from HL7. It represents the harmonization of the HL7 Health Story guides, HITSP C32, related components of IHE Patient Care Coordination (IHE PCC), and Continuity of Care (CCD). This R2.1 guide was developed and produced by the HL7 Structured Documents Workgroup. It updates the C–CDA R2 (2014) guide to support ''on-the-wire'' compatibility with R1.1 systems C–CDA Release 2.1 implementation guide, in conjunction with the HL7 CDA Release 2 (CDA R2) standard, is to be used for implementing the following CDA documents and header constraints for clinical notes.

The materials we propose to incorporate by reference are available to interested parties and can be inspected at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD 21244–1850. The X12 implementation guides are available at GLASS, *sso.x12.org.* The HL7 implementation guides are also available through the internet at *www.HL7.org.* A fee is charged for all implementation guides. Charging for such publications is consistent with the policies of other publishers of standards. If we wish to adopt any changes in this edition of the Code, we would submit the revised document to notice and comment rulemaking.

IV. Collection of Information Requirements

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. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The burden associated with the information collection requirements contained in § 162.1302 of this document are subject to the PRA; however, this one-time burden was previously approved and accounted for in the information collection request under OMB control number 0938–0866 and titled ''CMS–R–218: HIPAA Standards for Coding Electronic Transactions.'' This information collection request will be revised and reinstated to incorporate any proposed additional transaction standards and proposed modifications to transaction standards not currently captured in the PRA package associated with OMB approval number 0938–0866.

In addition, the collection requirements associated with this demonstration do not impose information collection and record

keeping requirements, because they meet the ''information'' definition exception under 5 CFR 1320.3(h)(4) which states: ''Information'' does not generally include items in the following categories: (4) Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration of the comment.

If you comment on this information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule. Comments must be received on/by February 21, 2023.

V. Regulatory Impact Analysis

A. Statement of Need

This rule proposes to adopt and modify standards, pursuant to HIPAA Administrative Simplification statutory provisions, for the electronic transmission of health care attachments, inclusive of attachments standards for both health care claims and prior authorizations. The health care industry has made it clear via NCVHS testimony, WEDI presentations, CAQH reports and direct inquiry that there is a clear need for government action with regard to attachments standards in order to bring consistency and reliable communications among the partners involved in health care transactions that require attachments. As a result of the absence of a federal attachments standard, health plans, providers and vendors lack the direction needed to support broad use of automation in the attachment workflow or for industry to coalesce around the use of even a small number of electronic solutions. In addition, lack of an attachments standards has deterred industry stakeholders from investing in system implementations to automate the attachments workflow, requiring a large manual administrative burden for the exchange of medical documentation. Industry SSOs and stakeholder alliances report this automation would yield substantial labor cost savings and administrative burden reduction. We believe standardizing electronic attachments transmissions would facilitate prior authorization decisions and claims processing, which would result in a decreased burden on providers and health plans, and quicker delivery of services to patients.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

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). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold. We believe that covered entities have already largely invested in the hardware, software, and connectivity necessary to conduct the new and modified standards proposed. We anticipate that the adoption of these changes would result in costs that would be outweighed by the benefits. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the proposed rulemaking.

C. Regulatory Flexibility Analysis

Executive Order 13272 requires that HHS thoroughly review rules to assess and take appropriate account of their potential impact on small businesses, small governmental jurisdictions, and small organizations (as mandated by the Regulatory Flexibility Act (RFA)). The RFA 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. If a proposed rule may have a significant economic impact on a substantial number of small entities, then the proposed rule must discuss steps taken, including alternatives considered, to minimize the burden on small entities. The RFA does not define the terms significant economic impact or substantial number. The Small Business Administration (SBA) advises that this absence of statutory specificity allows what is significant or substantial to vary, depending on the problem that is to be addressed in rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact. Nevertheless, HHS typically considers a significant impact to be three to five percent or more of the affected entities' costs or revenues.

The RFA generally defines a small entity as (1) a proprietary firm meeting the SBA size standards, (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. The North American Industry Classification System (NAICS) is used in the U.S., Canada, and Mexico to classify businesses by industry.[24] While there is no distinction between small and large businesses among the NAICS categories, the SBA develops size standards for each NAICS category. The most recently available update to the NAICS went into effect for the 2017 reference year, and the most recent SBA small business size regulations and Small Business Size Standards by NAICS Industry tables appear at 13 CFR 121.201. We have determined that the covered entities and their vendors affected by this proposed rule likely fall primarily in the categories listed in Table 1.

[24] *http://www.sba.gov/content/small-business-size-standards.*

TABLE 1—SBA SIZE STANDARDS FOR APPLICABLE NAICS INDUSTRY CODES

NAICS code	NAICS description	SBA standard ($ in million)
446110	Pharmacies and drug stores	30.0
522320	Financial transaction processing, reserve, and clearinghouse activities	41.5
524114	Direct health and medical insurance carriers	41.5
541511	Custom computer programming services	30.0
62111	Offices of physicians	12.0
621210	Offices of dentists	8.0
621491	Health plans	35.0
6221	Hospitals	41.5

Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million in any 1 year. Accordingly, it is our normal practice to treat all health care providers as small entities. For providers, the changes proposed by this rule may involve software upgrades for practice management and EHR systems. Thus, we expect that the vast majority of physicians and other health care provider practices will need to make relatively small changes in their systems and in their processes, but may incur additional service fees from their system vendors for additional functionality. Some of the smallest provider entities may elect to continue their current manual processes. We include pharmacies in this analysis, and consider most of them to be small businesses. While we believe few health plans meet the small business size standard, many health plans are non-profit organizations and would be considered small businesses; but we are unable to identify data to help us distinguish the number of these entities and therefore solicit industry feedback to complete this analysis for the final rule. We address clearinghouses, but we do not believe that there are a significant number of clearinghouses that would be considered small entities because of the level of consolidation in the marketplace. Because these proposals include initial standards for the exchange of both administrative and clinical documentation, we also address provider practice management system (PMS) and EHR vendors in our discussion, but are unable to identify data that would help identify the proportion of firms in these markets that meet the small business size standards. State Medicaid agencies are excluded from this analysis because states are not considered small entities in any RFA.

Table 8 in the impact analysis presents the estimated implementation costs of these proposals on all entities we anticipate would be affected by the rule. The data in that table are used in this analysis to provide cost information.

1. Number of Small Entities

We used the latest available (2017) Census business data records and other information to determine the number of affected entities, as summarized in Table 2.

TABLE 2—NUMBER OF AFFECTED ENTITIES

Type of entity	Number of entity firms or establishments
Hospitals	5,544
Physicians	171,722
Dentists	125,329
Pharmacies	19.234
Private Health Plans	772
Government Health Plans	3
Clearinghouses	162
Vendors	1,000
Totals	323,766

Based on the latest available (2017) Census business data records, we estimate that 321,639 health care provider entities may be considered small entities either because of their nonprofit status or because of their revenues, as detailed in Table 3. Approximately two percent (5,544) of these are hospitals, 57 percent (171,722) are physician practices, and 41 percent (125,329) are dental practices. To count hospitals, we are using data at the level of establishments, and to count physicians and dentists we are using data at the level of firms, as we did in the August 22, 2008 proposed rule titled ''Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards'' (73 FR 497742, 49758). We believe health information technology (HIT) systems are still more likely to differ at the level of the enterprise rather than at the level of the firm in hospitals. We believe that this way of counting may overstate the number of affected entities in these segments, given the recent trends toward consolidation among and between provider types and toward increasing integration of HIT systems across collaborating organizations. However, this overestimation may compensate for other types of affected health care providers potentially not reflected in these particular NAICS categories. We note that the number of 5,544 hospital establishments reflected in the 2017 Census business data roughly compares with more recent 2021 data from the American Hospital Association [25] indicating a total of 6,090 U.S. hospitals, of which approximately 25 percent are for-profit. However, we do not have more detail, including data on the size of the hospitals in this 25 percent, in order to determine whether any should be excluded from the count of small entities.

The Census business data records indicate that in 2017 there were a total of 19,234 pharmacy firms, and we estimate that most of these qualify as small entities. Available data do not permit us to clearly distinguish small pharmacy firms from firms that are parts of larger parent organizations, but we use employee size as a proxy for the firm size subject to the SBA size standard. For purposes of this analysis, we assume the firms with more than 500 employees (190) represent chain pharmacies and those with fewer than 500 employees (19,044) represent independently-owned open- or closed-door pharmacies. The 19,044 firms with fewer than 500 employees represented 20,901 establishments and accounted for total annual receipts of $70.9 billion and average annual receipts of $3.7 million—revenue that is well below the SBA standard of $30 million. By contrast, the 190 firms with 500 or more employees represented 27,123 establishments and accounted for over $211 billion in annual receipts, and thus, average annual receipts of $1.1

[25] Fast Facts on U.S. Hospitals, 2021; accessed 5/24/2021 at: *https://www.aha.org/statistics/fast-facts-us-hospitals.*

billion. Therefore, we assume 19,044 pharmacy firms qualify as small entities for this analysis.

For 2017, the Census Bureau counts 745 entities designated as Direct Health and Medical Insurance Carriers and 27 as Health Maintenance Organization (HMO) Medical Centers. We assume that these 772 firms represent health plans that would be subject to these proposals. Of the 745 Carriers, those with fewer than 500 employees (564) accounted for $35 billion in total and over $62 million in average annual receipts, exceeding the SBA size standard of $41.5 million. Comparable data on the eight smaller HMO Medical Centers is not available due to small cell size suppression. Although health plan firms may not qualify as small entities under the SBA receipts size standard, they may under non-profit status. However, we are not aware of data that would help us understand the relationship between health plan firm and ownership tax status to quantify the number of such firms. Therefore, we are not including an analysis of the impact on small health plans.

Clearinghouses provide transaction processing and data translation services to both providers and health plans that would be critical to implementing this proposed rule. The applicable NAICS category includes many types of financial transaction processing firms other than those affected by this rule, so the Census business data cannot be used to identify small entities of interest. In previous rulemaking, we have identified a largely consolidated market (74 FR 3312). More recently, in 2020, the national clearinghouse association, Cooperative Exchange, indicated its 23 member companies represent over 90 percent of the clearinghouse industry and provide services to over 750,000 provider organizations, through more than 7,000 payer connections and 1,000 HIT vendors.[26] While we do not have data on the size of these firms, or on the other firms constituting the remaining less than 10 percent of the market, we continue to believe the firms in this segment are either quite large or are affiliated with other very large firms, and do not include them in this small entity analysis. In the January 2009 Modification final rule, we identified the number of 162 clearinghouse entities (74 FR 3318). We are not aware of whether there has been further consolidation in this industry since 2009, so we continue to estimate that 162 clearinghouses serve the health care market in subsequent analyses.

Other vendors affected by this rule include provider PMS and EHR technology system vendors. Counting the affected entities in these two segments is complicated, in part because they are increasingly integrated. A health care provider entity's PMS and EHR systems may be bundled in one product offering, semi-integrated affiliated systems, or entirely independent systems offered by separate vendors.[27] We have not identified publicly available data on the number, size, or market share of these specific industry stakeholders. NAICS industry category 541511, Custom Computer Programming Services, seems to be the closest category. In 2017, the category included over 62,000 firms with 99 percent of these having less than 500 employees and 1 percent having 500 or more employees. However, this total seems out of proportion to other potential indicators of market size, leading us to believe it significantly overstates the affected entities of interest to the proposed rule. For instance, the aforementioned Cooperative Exchange description of member firm scope cited connections with 1,000 HIT vendors; 2019 market research estimates indicate there are over 500 vendors offering some type of EHR product;[28] the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule (85 FR 25642) estimated the number of certified HIT developers with health IT products capable of recording electronic health information certified in the 2015 Edition of health IT certification criteria to be 458; and the Electronic Health Record Association, a trade association of EHR companies addressing national efforts to create interoperable EHRs in hospital and ambulatory care settings, lists 29 companies as members.[29] A web search for NAICS codes associated with a sampling of these EHR Association member companies yielded many different NAICS codes (including some with 541511), possibly reflecting widely varying scopes of other products and services offered by firms in this market segment. Without more definitive data on the firms specific to the health care provider PMS and EHR business markets, we estimate that the number of affected firms is around 1,000, with the bulk of market share served by a relatively small number of large entities and the remainder of market share served by many smaller entities. However, we are unable to determine how many of these smaller entities may meet small business size standards and are not subsidiaries of larger firms, so we do not include them in this small entity analysis.

2. Costs to Small Entities

To determine the impact on the health care providers considered small entities for this analysis (identified in the previous section), we used the 2017 Census business data to collect revenue estimates and compared these to the high and low estimates for the range of costs calculated for each industry segment later in this analysis, as summarized in Table 8. We calculated the percentage of revenues represented by the high and low estimates, and none exceeded the 3 to 5 percent of revenue threshold, as summarized in Table 3. Thus, for purposes of the RFA analysis, we can conclude there is not a significant impact on small entities.

TABLE 3—ANALYSIS OF IMPLEMENTATION BURDEN ON SMALL COVERED ENTITIES

Entity type	Small entities (#)	Revenue ($ in billions)	Implementation cost range ($ in millions)	Cost/revenue range (%)
Pharmacies	19,044	282	0–0	NA
Vendors	NA	NA	NA	NA
Clearinghouses	NA	NA	NA	NA
Health plans	NA	NA	NA	NA

[26] From testimony submitted for the 8/25/2020 NCVHS Subcommittee on Standards Hearing on Proposed CAQH CORE Operating Rules;: *https://ncvhs.hhs.gov/wp-content/uploads/2020/08/Comments-CAQH%20CORE%20Proposed%20Operating%20Rules%20for%20Federal%20Adoption%20508.pdf.*

[27] The true cost of switching EHRs. May 30, 2018. Mary Pratt. Medical Economics Journal, June 10, 2018 edition, Volume 96, Issue 10. *https://www.medicaleconomics.com/view/true-cost-switching-ehrs.*

[28] Who are the largest EHR vendors. Jeff Green. EHR in Practice. October 18, 2019 *https://www.ehrinpractice.com/largest-ehr-vendors.html.*

[29] *https://www.ehra.org/membership/ehra-members.*

TABLE 3—ANALYSIS OF IMPLEMENTATION BURDEN ON SMALL COVERED ENTITIES—Continued

Entity type	Small entities (#)	Revenue ($ in billions)	Implementation cost range ($ in millions)	Cost/revenue range (%)
Programmers	NA	NA	NA	NA
Physicians	171,722	485	218–345	0.04–0.09
Dentists	125,329	126	149–299	0.12–0.24
Hospitals	5,544	994	466–932	0.05–0.09
Subtotal	321,639	1,887	833–1,666	0.04–0.09

3. Alternatives Considered

This rule proposes to adopt standards for ''health care attachments,'' which support both health care claims, as required by section 1173(a) of the Act, and prior authorization transactions, as recommended to the Secretary by NCVHS. It is our understanding that the standards recommended to the Secretary by NCVHS, and that we are proposing to adopt in this rule, are the only standards applicable to health care attachments that are ready for full implementation across the industry. Therefore, we considered the following regulatory alternatives: (1) not adopt standards for health care attachments, allowing for the industry's continued use of multiple processes, (2) wait to adopt standards for health care attachments until alternate standards, such as FHIR standards, are ready for full implementation and recommended to the Secretary by the industry, and (3) adopt a different version of the X12 implementation specifications than Version 6020, the version proposed to adopt in this rule. We chose to proceed with the proposals in this rule after identifying significant shortcomings with each of these alternatives.

We chose to propose to adopt attachments standards rather than allow for continued use of multiple standards because of the well-documented costs and administrative burdens associated with the many manual or partially electronic processes currently in use. These burdens were recently detailed in the 2020 CAQH Index. In response to CAQH surveys, industry stakeholders reported that the lack of federal standards and mandates has been a principal barrier to adoption of fully electronic standardized health care transactions.[30] Based on these survey responses, should we not adopt standards for health care attachments, most attachment transactions and many prior authorization transactions would continue to be conducted through fully manual processes. Not adopting standards for attachment transactions would also mean forgoing the opportunity to reduce the unnecessary back-and-forth between providers and health plans, accelerate claims adjudication and patient service approval timeframes, and reduce provider resources spent on manual follow-up activities. To the extent that future payer policies continue to trend toward increased levels of prior authorization or health care attachments requirements, these burdens could also increase.

Similarly, we chose not to hold off on proposing the adoption of attachment standards until alternate standards, such as FHIR standards, are available and recommended by the industry because we believe that adoption and implementation of the specifications in this proposed rule can immediately reduce the costs and burdens associated with the lack of national standards. While we are aware of HL7's efforts to create alternative implementation specifications to support health care attachments transactions, we note that at the time of writing this proposed rule, these FHIR implementation specifications have not been finalized nor have they been tested. We also note that the HL7 CDA standard we are proposing to adopt in this proposed rule is the only currently available SSO-created, NCVHS-recommended standard with published implementation specifications designed to support both claims and prior authorization attachment transactions. We believe that the industry's readiness for improvements to the manual or partially electronic process currently in place, as outlined the CAQH stakeholder surveys and supported by NCVHS's recommendation to adopt the specifications proposed in this rule, support proposing the adoption of attachments standards at this time. However, we invite comment on our understanding of the readiness of possible implementation specifications for health care attachments that support both claim and prior authorization transactions and whether the industry supports postponement of an adopted standard as it did for the previously mentioned proposed rule in the 2005 **Federal Register** (70 FR 55990), titled ''HIPAA Administrative Simplification: Standards for Electronic Health Care Claims Attachments; Proposed Rule.''

Finally, we chose to propose adoption of Version 6020 of the X12 implementation specifications, rather than an alternate version, such as Version 5010, because Version 5010 does not fully support attachments transactions. Version 6020 resolves technical issues and limitations in Version 5010 to enable attachments transactions that support both health care claims and prior authorization transactions. We also invite comment on any alternative implementation specifications that were not considered but meet the criteria outlined in this proposed rule.

4. Conclusion

As referenced earlier in this section, we use a baseline threshold of 3 to 5 percent of revenues to determine if a rule would have a significant economic impact on affected small entities. The small health care entities do not come close to this threshold. Therefore, the Secretary has certified that this proposed rule would not have a significant economic impact on a substantial number of small entities. However, because of the relative uncertainty in the data, the lack of consistent industry data, and our general assumptions, we invite public comments on the analysis and request any additional data that would help us determine more accurately the impact on all categories of entities affected by the proposed rule.

In addition, section 1102(b) of the Act requires us to prepare a Regulatory Impact Analysis if a rule would have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has

[30] Last accessed 5/28/2021 at: *https://www.caqh.org/explorations/caqh-index-report.*

fewer than 100 beds. This proposed rule would not have a significant effect on the operations of a substantial number of small rural hospitals because these entities would rely on contracted health information technology (HIT) vendors for the majority of implementation investment and efforts such hospitals elect to implement. We note that health care providers may choose not to conduct transactions electronically. Therefore, they would be required to use these standards only for transactions that they conduct electronically and would be expected to do so only when the benefits clearly outweigh the costs involved. Therefore, the Secretary has certified that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates would require spending more in any one year than threshold amounts in 1995 dollars, updated annually for inflation. In 2022, this threshold is approximately $165 million. This proposed rule would impose mandates that would result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of more than $165 million in any one year. The impact analysis in this proposed rule addresses those impacts both qualitatively and quantitatively. In general, each state Medicaid Agency and other government entity that is considered a covered entity would be required to ensure that its contracted claim processors update software and conduct testing and training to implement the adoption of the new standards and modified versions of a previously adopted standard. However, we have no reason to believe that ongoing contractual payment arrangements for these services would necessarily increase as a result of the proposed changes. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly federal mandate costs resulting from imposing enforceable duties on state, local, or tribal governments, or on the private sector; or increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs.

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. This proposed rule would have a substantial direct effect on state or local governments, could preempt state law, or otherwise have a federalism implication because state Medicaid agencies or their contractors would be implementing new standards and a modified version of an existing standard for which there would be expenses for implementation and wide-scale testing.

D. Anticipated Effects

The objective of this regulatory impact analysis is to summarize the costs and benefits of the following proposals:

- Adopting new standards for the exchange of health care attachment information consisting of—

++ A code set to be used for health care attachments transactions;

++ Proposed X12 standards for requesting and transmitting attachment information and HL7 standards for clinical information content; and

++ Proposed electronic signatures standards.

- Modifying the existing standard for referral certification and authorization by updating from Version 5010 to Version 6020.

This portion of the analysis is informed by a review of an earlier environmental scan produced for us in 2016 by the MITRE Corporation, industry testimony to the NCVHS, whitepapers from the Workgroup for Electronic Data Interchange (WEDI), and survey results produced by industry consensus-based organizations, and updated web-based research on specific topics.

Consistent with statutory and regulatory requirements, any recommendations for the adoption of HIPAA standard updates are the outcome of an extensive consensus-driven process that is open to all interested stakeholders. The standards development process involves direct participatory input from representatives of the industry stakeholders required to utilize the transactions.

For purposes of this analysis, we use the segmentation of health care industry stakeholders laid out in the 2009 Modifications final rule with some additional detail on vendors supporting the integration of the administrative and clinical data. As discussed in this proposed rule, providers and payers continue to use manual processing for health care attachments, therefore, these stakeholders are relevant for purposes of this RIA because there is no adopted health care attachments standard. As noted in the 2017 WEDI white paper, most payers send hard copy letters to request additional information to support a claim or prior authorization submitted by the provider.[31] These segments consist of the following:

- Providers

++ Hospitals

++ Physicians

++ Dentists

++ Pharmacies

- Health Plans

++ Private Health Plans and Issuers

++ Government Health Plans: Medicare, Medicaid, and Veterans Administration

- Clearinghouses
- Vendors

++ PMS Vendors

++ EHR Vendors

In analyzing the effects of this proposed rule, we referenced the 2019 and 2020 CAQH Index Reports issued on January 21, 2020 and February 3, 2021, respectively.[32] The 2020 CAQH Index [33] tracks adoption of HIPAA-mandated and other electronic administrative transactions and measures progress reducing the costs and burden associated with administrative transactions exchanged across the medical and dental industries. The CAQH Index includes estimates of the number of annual transactions by submission mode (phone, fax, mail, or email), electronic (HIPAA standard) or partially electronic (web portals or interactive voice response), as well as estimates of the associated labor cost and staff time. The reported costs and savings account only for the labor time required to conduct transactions, not the time and cost associated with gathering information or costs associated with the use of clearinghouses or third-party vendors.

For two types of transactions directly addressed by this proposed rule, attachments, and prior authorization, the 2020 CAQH Index estimates the annual industry national savings opportunity of full automation adoption of these transactions at $377 million and $417 million, respectively. These savings would accrue to both health plan payers and providers, with the vast majority of estimated savings accruing to providers. With respect to the category of providers, the report does not provide a breakdown of the type of providers that contributed to the survey

[31] Guidance on Implementation of Standard Electronic Attachments for Healthcare Transactions November 2017 Workgroup for Electronic Data Interchange. *https://www.wedi.org/2017/11/17/guidance-on-implementation-of-standard-electronic-attachments-for-healthcare-transactions/.*

[32] *https://www.caqh.org/sites/default/files/explorations/index/report/2019-caqh-index.pdf.*

[33] *https://www.caqh.org/explorations/caqh-index-report.*

results, but does distinguish between medical and dental providers, and does acknowledge partnering with both physician and hospital member organizations. Thus, we believe the medical provider savings reported include hospital-related responses.

In contrast to the data on labor cost savings, we are not aware of any reports or other industry estimates on the level of additional investments needed to fully implement these electronic processes for requesting and submitting attachment information, or the proportion of such costs that might be passed on to provider or health plan firms. By reviewing testimony submitted to the NCVHS and conducting web searches, such as for plan, clearinghouse, and vendor electronic data interchange (EDI) instructions and services, we understand some stakeholder segments have already largely built or acquired the capacity to implement these proposals (albeit possibly in inconsistent and proprietary ways in the absence of federal standards and operating rules). Similarly, based on NCVHS testimony, others (particularly health care providers and their vendors) have partially implemented the standards.[34] Thus, we conclude that implementation and readiness to fully implement the proposed standards vary among and within covered entity industry segments.

We also believe it is likely that firms directly involved in deploying additional capacity, in particular in upgrading PMS or EHR functionality, would not voluntarily share proprietary and competitive, market-sensitive data on the level of additional investment needed or on the effects on customer fees. Therefore, as further explained in the discussion of cost calculations, we estimate the incremental costs involved not through projected cost build-up, but rather as a function of the level of impact of implementing the previous HIPAA-standard modifications. We seek comment on this approach and on the appropriateness of the aggregate level estimates; data reflecting estimated changes to firm-specific costs and customer-specific fees would preferably be presented in a manner that facilitates aggregation.

We do not have good information on the extent of adoption of the proposed electronic standards for attachment information among industry stakeholders because HHS has not adopted an electronic transaction standard for health care attachments. However, we believe there is good reason to expect the proposed regulatory requirements, combined with the administrative cost savings opportunities identified by CAQH, would incentivize broad adoption of these attachment standards and lead to a significant uptake of the prior authorization standard. The remainder of this section provides details supporting the cost-benefit analysis for our proposals.

1. Affected Entities

As with previous standard updates, all HIPAA covered entities would be affected by this proposed rule. Covered entities include all health plans, all health care clearinghouses, and health care providers that transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a standard. Therefore, they would be required to use these standards only for transactions that they conduct electronically. See the Transactions and Code Sets rule for a discussion of affected entities (65 FR 50361).

In general, covered entities (or their vendors) would incur a number of one-time costs to implement the new and modified transactions in this proposed rule unless they have already implemented an adopted HIPAA standard, such as for prior authorization transactions. These costs would include analysis of business flow changes, software procurement or customized software development, integration of new software into existing provider/vendor systems, staff training, and collection of new data, testing, and transition processes. For some entities, new vendors may be needed for the creation and validation of the clinical documentation to be embedded in the attachment transactions. Systems implementation costs would account for most of the costs, with system testing alone likely accounting for a majority of costs for all covered entities. Ongoing operational costs would be expected to initially grow, as the implementation of electronic processes run in parallel with ongoing manual and partially automated processes, but to decline as higher proportions of transactions are automated. These HIT-related costs would be offset by significant reductions in labor costs for what are today largely manual processes to locate, collect, package, and mail clinical records needed to support requests for additional documentation to support claims and prior authorization requests. Other offsetting cost savings are expected from lower postage and other mailing costs, reductions in reprocessing volume due to higher clean claim acceptance rates, and delay in receiving payment.[35] [36]

It is likely that there are significant differences in readiness among payer and provider claims and prior authorization HIT systems, and we do not know the extent of incremental costs associated with HIT development, enablement (upgrade or licensing fees paid by users), or workflow adjustment and training to facilitate compliance with the standards proposed in this rule. So, though we are aware that the net benefits would likely vary among stakeholders, we lack the data to estimate these differential effects. An important consideration reflected in various industry testimonies submitted to the NCVHS is that some stakeholders, particularly smaller providers, would continue to have the option to leverage existing clearinghouses to provide these information exchange services based on negotiated rates. This is a standard practice today, where clearinghouses already manage 90 percent of the conversion of paper-to-electronic formats, as well as reformatting of non-compliant to compliant electronic claim transactions for the industry. Given the high costs of manual and partially electronic means for exchanging required information, we believe the impact of this rule would be significant net savings to the industry. However, the level and timing of uptake (as opposed to the retention of manual processes and clearinghouse intermediation) by provider entities are uncertain. We reflect this uncertainty with both the phasing in of and the estimation of minimum and maximums for costs and benefits. We solicit comments on this approach and our assumptions throughout this analysis.

2. Explanation of Cost Calculations

Based on consultation with industry workgroups, such as WEDI, we determined that the health care attachment standards in this proposed rule are already in common use by entities engaged in other lines of business, such as the workers' compensation and liability insurance

[34] NCVHS Letter to the Secretary of HHS on Recommendations for the Electronic Health Care Attachment Standard, July 5, 2016, *https://ncvhs.hhs.gov/wp-content/uploads/2018/03/2016-Ltr-Attachments-July-1-Final-Chair-CLEAN-for-Submission-Publication.pdf*.

[35] NCVHS Letter to the Secretary of HHS on Recommendations for the Electronic Health Care Attachment Standard, July 5, 2016, *https://ncvhs.hhs.gov/wp-content/uploads/2018/03/2016-Ltr-Attachments-July-1-Final-Chair-CLEAN-for-Submission-Publication.pdf*.

[36] In a regulatory impact analysis that, in accordance with OMB Circular A–4, takes a society-wide perspective, changes in timing of payments represent a transfer, rather than a net societal cost savings.

fields, that exchange medical records. Thus, there is clear evidence that the standards are fit for their intended purpose and have been successfully implemented in closely related business processes.

Although the attachments standards we are proposing to adopt are initial standards, as described in section 1175 of the Act, health plans surveyed by CAQH in 2020 reported electronic transaction submission levels of 22 percent for attachments and 21 percent for prior authorizations. Therefore, while the specification for attachments requests by the health plan (X12 277) and the subsequent response from the provider (X12 276) have not previously been adopted under HIPAA Administrative Simplification, some payer and provider systems are already exchanging HIPAA electronic prior authorization transactions using the adopted standards. Moreover, the HL–7 C–CDA has been widely adopted pursuant to the ONC 2014 and 2015 Editions of Health Information Technology Certification Criteria specifying content exchange standards and implementation specifications for exchanging electronic health information. According to the latest available posted data, as of 2017, nearly 4 in 5 (80 percent) office-based physicians had adopted a certified EHR.[37]

Similarly, while the standards we are proposing to adopt for electronic signatures are also initial standards, we believe they have already been widely implemented by the industry. For example, in 2010 the Drug Enforcement Agency (DEA) finalized a rule requiring similar standards for electronic prescribing of controlled substances.[38] The proposed electronic signature standard utilizes the same technology to expand electronic signature capabilities to all clinical documentation, rather than just electronic prescriptions. Therefore, we believe the implementation of the proposed electronic signature standard would not represent a significant incremental cost to providers.

Given much of the industry has already implemented some or all of the implementation specifications we are proposing to adopt in this proposed rule, or versions of the implementation specifications we are proposing to adopt in this proposed rule, we believe the level of effort involved in implementing the entire set of proposed implementation specifications herein is more akin to implementing standards modifications than to implementing transactions standards for the first time. Therefore, we anchor our cost estimates on the final cost estimates, updated for inflation,[39] in the Modifications final rule, and then make certain adjustments to address unique aspects of certain industry segments. While the systems required for implementing the specifications proposed for adoption in this proposed rule have been continuously updated since the publication of the Modifications final rule, the technologies within the proposed implementation specifications in this proposed rule are of the same type as those considered in the Modification rule and will be integrated into systems that continue to utilize the similar business models.

The cost estimates in the Modifications final rule were based on an estimate of the total costs to implement the initial HIPAA transaction standards (Version 4010/4010A) and informed by industry interviews.[40] To determine the costs for each provider sub-segment (that is, hospitals, physicians, and dentists), we established an estimate for what the total approximate Version 4010/4010A costs were for an individual entity within that sub-segment (based on the interviews and other data available through research) and then applied an estimated range of 20 to 40 percent of those costs to come up with estimated minimum and maximum costs for Version 5010. The range was accepted as a realistic proxy by all providers and plans who participated in the interviews. Through the course of the interviews, we identified more granular cost categories and reviewed these with the participants to help analyze and validate overall cost estimates by entity. The estimated cost for each individual entity within a segment was then multiplied by the number of entities to establish the estimated costs for entire segment.

With respect to the level and timing of the uptake of these standards, we assume that some portion of providers and their vendors may take longer to move from manual to fully automated transactions. For purposes of this analysis, we generally estimate that most stakeholders would incur costs over a 4-year period at the rate of 50 percent in the first implementation year, 30 percent in the second implementation year, and 10 percent each in the third and fourth years.

We note that, although many comments to the Modifications rule suggested we underestimated the costs, no substantive data or additional information was provided to counter our analysis at that time. We're not aware of more recent public research relating to costs of implementing modifications to HIPAA transaction standards. We invite public comments on our understanding and request any additional data that would help us determine more accurately the costs of implementing modifications to HIPAA transaction standards.

3. Explanation of Benefits Calculations

To determine the benefits for each segment of the industry, we primarily relied upon the 2020 CAQH Index. Based on survey responses, CAQH estimates that spending on labor time conducting attachment transactions accounts for about $590 million of spending on administrative transactions across the medical industry, with health care providers incurring about 88 percent of this spending at an average cost of $5.10 for each manually processed attachment. In moving from manual to electronic attachments transactions, CAQH estimates the health care industry could save $4.09 on average per transaction and an additional $377 million annually. These estimated savings would be split between health care providers ($328 million) and health plans ($49 million) and would be generated by the avoidance of 8 minutes in administrative labor time per attachment on average, as medical providers reported taking an average of 11 minutes to submit an attachment manually versus 3 minutes electronically. Comparable data on spending and savings opportunities on attachment transactions for dental providers were not available, although the survey reports that only 16 percent of dental attachment transactions in 2020 were fully electronic.

The 2019 CAQH Index reported that the use of the electronic standard for prior authorizations has remained very low due to barriers such as provider

[37] ONC Health IT Dashboard. Office-based Physician Electronic Health Record Adoption: *https://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php.*

[38] Electronic Prescribing of Controlled Substances. Drug Enforcement Administration, Department of Justice, Office of Diversion Control website. *http://www.deadiversion.usdoj.gov/ecomm/e_rx/.*

[39] Cost estimate ranges from the January 2009 Modifications final rule were adjusted for inflation using the Bureau of Labor Statistics Consumer Price Index Inflation Calculator, to reflect amounts for January 2020 and round up to the nearest whole number to match benefits estimates from the CAQH 2020 Index. *https://www.bls.gov/data/inflation_calculator.htm.*

[40] Version 5010 Regulatory Impact Analysis—Supplement. September 2008. *https://www.cms.gov/files/document/5010regulatoryimpactanalysissupplementpdf.*

awareness, vendor support, and inconsistent use of data content allowed in the standard, and the lack of an attachment standard to support the exchange of medical documentation. The 2020 CAQH Index reports that fully electronic prior authorization continues to have the lowest adoption rate of the medical transactions surveyed, although utilization between 2019 and 2020 increased by 8 percentage points to 21 percent. Since this rule proposes to adopt federal attachment standards, including those to address data content, we believe the proposed changes in this rule would substantially address these barriers and promote widespread adoption of electronic prior authorization processes. As described in section I.F. of this proposed rule, numerous organizations representing physician provider groups, insurance payers, health technology vendors, health care financial managers, and HIT standard advisory bodies have submitted recommendations to the Secretary strongly supporting this view.

CAQH reports that prior authorization is the most costly and time-consuming administrative transaction for providers, and administrative spending increased to $767 million as the cost to conduct prior authorizations rose for both plans and providers from the previous year. Based on survey responses, the 2020 CAQH Index estimates that, on average, providers spent about 20 minutes and $10.26 per transaction to conduct a prior authorization manually, and about 13 minutes and $7.07 via a partially electronic web portal in 2020. These costs compare with an average cost of $3.64 per fully electronic transaction. CAQH estimates that, based on 2020 survey data, switching to fully electronic transactions could yield an additional $417 million in annual administrative cost savings. Those savings would be split between health care providers ($322 million or 77 percent) and health plans ($95 million or 23 percent). Comparable data were not reported on prior authorization transactions for dental providers, suggesting this transaction is not generally utilized by this segment.

We utilize the CAQH national annual savings estimates as the basis for our benefits estimates. The CAQH national annual savings estimates are calculated based on potential savings moving from the reported state of 21 percent electronic processing for prior authorization transactions and 22 percent electronic processing for attachments to fully electronic processing. The total potential industry cost savings opportunity is an amount that declines as industry adoption increases. Although there was an apparent increase in electronic processing of prior authorization and health care attachments transactions from 2019 to 2020, we do not trend the benefits estimates forward because previously reported estimates of electronic processing adoption have tended to remain stable over a longer period of time. The CAQH estimation methodology only includes labor time savings, which it assesses to be the most significant component of savings, by far. We do not include estimates of other sources of savings, such as through elimination of mailing costs, so our benefit estimates may have a tendency toward understating actual industry savings.[41] Because we believe that some portion of providers and their vendors may take longer to move from manual to fully automated transactions, we also assume a phased-in realization of the level of annual benefits projected by CAQH. For purposes of this analysis, we generally estimate that most stakeholders would realize the benefits in labor savings over a 3-year period at the rate of 50 percent in the first operational year, 75 percent in the second operational year, and 100 percent in and after the third year after the compliance date.

4. Hospitals

As previously discussed, to determine the costs for each health care provider sub-segment, we started with the minimum and maximum cost estimates in the Modifications final rule for each type of entity. For hospitals, those estimates were within a range of $1,423 million to $2,848 million, adjusted for inflation (74 FR 3316). We further assume that these costs would be incurred by hospital HIT developers, which would both absorb some portion of the costs as a cost of doing business incorporated in the current level of HIT service and maintenance agreements and also pass some portion of the costs on to the hospital in the form of higher fees for enabling new functionality. This seems reasonable given our understanding that HIT vendors generally plan on, and finance, a certain level of ongoing system development through ongoing maintenance agreements, typically with annual increases, but also must keep these at a level that remains competitive in their niche market.[42] In other words, not all possible systems upgrades would be factored into current fees. We do not have any information on how this allocation would be made and expect there would be many variations in practice, but for purposes of this analysis, we assume a 60/40 split between costs borne by the vendor and costs passed on to the hospital. As summarized in Table 4, this results in the hospital share of costs in the range of $569 million to $1,139 million, with the remainder in the range of $854 million to $1,709 million borne by hospital HIT vendors.

TABLE 4—ATTACHMENTS COSTS BORNE BY PROVIDERS VERSUS VENDORS

[$ in millions]

Entity type	Proposed rule cost range	Provider share (40%)	Vendor share (60%)
Physicians	665–1,329	266–532	399–797
Dentists	456–913	182–365	274–548
Hospitals	1,423–2,848	569–1,139	854–1,709
Subtotals	2,544–5,090	1,017–2,036	1,527–3,054

[41] On the other hand, CAQH developed estimates from the experience of entities that voluntarily automated, and extrapolation from such voluntary experience to the regulatory context may generate a tendency toward overestimation of savings, on a per-unit basis and/or in the aggregate. We welcome comments that would facilitate refinement of estimates.

[42] The true cost of switching EHRs. May 30, 2018. Mary Pratt. Medical Economics Journal, June 10, 2018 edition, Volume 96, Issue 10. *https://www.medicaleconomics.com/view/true-cost-switching-ehrs.*

To determine the benefits for hospitals, we refer to the estimates of savings for medical providers reported by CAQH, and assume that hospitals would achieve 20 percent of these savings. We assume a rough 80/20 split between physicians and hospitals because we believe the vast majority of transactions needed to support claims and prior authorizations would come from clinician practices since plans and hospitals generally have other processes for utilization management of more expensive inpatient admissions and outpatient procedures. CAQH estimated the total annual savings opportunity for medical providers for fully automating attachments and prior authorization transactions to be $328 million and $322 million, respectively. So, we estimate the hospital share to be 20 percent of $650 million or $130 million. To reflect the uncertainty around the ultimate level of uptake of these standards, we estimate a range of 25 percent below this point estimate between $98 million to $130 million in annual savings, as summarized in Table 5.

TABLE 5—ATTACHMENTS BENEFITS BY ENTITY

[$ in millions]

Entity type	Estimated annual savings range (25%)
Pharmacies	0–0
Vendors	0–0
Clearinghouses	0–0
Private Health Plans	108–144
Government Health Plans	179–238
Physicians	390–520
Dentists	86–115
Hospitals	98–130
Total	860–1,147

With respect to timing of costs and benefits, we assume hospitals would have both the capital and business interest to move promptly to achieve the return on investment; would incur all costs during the 2-year implementation period; and would realize the full level of annual savings in and after the first operational year following the proposed compliance date, as summarized in Tables 8 and 9.

5. Physicians

We followed a similar methodology for estimating physician costs and benefits. For physicians, the Modifications final rule cost estimates were within a range of $665 million to $1,329 million, adjusted for inflation (74 FR 3317). We assume a comparable level of effort to implement the proposed attachments standards. We further assume that these costs would be incurred by physician practice PMS and EHR vendors, who would both absorb some portion of the costs as a cost of doing business incorporated in the current level of HIT service and maintenance agreements and also pass some portion of the costs on to the practices in the form of higher fees for enabling new functionality. We again assume a 60/40 split between costs borne by the vendor and costs passed on to the customer. As summarized in Table 4, this results in a physician share of costs in the range of $266 million to $532 million, with the remainder in the range of $399 million to $797 million to be borne by physician PMS and EHR vendors. We further assume that some physician entities and their vendors may take more time to implement the standards while continuing to use manual processes in the meantime. Therefore, we estimate physician costs would be incurred over a 4-year period at the rate of 50 percent in the first implementation year, 30 percent in the second implementation year, and 10 percent each in the third and fourth years, as summarized in Table 8.

To determine the benefits for physicians, we again referred to the estimates of savings for medical providers reported by CAQH and calculated the remaining 80 percent of these savings. CAQH estimated the total annual savings opportunity for medical providers for fully automating attachments and prior authorization transactions to be $328 million and $322 million, respectively, or $650 million in total. So, we estimate the physician share to be 80 percent of $650 million, or $520 million. To reflect the uncertainty around the ultimate level of uptake of these standards, we estimate a range of 25 percent below this point estimate, or between $390 million to $520 million in annual savings, as summarized in Table 5. We further estimate that these benefits in labor savings would phase in over a 3-year period at the rate of 50 percent in the first operational year, 75 percent in the second operational year, and 100 percent in and after the third year after the compliance date, as summarized in Table 9.

6. Dentists

For dentists, we follow the same methodology for costs as we do for physicians. The Modifications final rule cost estimates for dentists were within a range of $456 million to $913 million, adjusted for inflation (74 FR 3317). We assume a comparable level of effort to implement the proposed attachments standards. We further assume that these costs would be incurred by dental practice PMS and EHR vendors, who would both absorb some portion of the costs as a cost of doing business incorporated in the current level of HIT service and maintenance agreements and also pass some portion of the costs on to the dental practices in the form of higher fees for enabling new functionality. We again assume a 60/40 split between costs borne by the vendor and costs passed on the customer. As summarized in Table 4, this results in the dentist share of costs in the range of $182 million to $365 million, with the remainder in the range of $274 million to $548 million borne by dental practice PMS and EHR vendors. As with physicians, we further assume that some dental practices and their vendors may take more time to implement the standards, while continuing to use manual processes in the meantime. Therefore, we estimate dentists' costs would be incurred over a 4-year period at the rate of 50 percent in the first implementation year, 30 percent in the second implementation year, and 10 percent each in the third and fourth years, as summarized in Table 8.

Given that the 2020 CAQH Index did not report on the potential savings opportunity for dental providers for full automation of attachments transactions, we take a different approach to benefits estimation. Comments included in testimony submitted to the NCVHS in 2016 on the Attachment Standard [43] (2016 NCVHS Hearing) indicated that dentists supported the proposal to make the X12N 275 transaction the standard vehicle for transporting attachment content to dental claims, but made no mention of the prior authorization transaction. These comments also indicated that many dental PMS vendor technologies may lack the capability to generate HL7 documents, requiring dentists to either upgrade existing systems or find alternative methods, such as using a clearinghouse or payer portals. Thus, we conclude that some dentists and their PMS vendors would incur costs associated with submitting attachment information to support claims, and others may maintain current manual or clearinghouse-mediated processes. Therefore, we assume that the savings opportunity for full automation of claims attachments for

[43] NCVHS Subcommittee on Standards. Agenda of the February 16, 2016 NCVHS Subcommittee on Standards Hearing *https://ncvhs.hhs.gov/meetings/agenda-of-the-february-16-2016-ncvhs-subcommittee-on-standards-hearing/*.

dentists would be a portion of the savings opportunity for medical providers. Since the total number of dental entities (125,329) is about 70 percent of the number of other provider entities (177,266, or 5,544 hospital establishments and 171,722 physician firms), we estimate their savings opportunity would be no greater than 70 percent of the annual $328 million medical provider savings opportunity for attachments estimated by CAQH. In addition, we assume that, given the relatively smaller size of dental practices, a greater proportion of dentists than physicians may choose to retain manual processes. So, as summarized in Table 5, we estimate that the annual dentist savings opportunity is 50 percent of 70 percent of the medical provider opportunity, or $115 million ($328 \times 0.70 \times 0.50$). To reflect the uncertainty around the ultimate level of uptake of these standards, we estimate a range of 25 percent below this point estimate, or between $86 million to $115 million in annual savings. As with the physician estimates, we further estimate that these benefits in labor savings would phase in over a 3-year period at the rate of 50 percent in the first operational year, 75 percent in the second operational year, and 100 percent in and after the third year after the compliance date, as summarized in Table 9.

7. PMS and EHR Vendors

In testimony to the 2016 NCVHS Hearing, WEDI noted that the functionality that would be new to providers in implementing the attachment standards would consist of automating EHR systems to exchange data with the PMS and digital signatures. Consistent with this assessment, the 2016 MITRE environmental scan found that many EHR vendors had the capability of sending X12N 275 and X12N 278 EDI transactions, but that substantial work remained to routinely and reliably extract structured clinical data for C–CDA attachments. Since that time there has been both growth and consolidation in these industry segments. A health care provider entity's PMS and EHR systems may be bundled in one product offering, semi-integrated affiliated systems, or entirely independent systems offered by separate vendors.[44] So, readiness would vary widely for provider entities based on their HIT contractors.

Because vendors of certified electronic health record technology are already familiar with CDA for meeting requirements under the ONC Health IT Certification Program, we believe all EHR vendors have some ability to extract data for C–CDA templates, although all may not have fully implemented or provided this functionality as part of core product offerings. A review of some of the largest EHR vendor websites in May 2021, provided informal evidence suggesting that about 80 percent of vendors had this functionality in place, that another 17 percent had at least partial functionality, and that only 3 percent might still have no C–CDA functionality. The many other smaller EHR vendors are also likely in varying stages of readiness. Thus, we assume that additional implementation costs may be needed to reliably extract C–CDA documentation and to either integrate this content into internal EDI processes or exchange the documentation with another PMS.

Similarly, we assume PMS vendors contracted with clients that have a certified EHR have already largely developed the ability to create the X12N 275 and X12N 278, even if this functionality has not been enabled for all customers, and that the majority of the additional cost would be associated with receiving and managing the C–CDA payload. Because of this pre-existing functionality, we are again persuaded that implementing these proposals is more akin to a standards upgrade than implementing a new standard for the first time. Based on 2020 CAQH Index results that report 22 percent of medical and 16 percent of dental attachment exchanges occurring electronically, we are aware that some provider vendors have already successfully implemented the transmission of electronic attachments. Without data on the extent of the gaps, or on the difference in readiness between EHR and PMS vendors, we assume similar costs across both types of vendors and treat them together. We also assume that other significant components of implementation costs would consist of trading partner testing and user training.

As the result of the estimates already described for hospitals, physicians, and dentists and the split with their HIT vendors in Table 4, we estimate that PMS and EHR vendor costs would add up across all customer segments to a range of $1,527 to 3,054 million. And since we assume some vendors and/or their customers may take more time to implement the standards, we estimate vendors' costs would be incurred over a 4-year period at the rate of 50 percent in the first implementation year, 30 percent in the second implementation year, and 10 percent each in the third and fourth years, as summarized in Table 8.

We have not identified any evidence that suggests there would be savings for this segment as the result of the changes in this proposed rule and do not include any estimates of benefits for this segment.

8. Clearinghouses

From remarks recorded at the 2016 NCVHS Hearing,[45] we understand that by 2016 many entities in the clearinghouse industry had already fully implemented the standards proposed in this rule and were exchanging the transactions and clinical payloads with government and commercial health care entities, as well as with entities in other lines of business. Fundamental to the clearinghouse business role is the ability to normalize disparate data formats, including both structured and unstructured clinical data, and unwrap and convert the data into standard or proprietary formats based on the varying capabilities and needs of payer and provider clients. We assume that, by 2022, this ability has generally become the business norm throughout the clearinghouse industry. As a result, we assume that clearinghouses would not have significant new technology development costs as the result of our proposals, but would have significant new trading partner testing costs.

To estimate clearinghouse implementation costs, we considered a commenter, described in the Modifications final rule (74 FR 3318), that identified as a large clearinghouse and reported that projected costs would be at least $3.5 million, $4.3 adjusted for inflation, and would be affected specifically by the amount of testing that would be required with trading partners—both providers and health plans. On the basis of this data point, as summarized in Table 6, we estimate that 23 large clearinghouse entities would incur $4.3 million in implementation costs, and that the remainder of 139 smaller clearinghouses would incur $1.8 million, for a segment total of $349 million. To reflect the uncertainty around these projections, we estimate a range of 25 percent below and above this point estimate of between $262

[44] The true cost of switching EHRs. May 30, 2018. Mary Pratt. Medical Economics Journal, June 10, 2018 edition, Volume 96, Issue 10. *https://www.medicaleconomics.com/view/true-cost-switching-ehrs.*

[45] Transcript of the February 16, 2016 NCVHS Subcommittee on Standards *https://ncvhs.hhs.gov/transcripts-minutes/transcript-of-the-february-16-2016-ncvhs-subcommittee-on-standards/.*

million to $436 million in total costs. And since we assume some customers may take more time to implement the standards, we estimate clearinghouse costs would be incurred over a 4-year period at the rate of 50 percent in the first implementation year, 30 percent in the second implementation year, and 10 percent each in the third and fourth years, as summarized in Table 8.

We have not identified any evidence that suggests there would be savings for clearinghouses as the result of the changes in this proposed rule and have not estimated any benefits for this segment.

TABLE 6—CLEARINGHOUSE COSTS

Firm size	Large	Small	Total
Firms (#)	23	139	162
Cost per Firm ($ million)	4.3	1.8	
Total Segment Cost ($ million)	99	250	349
Cost Range ± 25% ($ million)			262–436

9. Private Health Plans and Issuers

Based on our informal web searches in May 2021, for plan websites that include EDI instructions for providers on submitting X12N 275 and X12N 278 transactions, and the general absence of comments describing significant implementation burden in testimony submitted to the 2016 NCVHS Hearing, we believe health plans (or their clearinghouses) have generally already implemented the technology for these proposed changes. We believe health plans (or their clearinghouses) have already implemented both the X12N transactions and have processes for collecting at least unstructured medical record data currently used for auditing, risk coding validation, and other quality and utilization management processes. CAQH reports that 22 percent of medical and 16 percent of dental attachment exchanges were occurring electronically in 2020. In addition, we are aware that all health plans routinely collect medical record documentation from providers in a variety of ways, including through web portals and direct access to EHRs.[46] These facts suggest to us that health plans have either already automated these processes or have workarounds to manage the receipt of this information. Thus, we believe the additional effort associated with implementing our proposals may be limited to mapping existing backend processes to the new transaction processing front-end systems. Alternatively, the smaller the health plan, the more likely that entity may rely upon a clearinghouse for administrative and clinical data exchange and the more likely the status quo would continue.

In testimony to the 2016 NCVHS Hearing, WEDI noted that the functionality that would be new to payers in implementing the attachment standards would be the HL7 CDA, LOINC codes, and other transport models requiring different skill sets than EDI. Although payers routinely collect medical record documentation today, this does not necessarily mean that the ingestion, interpretation, and integration of clinical data is fully automated. However, we do not see evidence in testimony or public comments that plans anticipate a significant implementation effort related to additional technology development to handle the HL7 CDA and LOINC codes required by federal adoption of attachment standards. It is possible, given payer involvement with the rapid evolution of clinical data exchange standards, that health plans may not be incentivized to significantly enhance their current state of C–CDA handling, and may instead continue to rely on current state processes, including the use of clearinghouses for intermediation where necessary.[47] For these reasons, we do not believe health plans would bear as significant a level of investment for system development for these proposals as they did for the requirements of the Modifications final rule. However, they would likely incur implementation costs for trading partner testing if they exchange these transactions directly with providers in lieu of via clearinghouses.

In light of these considerations, we assume that the costs of implementation for health plans may be somewhat analogous to those for clearinghouses, but generally with fewer connections to test, since many transactions would be expected to continue to be exchanged through existing clearinghouse connections. Therefore, as summarized in Table 7, we estimate that private health plans would incur 50 percent of clearinghouse costs, and we increase that estimated range of $262 million to $436 million to reflect 4.8 times as many health plan entities (772/162 = 4.8). Thus, we estimate private health plans would incur implementation costs, driven mostly by trading partner testing, of $838 million ($349 \times 0.50 \times 4.8$). To reflect the uncertainty around these projections, we estimate a range of 25 percent below and above this point estimate of between $629 million to $1,048 million.

TABLE 7—PRIVATE HEALTH PLAN COSTS

Entity type	Clearinghouses	Private plans
Firms (#)	162	772
Difference in # of Firms		4.8
Total cost from Table 6 ($ in millions)	349	
Plan cost (50% of above × multiple of firms) ($ in millions)		838
Cost Range ± 25% ($ in millions)		629–1,048

[46] For example, see: Payer Access to EHRs: What Providers Need to Know. Journal of AHIMA. October 9, 2019 *https://journal.ahima.org/page/payer-access-to-ehrs-what-providers-need-to-know.*

[47] A Path Toward Further Clinical and Administrative Data Integration. Final Report Of The Health Information Technology Advisory Committee's Intersection of Clinical And Administrative Data Task Force To The National Coordinator For Health Information Technology. November 17, 2020 *https://www.healthit.gov/sites/default/files/page/2020-11/2020-11-17_ICAD_TF_FINAL_Report_HITAC.pdf.*

Given that we assume some portion of providers and their vendors may take longer to move from manual to fully automated transactions, we assume health plan testing costs would extend beyond the 2-year implementation period. So, for purposes of this analysis, we estimate that private health plans would incur costs over a 4-year period at the rate of 50 percent in the first implementation year, 30 percent in the second implementation year, and 10 percent each in the third and fourth years.

In estimating the benefits of the proposed rule for private health plans, we again referred to the estimates of savings reported by CAQH, but this time to those reported for plans. CAQH estimated the 2020 national annual plan savings opportunities for attachments and prior authorizations at $49 million and $95 million, respectively, for a total of $144 million annually. To reflect the uncertainty around the ultimate level of uptake of these standards, we estimate a range of 25 percent below this point estimate between $108 million to $144 million in annual savings. We further assume plans would realize the benefits in labor savings over a 3-year period at the rate of 50 percent in the first operational year, 75 percent in the second operational year, and 100 percent in and after the third year after the compliance date, as summarized in Table 9.

10. Government Health Plans

Similar to private health plans, we believe Medicare, Medicaid, and the Veteran's Administration systems have largely implemented the ability to receive and manage these transactions through their HIT processing vendors and contracted managed care plans, especially with respect to claims attachments, and would incur costs in rough magnitude to the impacts estimated in the Modifications final rule for testing and training. We assume these costs would again largely be borne by the contracted vendors under existing contractual terms and agreements. Accordingly, to calculate government health plan costs, we used the same range of costs estimated in the Modifications final rule of $384 million to $734 million (74 FR 3318), adjusted for inflation. As we do with providers and private health plans, we further assume that costs would be incurred over a 4-year period. As summarized in Table 8, we estimate costs would be incurred at the rate of 50 percent in the first implementation year, 30 percent in the second implementation year, and 10 percent each in the third and fourth years.

To calculate government health plan benefits, we started with the point estimate of $238 million savings due to the use of better standards in the Modifications final rule (74 FR 3318). To reflect the uncertainty around the ultimate level of uptake of these standards, we estimate a range of 25 percent below this point estimate or between $179 million to $238 million in annual savings. As with other industry segments, and as summarized in Table 9, we further assume government health plans would realize the benefits in these savings over a 3-year period at the rate of 50 percent in the first operational year, 75 percent in the second operational year, and 100 percent in and after the third year after the compliance date.

11. Pharmacies

We believe pharmacies would generally not be impacted by the changes in this proposed rule. Comments from NCPDP submitted to the 2016 NCVHS Hearing indicated: that pharmacies use the X12N 837 to bill medications and supplies covered under the Medicare Part B program and for professional pharmacy services covered under a medical plan; the type of claims submitted by pharmacy providers using the X12N 837 rarely requires an attachment; the electronic prior authorization (ePA) transactions approved as part of the NCPDP SCRIPT standard in 2013 address the documentation needs around prior authorization attachments; and that while the ePA transactions do accommodate attachments, NCPDP was not aware of any organization using a HL7 C–CDA attachment for pharmacy prior authorizations. In addition, contextual comments submitted by NCPDP to the NCVHS in 2020 in response to a Request for Comments on CAQH CORE Operating Rules [48] indicated there is very little use in the pharmacy industry of the X12N 278 transaction. As a result, we assume pharmacies would be affected by these proposals only rarely to support the billing of retail pharmacy supplies and professional services claims. Based on an NCPDP whitepaper, we further understand that a pharmacy needing to send attachment information to support an X12N 837 claim would generally be expected to employ existing batch processes to send attachment information to the same clearinghouse that converts their NCPDP billing transactions to X12 837 Professional Claims for formatting and transmittal in the X12N 275.[49] Therefore, we assume the proposed changes to information exchanges between clearinghouses and health plans would continue to be managed by clearinghouses that serve this particular market. As a result, we conclude that pharmacies would generally not be affected by this proposed rule, and we estimate no costs and benefits for this segment.

12. Summary of Costs and Benefits for This Proposed Rule

Tables 8 and 9 are the compilation of the estimated costs and benefits for all of the standards proposed in this proposed rule.

TABLE 8—ESTIMATED MINIMUM AND MAXIMUM COSTS FOR IMPLEMENTATION OF ATTACHMENT STANDARDS—2025 THROUGH 2034

[$ in millions]

Industry	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
Hospitals minimum	284.5	284.5	.....	.....	.....	.....	.....	.....	.....	.....	569
Hospital maximum	569.5	569.5	.....	.....	.....	.....	.....	.....	.....	.....	1,1395.0
Physicians minimum	133.0	79.8	26.6	26.6	.....	.....	.....	.....	.....	.....	266.0
Physicians maximum	266	159.6	53.2	53.2	.....	.....	.....	.....	.....	.....	532.0
Dentists minimum	91	54.6	18.2	18.2	.....	.....	.....	.....	.....	.....	182.0
Dentists maximum	182.5	109.5	36.5	36.5	.....	.....	.....	.....	.....	.....	365.0
Pharmacies minimum	0.0	0.0	0.0	0.0	.....	.....	.....	.....	.....	.....	0.0
Pharmacies maximum	0.0	0.0	0.0	0.0	.....	.....	.....	.....	.....	.....	0.0

[48] NCVHS Subcommittee on Standards, Comments Received in Response to Request for Comment (**Federal Register** Notice 85 FR 37666] (on CAQH CORE Operating Rules) August 20, 2020 *https://ncvhs.hhs.gov/wp-content/uploads/2020/08/Comments-CAQH%20CORE%20Proposed%20Operating%20Rules%20for%20Federal%20Adoption%20508.pdf.*

[49] NCPDP White Paper on Pharmacy Professional Service Billing *https://www.ncpdp.org/NCPDP/media/pdf/WhitePaper/Billing-Guidance-for-Pharmacists-Professional-and-Patient-Care-Services-White-Paper.pdf?ext=.pdf.*

TABLE 8—ESTIMATED MINIMUM AND MAXIMUM COSTS FOR IMPLEMENTATION OF ATTACHMENT STANDARDS—2025 THROUGH 2034—Continued

[$ in millions]

Industry	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
Private Health Plans minimum	314.5	188.7	62.9	62.9	.....	.....	.....	.....	.....	.....	629.0
Private Health Plans maximum	524	314.4	104.8	104.8	.....	.....	.....	.....	.....	.....	1,048.0
Government Health Plans minimum	192.0	115.2	38.4	38.4	.....	.....	.....	.....	.....	.....	384.0
Government Health Plans maximum	367	220.2	73.4	73.4	.....	.....	.....	.....	.....	.....	734.0
Clearinghouses minimum	131	78.6	26.2	26.2	.....	.....	.....	.....	.....	.....	262.0
Clearinghouses maximum	218	130.8	43.6	43.6	.....	.....	.....	.....	.....	.....	436.0
Vendors minimum	763.5	458.1	152.7	152.7	.....	.....	.....	.....	.....	.....	1,527.0
Vendors maximum	1,527	916.2	305.4	305.4	.....	.....	.....	.....	.....	.....	3,054.0
Total Minimums	1,910	1,260	325	235	0.0	0.0	0.0	0.0	0.0	0.0	3,819.0
Total Maximums	3,654	2,420.2	616.9	616.9	0.0	0.0	0.0	0.0	0.0	0.0	7,308.0

TABLE 9—ESTIMATED MINIMUM AND MAXIMUM BENEFITS FOR IMPLEMENTATION OF ATTACHMENT STANDARDS—2025 THROUGH 2034

[$ in millions]

Industry	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
Hospitals minimum	0.0	0.0	97.5	97.5	97.5	97.5	97.5	97.5	97.5	97.5	780.0
Hospital maximum	0.0	0.0	130.0	130.0	130.0	130.0	130.0	130.0	130.0	130.0	1,040.0
Physicians minimum	0.0	0.0	195.0	292.5	390.0	390.0	390.0	390.0	390.0	390.0	2,827.5
Physicians maximum	0.0	0.0	260.0	390.0	520.0	520.0	520.0	520.0	520.0	520.0	3,770.0
Dentists minimum	0.0	0.0	43	64.6	86.1	86.1	86.1	86.1	86.1	86.1	624.2
Dentists maximum	0.0	0.0	57.5	86.3	115.0	115.0	115.0	115.0	115.0	115.0	833.8
Pharmacies minimum	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pharmacies maximum	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Private Health Plans minimum	0.0	0.0	54.0	81.0	108.0	108.0	108.0	108.0	108.0	108.0	783.0
Private Health Plans maximum	0.0	0.0	72.0	108.0	144.0	144.0	144.0	144.0	144.0	144.0	1,044.0
Government Health Plans minimum	0.0	0.0	89.3	133.9	178.5	178.5	178.5	178.5	178.5	178.5	1,294.2
Government Health Plans maximum	0.0	0.0	119.0	178.5	238.0	238.0	238.0	238.0	238.0	238.0	1,725.5
Clearinghouse minimum	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Clearinghouse maximum	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Vendors minimum	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Vendors maximum	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Minimums	0.0	0.0	478.8	669.5	860.1	860.1	860.1	860.1	860.1	860.1	6,308.9
Total Maximums	0.0	0.0	638.5	892.8	1,147.0	1,147.0	1,147.0	1,147.0	1,147.0	1,147.0	8,413.3

E. Regulatory Review Costs Estimate

One of the costs of compliance with a proposed rule is the necessity for affected entities to review the rule in order to understand what it requires and what changes the entity would have to make to come into compliance. We assume that 323,766 affected entities (listed in Table 2) would incur some of these costs, as they are the entities that would have to implement the proposed changes. The particular staff involved in such a review would vary from entity to entity, but would generally consist of lawyers responsible for compliance activities (at all 323,766 entities) and individuals familiar with the technical X12N and HL7 standards at the level of a computer and information systems manager at private and government health plans, clearinghouses, and PMS and EHR vendors (a total of 1,937 entities). Using the Occupational Employment and Wages for May 2020 from the Bureau of Labor Statistics for lawyers (Code 23–1011) and computer and information system managers (Code 11–3021), we estimate that the national average labor costs of reviewing this rule are $100 and $109 per hour, respectively, including overhead and fringe benefits. We estimate that it would take approximately 2 hours for each staff person involved to review this proposed rule and its relevant sections and that, on average, one lawyer and two computer and information manager-level staff persons would engage in this review. For each entity that reviews the rule, the estimated costs are therefore $200 for lawyers, or $64.8 million (2 hours each × 1 staff × $100 × 323,766) for all affected entities. For each plan, clearinghouse, and PMS or EHR vendor, the estimated costs are therefore $436 for information system managers, or $0.8 million (2 hours each × 2 staff × $109 × 1,937) in total. Therefore, we estimate that the total cost of reviewing this rule is $65.6 million ($64.8 + 0.8 million).

F. Accounting Statement

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an Accounting Statement. This statement must state that we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. Monetary annualized benefits and non-budgetary costs are presented using 3 percent and 7 percent discount rates.

TABLE 10—ACCOUNTING STATEMENT—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2025 TO FY 2034

[$ in millions]

Category	Primary estimate	Minimum estimate	Maximum estimate	Source
Benefits				
Annualized monetized benefits:				
7% Discount	670	574	765	RIA.
3% Discount	708	606	809	RIA.
Qualitative (un-quantified benefits)	Increased productivity due to decrease in manual processing; reduced delays in patient care.			
Providers and health plans would benefit from efficiencies in resource use stemming from changes implemented by plans, clearinghouses, and vendors.				
Costs				
Annualized monetized costs:				
7% Discount	700	474	926	RIA.
3% Discount	615	416	814	RIA.
Qualitative (un-quantified costs)	None.			
Providers, health plans, and government plans would pay for IT staff and other contractors, as well as clearinghouses and vendors for changes in the forms of new and ongoing fees.				
Transfers				
Annualized monetized transfers: ''on budget''	None	None	None..	
Annualized monetized transfers: ''off budget''	None	None	None.	

VI. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects

45 CFR Part 160

Administrative practice and procedure, Computer technology, Health care, Health facilities, Health insurance, Health records, Hospitals, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 162

Administrative practice and procedures, electronic transactions, health facilities, health insurance, hospitals, incorporation by reference, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in this preamble, the Department of Health and Human Services proposed to amend 45 CFR subchapter C to read as follows:

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 160 continues to read as follows:

Authority: 42 U.S.C. 1302(a), 42 U.S.C. 1320d–1320d–8, sec. 264 of Pub. L. 104 191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)), 5 U.S.C. 552; secs. 13400 and 13424, Pub. L. 111–5, 123 Stat. 258–279, and sec. 1104 of Pub. L. 111–148, 124 Stat. 146–154.

§ 160.103 [Amended]

■ 2. In § 160.103, paragraph (10) of the definition of ''Transaction'' is amended by removing the word ''claims'' and adding in its place the word ''care''.

PART 162—ADMINISTRATIVE REQUIREMENTS

■ 3. The authority citation for part 162 continues to read as follows:

Authority: 42 U.S.C. 1320d—1320d–9 and secs. 1104 and 10109 of Pub. L. 111–148, 124 Stat. 146–154 and 915–917.

■ 4. Section 162.103 is amended by adding the definitions of ''Attachment information'' and ''Electronic signature'' to read as follows:

§ 162.103 Definitions.

* * * * *

Attachment information means documentation that enables the health plan to make a decision about health care that is not included in either of the following:

(1) A health care claims or equivalent encounter information transaction, as described in § 162.1101.

(2) A referral certification and authorization transaction, as described in § 162.1301(a) and the portion of § 162.1301(c) that pertains to authorization.

* * * * *

Electronic signature means an electronic sound, symbol, or process, attached to or logically associated with attachment information and executed by a person with the intent to sign the attachment information.

* * * * *

■ 5. Section 162.920 is amended by:
■ a. Revising the introductory text and paragraph (a) introductory text; and
■ b. Adding paragraphs (a)(19) through (22) and (e).

The revisions and additions read as follows:

§ 162.920 Availability of implementation specifications and operating rules.

Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish a document in

the **Federal Register** and the material must be available to the public. All approved incorporation by reference (IBR) material is available for inspection at the Centers for Medicaid & Medicare Services (CMS) and the National Archives and Records Administration (NARA). Contact CMS at: 7500 Security Boulevard, Baltimore, Maryland 21244; *administrativesimplification@cms.hhs.gov;* (410) 786–6597. For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations.html* or email *fr.inspection@nara.gov.* The material may be obtained from the following source(s):

(a) ASC X12, 7600 Leesburg Pike, Suite 430, Falls Church, VA 22043; Telephone (703) 970–4480; FAX (703) 970–4488; *https://www.X12.org.*

(19) The X12N 275—Additional Information to Support a Health Care Claim or Encounter (006020X314), September 2014; IBR approved for § 162.2002(d).

(20) The X12N 275—Additional Information to Support a Health Care Services Review (006020X316), August 2021; IBR approved for § 162.2002(c).

(21) The X12N 277—Health Care Claim Request for Additional Information (006020X313), September 2014; IBR approved for § 162.2002(e).

(22) The X12N 278—Health Care Services Request for Review and Response (006020X315), September 2014; IBR approved for § 162.1302(e).

* * * * *

(e) Health Level Seven International (HL–7), 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104; Telephone (734) 677–7777; FAX (734) 677–6622; *www.hl7.org.*

(1) HL7 CDA R2 Attachment Implementation Guide: Exchange of C–CDA Based Documents, Release 1—March 2017; IBR approved for § 162.2002(a).

(2) HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 1—Introductory Material, June 2019 with Errata; IBR approved for § 162.2002(b).

(3) HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 2—Templates and Supporting Material, June 2019 with Errata; IBR approved for § 162.2002(b).

■ 6. Section 162.1302 is amended—

■ a. In paragraph (c), by removing the phrase ''standards identified in paragraph (b)(2)'' and adding in its place the phrase ''standard identified in paragraph (b)(2)(i)''; and

■ b. By adding paragraph (e).

The addition reads as follows:

§ 162.1302 Standards for referral certification and prior authorization transaction.

* * * * *

(e) For the period from January 1, 2012—

(1) Through [24 months from effective date of the final rule], the standard identified in paragraph (b)(2)(ii) of this section;

(2) On and after [24 months from the effective date of the final rule], the X12N 278—Health Care Services Request for Review and Response (006020X315) (incorporated by reference, see § 162.920).

■ 7. Add subpart T, consisting of §§ 162.2001 and 162.2002 to read as follows:

Subpart T—Health Care Attachments

Sec.

Subpart T—Health Care Attachments

§ 162.2001 Health care attachments transaction.

A health care attachments transaction is the transmission of any of the following:

(a) Attachment information from a health care provider to a health plan for any of the following purposes:

(1) In support of a referral certification and authorization transaction, as described in § 162.1301(a).

(2) In support of a health care claims or equivalent encounter transaction, as described in § 162.1101.

(b) A request from a health plan to a health care provider for attachment information.

§ 162.2002 Standards for health care attachments transaction.

The Secretary adopts the following standards for the period on and after [24 months from effective date of the final rule]:

(a) For transmissions described in § 162.2001, HL7 CDA R2: Attachment Implementation Guide: Exchange of C–CDA Based Documents, Release 1—March 2017 (incorporated by reference, see § 162.920).

(b) For transmissions described in § 162.2001(a) —

(1) HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 1—Introductory Material, June 2019 with Errata (incorporated by reference, see § 162.920)

(2) HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1, Volume 2 — Templates and Supporting Material, June 2019 with Errata (incorporated by reference, see § 162.920).

(c) For transmissions described in § 162.2001(a)(1), the X12N 275 Additional Information to Support a Health Care Services Review (06020X316).

(d) For transmissions described in § 162.2001(a)(2), the X12N 275 Additional Information to Support a Health Care Claim or Encounter (06020X314).

(e) For transmissions described in the following:

(1) Section 162.2001(b) that pertain to § 162.2001(a)(2) transmissions, the X12N 277—Health Care Claim Request for Additional Information (006020X313) (incorporated by reference, see § 162.920).

(2) Section 162.2001(b) that pertain to § 162.2001(a)(1) transmissions, the standard specified in 45 CFR 1302(e)(2).

Dated: December 14, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–27437 Filed 12–15–22; 4:15 pm]

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FEDERAL REGISTER

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Part VI

Department of the Treasury

Office of Foreign Assets Control

31 Parts 510, 525, et al.

Addition of General Licenses for the Official Business of the United States Government and Certain International Organizations and Entities and Updates to the 50 Percent Rule Interpretive in OFAC Sanctions Regulations; Final Rule

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Parts 510, 525, 536, 539, 541, 542, 544, 546, 547, 548, 549, 551, 552, 555, 558, 560, 561, 562, 569, 576, 579, 582, 583, 584, 585, 591, 594, 596, 597, and 598

Addition of General Licenses for the Official Business of the United States Government and Certain International Organizations and Entities and Updates to the 50 Percent Rule Interpretive in OFAC Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is amending its regulations in multiple sanctions programs to add, amend, or update general licenses authorizing official business of the United States government and official business of certain international organizations and entities, and update an interpretation explaining that the property and interests in property of an entity are blocked if one or more blocked persons own, whether individually or in the aggregate, directly or indirectly, a 50 percent or greater interest in the entity. Additionally, OFAC is updating the authority citation of several CFR parts to consolidate or shorten citations to conform to **Federal Register** requirements.

DATES: This rule is effective December 21, 2022.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website (*www.treas.gov/ofac*).

Background

OFAC, in consultation with the Department of State, is amending regulations in multiple OFAC-administered sanctions programs to generally official business of the United States government, as well as official business of certain international organizations and entities, in multiple sanctions programs OFAC administers. Specifically, OFAC is amending regulations to add a general license authorizing official business of the United States government to the following parts of 31 CFR: 536, 539, 541, 544, 546, 547, 548, 549, 552, 555, 558, 560, 561, 562, 569, 576, 579, 583, 584, 594, 596, 597, and 598. Additionally, OFAC is updating the existing general licenses authorizing official business of the United States government in 31 CFR 510.513 and 542.522, as well as corresponding text in 31 CFR 510.213 and 542.211 to conform to current standards for OFAC general licenses.

OFAC is also adding a general license authorizing official business of certain international organizations and entities to the following parts of 31 CFR: 536, 539, 541, 544, 546, 547, 548, 549, 555, 558, 561, 562, 569, 576, 579, 582, 583, 584, 585, 594, 596, 597, and 598. OFAC is also adding this general license to 31 CFR parts 525 and 591, incorporating into 31 CFR part 525 the existing Burma General License No. 2, which was previously issued on OFAC's website on March 25, 2021, and incorporating into 31 CFR part 591 the existing Venezuela General License No. 20B, which was previously issued on OFAC's website on January 21, 2020. OFAC is also adding this general license to 31 CFR parts 594 and 597, incorporating and expanding into both parts the authorization found in Counter Terrorism General License No. 1, which was previously issued on OFAC's website on April 12, 2006. The aforementioned web general licenses in parts 525, 591, 594, and 597 will be removed from OFAC's website upon final issuance of this rule. Finally, OFAC is updating the existing general license authorizing activities of certain international organizations in 31 CFR parts 510, 551, 552, and 560 to conform to current standards for OFAC general licenses. Based on the foreign policy considerations of each sanctions program, the general licenses may list different sets of international organizations across different programs, and some general licenses exclude funds transfers made with knowledge or reason to know they are intended for blocked persons, unless certain criteria are met.

OFAC is also updating an interpretation in several regulations to explain that the property and interests in property of an entity are blocked if one or more blocked persons own, whether individually or in the aggregate, directly or indirectly, a 50 percent or greater interest in the entity, whether or not the entity itself is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List). This interpretation conforms with current OFAC guidance. The regulatory sections being updated with this interpretation are: §§ 541.411, 542.411, 544.411, 546.411, 548.411, 549.411, 558.406, 560.425, 562.406, 576.412, 584.410, 591.406, and 594.412. In addition, relevant cross-references in the notes to the following sections are also being updated: §§ 541.301, 542.301, 544.301, 546.302, 548.301, 549.301, 558.301, 560.322, 562.301, 576.301, and 591.301.

Finally, OFAC is updating the authority citations of 31 CFR parts 555, 558, 562, 569, 579, 582, and 591 to consolidate or shorten citations to conform to **Federal Register** requirements or make other technical updates.

Public Participation

Because the regulations being amended involve a foreign affairs function, the provisions of Executive Order (E.O.) 12866 of September 30, 1993, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The collections of information related to 31 CFR parts 510, 525, 536, 539, 541, 542, 544, 546, 547, 548, 549, 551, 552, 555, 558, 560, 561, 562, 569, 576, 579, 582, 583, 584, 585, 591, 594, 596, 597, and 598 are contained in 31 CFR part 501 (the ''Reporting, Procedures and Penalties Regulations''). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget (OMB) under control number 1505–0164. The collection of information in 31 CFR 561.504(b) has been approved by OMB under control number 1505–0243. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

List of Subjects in 31 CFR Parts 510, 525, 536, 539, 541, 542, 544, 546, 547, 548, 549, 551, 552, 555, 558, 560, 561, 562, 569, 576, 579, 582, 583, 584, 585, 591, 594, 596, 597, and 598

Administrative practice and procedure, Banks, Banking, Blocking of assets, Credit, Foreign trade, Penalties,

Reporting and recordkeeping requirements, Sanctions, Securities, Services.

For the reasons set forth in the preamble, OFAC amends 31 CFR chapter V as follows:

PART 510—NORTH KOREA SANCTIONS REGULATIONS

■ 1. The authority citation for part 510 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; 22 U.S.C. 287c, 9201–9255; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); Pub. L. 115–44, 131 Stat. 886 (codified in scattered sections of 22 U.S.C.); E.O. 13466, 73 FR 36787, 3 CFR, 2008 Comp., p. 195; E.O. 13551, 75 FR 53837, 3 CFR, 2010 Comp., p. 242; E.O. 13570, 76 FR 22291, 3 CFR, 2011 Comp., p. 233; E.O. 13687, 80 FR 819, 3 CFR, 2015 Comp., p. 259; E.O. 13722, 81 FR 14943, 3 CFR, 2016 Comp., p. 446; E.O. 13810, 82 FR 44705, 3 CFR, 2017 Comp., p. 379.

Subpart B—Prohibitions

§ 510.213 [Amended]

■ 2. In § 510.213, in paragraph (e) introductory text, remove the word ''Federal'' and add in its place ''United States'' and remove note 3 to paragraph (e).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 3. Revise § 510.513 to read as follows:

§ 510.513 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

Note 1 to § 510.513. Section 510.213(e) exempts transactions for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof to the extent such transactions are subject to the prohibitions contained in §§ 510.201(a)(1), (a)(3)(iv) through (vi), and (d), 510.206, and 510.208 through 510.211.

■ 4. Revise § 510.514 to read as follows:

§ 510.514 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(e) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

Note 1 to § 510.514. Section 510.213(e) exempts transactions for the conduct of the official business of the United Nations by employees, grantees, or contractors thereof to the extent such transactions are subject to the prohibitions contained in §§ 510.201(a)(1), (a)(3)(iv) through (vi), and (d), 510.206, and 510.208 through 510.211.

Note 2 to § 510.514. Separate authorization from the Department of Commerce may be required for the export or reexport of items related to such transactions, if the items are subject to the Export Administration Regulations, 15 CFR parts 730 through 774.

PART 525—BURMA SANCTIONS REGULATIONS

■ 5. The authority citation for part 525 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 14014, 86 FR 9429, February 12, 2021.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 6. Add § 525.510 to read as follows:

§ 525.510 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies;

(e) International Development Law Organization (IDLO);

(f) The Association of Southeast Asian Nations (ASEAN);

(g) The Colombo Plan;

(h) The Consultative Group on International Agricultural Research (CGIAR) System Organization and the International Agricultural Research Centers supported by the CGIAR;

(i) The Extractive Industries Transparency Initiative (EITI); and

(j) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

PART 536—NARCOTICS TRAFFICKING SANCTION REGULATIONS

■ 7. The authority citation for part 536 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 12978, 60 FR 54579, 3 CFR, 1995 Comp., p. 415; E.O. 13286, 68 FR 10619, 3 CFR, 2003 Comp., p. 166.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 8. Add § 536.512 to read as follows:

§ 536.512 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 9. Add § 536.513 to read as follows:

§ 536.513 Official business of certain international organizations and entities.

(a) Except as provided in paragraph (b) of this section, all transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(1) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(2) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(3) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group

(IDB Group), including any fund entity administered or established by any of the foregoing;

(4) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(5) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

(b) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

PART 539—WEAPONS OF MASS DESTRUCTION TRADE CONTROL REGULATIONS

■ 10. The authority citation for part 539 continues to read as follows:

Authority: 3 U.S.C. 301; 22 U.S.C. 2751–2799aa–2; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 12938; 59 FR 59099; 3 CFR, 1994 Comp., p. 950; E.O. 13094; 63 FR 40803; 3 CFR, 1998 Comp., p. 200; E.O. 13382; 70 FR 38567, 3 CFR, 2005 Comp. p. 170.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 11. Revise § 539.504 to read as follows:

§ 539.504 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 12. Add § 539.505 to read as follows:

§ 539.505 Official business of certain international organizations and entities.

(a) Except as provided in paragraph (b) of this section, all transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(1) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(2) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(3) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(4) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(5) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

(b) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

PART 541—ZIMBABWE SANCTIONS REGULATIONS

■ 13. The authority citation for part 541 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13288, 68 FR 11457, 3 CFR, 2003 Comp., p. 186; E.O. 13391, 70 FR 71201, 3 CFR, 2005 Comp., p. 206; E.O. 13469, 73 FR 43841, 3 CFR, 2008 Comp., p. 1025.

Subpart C—General Definitions

§ 541.301 [Amended]

■ 14. In § 541.301, designate Note to § 541.301 as Note 1 to § 541.301 and remove the text ''50 percent or more owned by a person'' and add in its place ''directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons''.

Subpart D—Interpretations

■ 15. Revise § 541.411 to read as follows:

§ 541.411 Entities owned by one or more persons whose property and interests in property are blocked.

Persons whose property and interests in property are blocked pursuant to § 541.201 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 541.201, regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 16. Add § 541.510 to read as follows:

§ 541.510 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 17. Add § 541.511 to read as follows:

§ 541.511 Official business of certain international organizations and entities.

(a) Except as provided in paragraph (b) of this section, all transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(1) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(2) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(3) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(4) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(5) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

(b) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

PART 542—SYRIAN SANCTIONS REGULATIONS

■ 18. The authority citation continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 18 U.S.C. 2332d; 22 U.S.C. 287c; 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104

Stat. 890, as amended (28 U.S.C. 2461 note); Pub. L. 116–92, Div. F, Title LXXIV, 133 Stat. 2290 (22 U.S.C. 8791 note); E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; E.O. 13399, 71 FR 25059, 3 CFR, 2006 Comp., p. 218; E.O. 13460, 73 FR 8991, 3 CFR 2008 Comp., p. 181; E.O. 13572, 76 FR 24787, 3 CFR 2011 Comp., p. 236; E.O. 13573, 76 FR 29143, 3 CFR 2011 Comp., p. 241; E.O. 13582, 76 FR 52209, 3 CFR 2011 Comp., p. 264; E.O. 13606, 77 FR 24571, 3 CFR 2012 Comp., p. 243.

Subpart B—Prohibitions

§ 542.211 [Amended]

■ 19. In § 542.211, in paragraph (d) introductory text, remove the word ''Federal'' and add in its place ''United States''.

Subpart C—General Definitions

§ 542.301 [Amended]

■ 20. In § 542.301, designate Note to § 542.301 as Note 1 to § 542.301 and remove the text ''50 percent or more owned by a person'' and add in its place ''directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons''.

Subpart D—Interpretations

■ 21. Revise § 542.411 to read as follows:

§ 542.411 Entities owned by one or more persons whose property and interests in property are blocked.

(a) Persons whose property and interests in property are blocked pursuant to § 542.201 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 542.201, regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

(b) This section, which deals with the consequences of ownership of entities, in no way limits the definition of the Government of Syria in § 542.305, which includes within its definition other persons whose property and interests in property are blocked but who are not on the SDN List.

■ 22. Revise § 542.522 to read as follows:

§ 542.522 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

PART 544—WEAPONS OF MASS DESTRUCTION PROLIFERATORS SANCTIONS REGULATIONS

■ 23. The authority citation for part 544 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13094, 63 FR 40803, 3 CFR, 1998 Comp., p. 200; E.O. 13382, 70 FR 38567, 3 CFR, 2005 Comp., p. 170.

Subpart C—General Definitions

§ 544.301 [Amended]

■ 24. In § 544.301, designate Note to § 544.301 as Note 1 to § 544.301 and remove the text ''50 percent or more owned by a person'' and add in its place ''directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons''.

Subpart D—Interpretations

■ 25. Revise § 544.411 to read as follows:

§ 544.411 Entities owned by one or more persons whose property and interests in property are blocked.

Persons whose property and interests in property are blocked pursuant to § 544.201 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 544.201, regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 26. Add § 544.510 to read as follows:

§ 544.510 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 27. Add § 544.511 to read as follows:

§ 544.511 Official business of certain international organizations and entities.

(a) Except as provided in paragraph (b) of this section, all transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(1) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(2) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(3) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(4) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(5) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

(b) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

PART 546—DARFUR SANCTIONS REGULATIONS

■ 28. The authority citation for part 546 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; 22 U.S.C. 287c; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13067, 62 FR 59989, 3 CFR, 1997 Comp., p. 230; E.O. 13400, 71 FR 25483, 3 CFR, 2006 Comp., p. 220.

Subpart C—General Definitions

§ 546.302 [Amended]

■ 29. In § 546.302, designate Note to § 546.302 as Note 1 to § 546.302 and remove the text ''50 percent or more owned by a person'' and add in its place ''directly or indirectly owned, whether individually or in the aggregate, 50

percent or more by one or more persons''.

Subpart D—Interpretations

■ 30. Revise § 546.411 to read as follows:

§ 546.411 Entities owned by one or more persons whose property and interests in property are blocked.

Persons whose property and interests in property are blocked pursuant to § 546.201 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 546.201, regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 31. Add § 546.509 to read as follows:

§ 546.509 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 32. Add § 546.510 to read as follows:

§ 546.510 Official business of certain international organizations and entities.

(a) Except as provided in paragraph (b) of this section, all transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(1) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(2) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(3) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(4) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies;

(5) The Intergovernmental Authority on Development (IGAD); and

(6) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

(b) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

PART 547—DEMOCRATIC REPUBLIC OF THE CONGO SANCTIONS REGULATIONS

■ 33. The authority citation for part 547 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; 22 U.S.C. 287c; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13413, 71 FR 64105, 3 CFR, 2006 Comp., p. 247; E.O. 13671, 79 FR 39949, 3 CFR, 2015 Comp., p. 280.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 34. Add § 547.510 to read as follows:

§ 547.510 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 35. Add § 547.511 to read as follows:

§ 547.511 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies;

(e) The Extractive Industries Transparency Initiative (EITI); and

(f) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

PART 548—BELARUS SANCTIONS REGULATIONS

■ 36. The authority citation for part 548 is revised to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13405, 71 FR 35485, 3 CFR, 2006 Comp., p. 231.

Subpart C—General Definitions

§ 548.301 [Amended]

■ 37. In § 548.301, designate Note to § 548.301 as Note 1 to § 548.301 and remove the text ''50 percent or more owned by a person'' and add in its place ''directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons''.

Subpart D—Interpretations

■ 38. Revise § 548.411 to read as follows:

§ 548.411 Entities owned by one or more persons whose property and interests in property are blocked.

Persons whose property and interests in property are blocked pursuant to § 548.201 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 548.201, regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 39. Add § 548.509 to read as follows:

§ 548.509 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 40. Add § 548.510 to read as follows:

§ 548.510 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(e) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

PART 549—LEBANON SANCTIONS REGULATIONS

■ 41. The authority citation for part 549 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13441, 72 FR 43499, 3 CFR, 2008 Comp., p. 232.

Subpart C—General Definitions

§ 549.301 [Amended]

■ 42. In § 549.301, designate Note to § 549.301 as Note 1 to § 549.301 and remove the text ''50 percent or more owned by a person'' and add in its place ''directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons''.

Subpart D—Interpretations

■ 43. Revise § 549.411 to read as follows:

§ 549.411 Entities owned by one or more persons whose property and interests in property are blocked.

Persons whose property and interests in property are blocked pursuant to § 549.201 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 549.201, regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 44. Add § 549.509 to read as follows:

§ 549.509 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 45. Add § 549.510 to read as follows:

§ 549.510 Official business of certain international organizations and entities.

(a) Except as provided in paragraph (b) of this section, all transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(1) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(2) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(3) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(4) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies;

(5) The Arab Monetary Fund and the Islamic Development Bank; and

(6) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

(b) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

PART 551—SOMALIA SANCTIONS REGULATIONS

■ 46. The authority citation for part 551 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; 22 U.S.C. 287c; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13536, 75 FR 19869, 3 CFR, 2010 Comp., p. 203; E.O. 13620, 77 FR 43483, 3 CFR, 2012 Comp., p. 281.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 47. Revise § 551.511 to read as follows:

§ 551.511 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies;

(e) Gavi, the Vaccine Alliance; and

(f) The Intergovernmental Authority on Development (IGAD).

PART 552—YEMEN SANCTIONS REGULATIONS

■ 48. The authority citation continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13611, 77 FR 29533, 3 CFR, 2012 Comp., p. 260.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

§ 552.510 [Redesignated as § 552.511]

■ 49. Redesignate § 552.510 as § 552.511.

■ 50. Add new § 552.510 to read as follows:

§ 552.510 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 51. Revise newly redesignated § 552.511 to read as follows:

§ 552.511 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(e) The Arab Monetary Fund and the Islamic Development Bank; and

(f) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

PART 555—MALI SANCTIONS REGULATIONS

■ 52. The authority citation for part 555 is revised to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13882, 84 FR 37055, 3 CFR, 2019 Comp., p. 346.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 53. Add § 555.509 to read as follows:

§ 555.509 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 54. Add § 555.510 to read as follows:

§ 555.510 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(e) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

PART 558—SOUTH SUDAN SANCTIONS REGULATIONS

■ 55. The authority citation for part 558 is revised to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13664, 79 FR 19283, 3 CFR, 2014 Comp., p. 238.

Subpart C—General Definitions

§ 558.301 [Amended]

■ 56. In § 558.301, designate Note to § 558.301 as Note 1 to § 558.301 and remove the text ''50 percent or more owned by a person'' and add in its place ''directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons''.

Subpart D—Interpretations

■ 57. Revise § 558.406 to read as follows:

§ 558.406 Entities owned by one or more persons whose property and interests in property are blocked.

Persons whose property and interests in property are blocked pursuant to § 558.201 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 558.201, regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 58. Add § 558.509 to read as follows:

§ 558.509 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 59. Add § 558.510 to read as follows:

§ 558.510 Official business of certain international organizations and entities.

(a) Except as provided in paragraph (b) of this section, all transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(1) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(2) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(3) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(4) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies;

(5) The Intergovernmental Authority on Development (IGAD); and

(6) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

(b) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

PART 560—IRANIAN TRANSACTIONS AND SANCTIONS REGULATIONS

■ 60. The authority citation for part 560 continues to read as follows:

Authority: 3 U.S.C. 301; 18 U.S.C. 2339B, 2332d; 22 U.S.C. 2349aa-9, 7201–7211, 8501–8551, 8701–8795; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 12613, 52 FR 41940, 3 CFR, 1987 Comp., p. 256; E.O. 12957, 60 FR 14615, 3 CFR, 1995 Comp., p. 332; E.O. 12959, 60 FR 24757, 3 CFR, 1995 Comp., p. 356; E.O. 13059, 62 FR 44531, 3 CFR, 1997 Comp., p. 217; E.O. 13599, 77 FR 6659, 3 CFR, 2012 Comp., p. 215; E.O. 13846, 83 FR 38939, 3 CFR, 2018 Comp., p. 854.

Subpart C—General Definitions

§ 560.322 [Amended]

■ 61. In § 560.322, designate Note to § 560.322 as Note 1 to § 560.322 and remove the text ''50 percent or more owned by a person'' and add in its place ''directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons''.

Subpart D—Interpretations

■ 62. Revise § 560.425 to read as follows:

§ 560.425 Entities owned by one or more persons whose property and interests in property are blocked.

(a) Persons whose property and interests in property are blocked pursuant to § 560.211 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 560.211, regardless of whether the entity itself is identified as a person whose property and interests in property are blocked pursuant to § 560.211.

(b) This section, which deals with the consequences of ownership of entities, in no way limits the definition of the Government of Iran in § 560.304.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 63. Revise § 560.539 to read as follows:

§ 560.539 Official business of certain international organizations and entities.

(a) Except as provided in paragraph (b) of this section, all transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(1) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(2) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(3) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(4) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(5) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

(b) This section does not authorize any transactions or activities involving the Iranian Red Crescent Society.

■ 64. Add § 560.557 to read as follows:

§ 560.557 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

PART 561—IRANIAN FINANCIAL SANCTIONS REGULATIONS

■ 65. The authority citation for part 561 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; 22 U.S.C. 8501–8551, 8701–8795; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 12957, 60 FR 14615, 3 CFR, 1995 Comp., p. 332; E.O. 13553, 75 FR 60567, 3 CFR, 2010 Comp., p. 253; E.O. 13599, 77 FR 6659, 3 CFR, 2012 Comp., p. 215; E.O. 13846, 83 FR 38939, 3 CFR, 2018 Comp., p. 854; E.O. 13871, 84 FR 20761, 3 CFR, 2019 Comp., p. 309.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 66. Add § 561.505 to read as follows:

§ 561.505 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

PART 562—IRANIAN SECTOR AND HUMAN RIGHTS ABUSES SANCTIONS REGULATIONS

■ 67. The authority citation for part 562 is revised to read as follows:

Authority: 3 U.S.C. 301; 18 U.S.C. 2332d; 22 U.S.C. 8501–8551; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 12957, 60 FR 14615, 3 CFR, 1995 Comp., p. 332; E.O. 13553, 75 FR 60567, 3 CFR, 2010 Comp., p. 253; E.O. 13871, 84 FR 20761, 3 CFR, 2019 Comp., p. 308.

Subpart C—General Definitions

§ 562.301 [Amended]

■ 68. In § 562.301, designate Note to § 562.301 as Note 1 to § 562.301 and remove the text ''50 percent or more owned by a person'' and add in its place ''directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons''.

Subpart D—Interpretations

■ 69. Revise § 562.406 to read as follows:

§ 562.406 Entities owned by one or more persons whose property and interests in property are blocked.

Persons whose property and interests in property are blocked pursuant to § 562.201 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 562.201, regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 70. Add § 562.508 to read as follows:

§ 562.508 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 71. Add § 562.509 to read as follows:

§ 562.509 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities

by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(e) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

PART 569—SYRIA–RELATED SANCTIONS REGULATIONS

■ 72. The authority citation for part 569 is revised to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13894, 84 FR 55851, 3 CFR, 2019 Comp., p. 382.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 73. Add § 569.509 to read as follows:

§ 569.509 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 74. Add § 569.510 to read as follows:

§ 569.510 Official business of certain international organizations and entities.

(a) Except as provided in paragraph (b) of this section, all transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(1) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(2) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(3) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(4) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies;

(5) The Arab Monetary Fund and the Islamic Development Bank; and

(6) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

(b) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

PART 576—IRAQ STABILIZATION AND INSURGENCY SANCTIONS REGULATIONS

■ 75. The authority citation for part 576 continues to read as follows:

Authority: 3 U.S.C. 301; 22 U.S.C. 287c; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13303, 68 FR 31931, 3 CFR, 2003 Comp., p. 227; E.O. 13315, 68 FR 52315, 3 CFR, 2003 Comp., p. 252; E.O. 13350, 69 FR 46055, 3 CFR, 2004 Comp., p. 196; E.O. 13364, 69 FR 70177, 3 CFR, 2004 Comp., p. 236; E.O. 13438, 72 FR 39719, 3 CFR, 2007 Comp., p. 224; E.O. 13668, 79 FR 31019, 3 CFR, 2014 Comp., p. 248.

Subpart C—General Definitions

§ 576.301 [Amended]

■ 76. In § 576.301, designate Note to § 576.301 as Note 1 to § 576 and remove the text ''50 percent or more owned by a person'' and add in its place ''directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons''.

Subpart D—Interpretations

■ 77. Revise § 576.412 to read as follows:

§ 576.412 Entities owned by one or more persons whose property and interests in property are blocked.

Persons whose property and interests in property are blocked pursuant to § 576.201 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 576.201, regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 78. Add § 576.513 to read as follows:

§ 576.513 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 79. Add § 576.514 to read as follows:

§ 576.514 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(e) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

PART 579—FOREIGN INTERFERENCE IN U.S. ELECTIONS SANCTIONS REGULATIONS

■ 80. The authority citation for part 579 is revised to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13848, 83 FR 46843, 3 CFR, 2018 Comp., p. 869.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 81. Add § 579.509 to read as follows:

§ 579.509 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 82. Add § 579.510 to read as follows:

§ 579.510 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(e) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

PART 582—NICARAGUA SANCTIONS REGULATIONS

■ 83. The authority citation for part 582 is revised to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); Pub. L. 115–335, 132 Stat. 5019 (50 U.S.C. 1701 note); E.O. 13851, 83 FR 61505, 3 CFR, 2018 Comp., p. 884.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

§ 582.509 [Amended]

■ 84. In § 582.509, add a period to the end of the section heading.

■ 85. Add § 582.510 to read as follows:

§ 582.510 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(e) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

PART 583—GLOBAL MAGNITSKY SANCTIONS REGULATIONS

■ 86. The authority citation for part 583 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); Pub. L. 114–328, Div. A, Title XII, Subt. F, 130 Stat. 2533 (22 U.S.C. 2656 note); E.O. 13818, 82 FR 60839, 3 CFR, 2017 Comp., p. 399.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 87. Add § 583.509 to read as follows:

§ 583.509 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 88. Add § 583.510 to read as follows:

§ 583.510 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(e) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

PART 584—MAGNITSKY ACT SANCTIONS REGULATIONS

■ 89. The authority citation for part 584 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); Pub. L. 112–208, Title IV, 126 Stat. 1502 (22 U.S.C. 5811 note).

Subpart D—Interpretations

§ 584.410 [Amended]

■ 90. In § 584.410, remove the text ''§ 584.201(a)'' and add in its place ''§ 584.201'' in both instances where it appears, and remove the text ''in which such blocked'' and add in its place ''of an entity in which such''.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 91. Add § 584.510 to read as follows:

§ 584.510 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 92. Add § 584.511 to read as follows:

§ 584.511 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity

administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(e) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

PART 585—HONG KONG-RELATED SANCTIONS REGULATIONS

■ 93. The authority citation for part 585 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); E.O. 13936, 85 FR 43413, July 17, 2020.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 94. Add § 585.510 to read as follows:

§ 585.510 Official business of certain international organizations and entities.

All transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(b) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(c) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(d) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(e) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

PART 591—VENEZUELA SANCTIONS REGULATIONS

■ 95. The authority citation for part 591 is revised to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); Pub. L. 113–278, 128 Stat. 3011 (50 U.S.C. 1701 note); E.O. 13692, 80 FR 12747, 3 CFR, 2015 Comp., p. 276; E.O. 13808, 82 FR 41155, 3 CFR, 2017 Comp., p. 377; E.O. 13827, 83 FR 12469, 3 CFR, 2018 Comp., p. 794; E.O. 13835, 83 FR 24001, 3 CFR, 2018 Comp., p. 817; E.O. 13850, 83 FR 55243, 3 CFR, 2018 Comp., p. 881; E.O. 13857, 84 FR 509, 3 CFR, 2019 Comp., p 251; E.O. 13884, 84 FR 38843, 3 CFR, 2019 Comp., p. 351.

Subpart C—General Definitions

§ 591.301 [Amended]

■ 96. In § 591.301, designate Note to § 591.301 as Note 1 to § 591.301 and remove the text ''50 percent or more owned by a person'' and add in its place ''directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons''.

Subpart D—Interpretations

■ 97. Revise § 591.406 to read as follows:

§ 591.406 Entities owned by one or more persons whose property and interests in property are blocked.

(a) Persons whose property and interests in property are blocked pursuant to § 591.201 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 591.201, regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

(b) This section, which deals with the consequences of ownership of entities, in no way limits the definition of the Government of Venezuela in E.O. 13884, which includes within its definition other persons whose property and interests in property are blocked but who are not on the SDN List.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 98. Add § 591.510 to read as follows:

§ 591.510 Official business of certain international organizations and entities.

All transactions prohibited by Executive Order (E.O.) 13850, as amended by E.O. 13857 of January 25, 2019, involving Banco Central de Venezuela, or E.O. 13884 involving the Government of Venezuela, that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(a) Corporación Andina de Fomento (CAF)

(b) Fondo Latinoamericano de Reservas

(c) Inter-American Development Bank

(d) International Committee of the Red Cross

(e) International Federation of the Red Cross and Red Crescent Societies

(f) Organization of American States, and its specialized organizations, other autonomous and decentralized organs, agencies, entities, and dependencies

(g) The World Bank Group (also referred to as the World Bank), including the International Bank for Reconstruction and Development (IBRD), International Development Association (IDA), International Finance Corporation (IFC), Multilateral Investment Guarantee Agency (MIGA), and International Centre for Settlement of Investment Disputes (ICSID)

(h) United Nations, including its Programmes and Funds, and its Specialized Agencies and Related Organizations, including those entities specifically listed separately below:

(1) IMF (International Monetary Fund)

(2) FAO (UN Food and Agriculture Organization)

(3) IOM (International Organization for Migration)

(4) OCHA (UN Office for the Coordination of Humanitarian Affairs)

(5) OHCHR (UN Office of the United Nations High Commissioner for Human Rights)

(6) UN Habitat

(7) UNDP (UN Development Program)

(8) UNFPA (UN Population Fund)

(9) UNHCR (Office of the UN High Commissioner for Refugees)

(10) UNICEF (UN Children's Fund)

(11) WFP (World Food Program)

(12) The World Health Organization (WHO), including the Pan-American Health Organization (PAHO)

PART 594—GLOBAL TERRORISM SANCTIONS REGULATIONS

■ 99. The authority citation for part 594 continues to read as follows:

Authority: 3 U.S.C. 301; 22 U.S.C. 287c; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); Pub. L. 115–44, 131 Stat 886 (codified in scattered sections of 22 U.S.C.); Pub. L. 115–348, 132 Stat. 5055 (50 U.S.C. 1701 note); Pub. L. 114–102, 129 Stat. 2205, as amended (50 U.S.C. 1701 note); E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; E.O. 13268, 67 FR 44751, 3 CFR 2002 Comp., p. 240; E.O. 13284, 68 FR 4075, 3 CFR, 2003 Comp., p. 161; E.O. 13372, 70 FR 8499, 3 CFR, 2006 Comp., p. 159.

Subpart C—General Definitions

■ 100. Amend § 594.301 by adding note 1 to § 594.301 to read as follows:

§ 594.301 Blocked account; blocked property.

* * * * *

Note 1 to § 594.301. See § 594.412 concerning the blocked status of property and interests in property of an entity that is directly or indirectly owned, whether individually or in the aggregate, 50 percent or more by one or more persons whose property and interests in property are blocked pursuant to § 594.201.

Subpart D—Interpretations

■ 101. Revise § 594.412 to read as follows:

§ 594.412 Entities owned by one or more persons whose property and interests in property are blocked.

Persons whose property and interests in property are blocked pursuant to § 594.201 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 594.201, regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

§ 594.510 [Amended]

■ 102. Amend § 594.510 as follows:
■ a. In the section heading;, remove the text ''Official activities of certain international organizations;'';
■ b. Remove paragraphs (a) and (c); and
■ c. Remove the paragraph designation of paragraph (b).

■ 103. Add § 594.518 to read as follows:

§ 594.518 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 104. Add § 594.519 to read as follows:

§ 594.519 Official business of certain international organizations and entities.

(a) Except as provided in paragraph (b) of this section, all transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(1) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(2) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(3) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing; and

(4) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(5) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

(b) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

PART 596—TERRORISM LIST GOVERNMENTS SANCTIONS REGULATIONS

■ 105. The authority citation for part 596 continues to read as follows:

Authority: 18 U.S.C. 2332d; 22 U.S.C. 7201–7211; 31 U.S.C. 321(b).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 106. Add § 596.507 to read as follows:

§ 596.507 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 107. Add § 596.508 to read as follows:

§ 596.508 Official business of certain international organizations and entities.

(a) Except as provided in paragraph (b) of this section, all transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(1) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(2) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(3) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(4) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(5) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

(b) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

PART 597—FOREIGN TERRORIST ORGANIZATIONS SANCTIONS REGULATIONS

■ 108. The authority citation for part 597 continues to read as follows:

Authority: 8 U.S.C. 1189; 18 U.S.C. 2339B; 31 U.S.C. 321(b); Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 109. Add § 597.514 to read as follows:

§ 597.514 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 110. Add § 597.515 to read as follows:

§ 597.515 Official business of certain international organizations and entities.

(a) Except as provided in paragraph (b) of this section, all transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(1) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(2) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(3) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing; and

(4) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(5) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

(b) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

PART 598—FOREIGN NARCOTICS KINGPIN SANCTIONS REGULATIONS

■ 111. The authority citation for part 598 continues to read as follows:

Authority: 3 U.S.C. 301; 21 U.S.C. 1901–1908; 31 U.S.C. 321(b); Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 112. Add § 598.513 to read as follows:

§ 598.513 Official business of the United States Government.

All transactions prohibited by this part that are for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof are authorized.

■ 113. Add § 598.514 to read as follows:

§ 598.514 Official business of certain international organizations and entities.

(a) Except as provided in paragraph (b) of this section, all transactions prohibited by this part that are for the conduct of the official business of the following entities by employees, grantees, or contractors thereof are authorized:

(1) The United Nations, including its Programmes, Funds, and Other Entities and Bodies, as well as its Specialized Agencies and Related Organizations;

(2) The International Centre for Settlement of Investment Disputes (ICSID) and the Multilateral Investment Guarantee Agency (MIGA);

(3) The African Development Bank Group, the Asian Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank Group (IDB Group), including any fund entity administered or established by any of the foregoing;

(4) The International Committee of the Red Cross and the International Federation of Red Cross and Red Crescent Societies; and

(5) The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and Gavi, the Vaccine Alliance.

(b) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2022–27564 Filed 12–20–22; 8:45 am]

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FEDERAL REGISTER

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Part VII

Department of the Treasury

Office of Foreign Assets Control

31 CFR Parts 536, 539, 541, et al.
Addition of General Licenses to OFAC Sanctions Regulations for Certain Transactions of Nongovernmental Organizations and Related to Agricultural Commodities, Medicine, Medical Devices, Replacement Parts and Components, or Software Updates for Medical Devices; Final Rule

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Parts 536, 539, 541, 544, 546, 547, 548, 549, 551, 552, 553, 555, 558, 562, 569, 570, 576, 578, 579, 582, 583, 584, 585, 588, 590, 594, 597, 598, and 599

Addition of General Licenses to OFAC Sanctions Regulations for Certain Transactions of Nongovernmental Organizations and Related to Agricultural Commodities, Medicine, Medical Devices, Replacement Parts and Components, or Software Updates for Medical Devices

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is amending its regulations in multiple sanctions programs to add general licenses authorizing certain transactions of nongovernmental organizations and certain transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates.

DATES: This rule is effective December 21, 2022.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website (*www.treas.gov/ofac*).

Background

OFAC, in consultation with the Department of State, is amending regulations in multiple OFAC-administered sanctions programs to generally license certain transactions of nongovernmental organizations (NGOs), as well as certain transactions related to the exportation or reexportation of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for medical devices. Specifically, OFAC is amending regulations to add a general license authorizing certain transactions of NGOs to the following parts of 31 CFR: 536, 539, 541, 544, 546, 547, 548, 549, 551, 552, 553, 555, 558, 562, 569, 570, 576, 578, 579, 582, 583, 584, 585, 588, 590, 594, 597, 598, and 599. These NGO general licenses exclude funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a blocked person, unless certain criteria are met.

OFAC is also adding a general license authorizing transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates to an individual whose property and interests in property are blocked, provided the items are in quantities consistent with personal, non-commercial use, to the following parts of 31 CFR: 536, 539, 541, 544, 546, 547, 548, 549, 551, 552, 553, 555, 558, 562, 569, 570, 576, 578, 579, 582, 583, 584, 585, 588, 590, 594, 597, 598, and 599.

Public Participation

Because the regulations being amended involve a foreign affairs function, the provisions of Executive Order 12866 of September 30, 1993, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The collections of information related to 31 CFR parts 536, 539, 541, 544, 546, 547, 548, 549, 551, 552, 553, 555, 558, 562, 569, 570, 576, 578, 579, 582, 583, 584, 585, 588, 590, 594, 597, 598, and 599 are contained in 31 CFR part 501 (the ''Reporting, Procedures and Penalties Regulations''). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505–0164. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

List of Subjects in 31 CFR Parts 536, 539, 541, 544, 546, 547, 548, 549, 551, 552, 553, 555, 558, 562, 569, 570, 576, 578, 579, 582, 583, 584, 585, 588, 590, 594, 597, 598, and 599

Administrative practice and procedure, Agricultural commodities, Banks, Banking, Blocking of assets, Credit, Foreign trade, Medicine, Medical devices, Penalties, Reporting and recordkeeping requirements, Sanctions, Securities, Services.

For the reasons set forth in the preamble, OFAC amends 31 CFR chapter V as follows:

PART 536—NARCOTICS TRAFFICKING SANCTIONS REGULATIONS

■ 1. The authority citation for part 536 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 12978, 60 FR 54579, 3 CFR, 1995 Comp., p. 415; E.O. 13286, 68 FR 10619, 3 CFR, 2003 Comp., p. 166.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 2. Add § 536.514 to subpart E read as follows:

§ 536.514 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a specially designated narcotics trafficker.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects

directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a specially designated narcotics trafficker, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects to directly benefit the civilian population.

Note 1 to § 536.514. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 3. Add § 536.515 to subpart E to read as follows:

§ 536.515 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual who is a specially designated narcotics trafficker are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 536.515. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 539—WEAPONS OF MASS DESTRUCTION TRADE CONTROL REGULATIONS

■ 4. The authority citation for part 539 continues to read as follows:

Authority: 3 U.S.C. 301; 22 U.S.C. 2751–2799aa–2; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13094, 63 FR 40803, 3 CFR, 1998 Comp., p. 200; E.O. 13382, 70 FR 38567, 3 CFR, 2005 Comp., p. 170.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 5. Add § 539.506 to subpart E to read as follows:

§ 539.506 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 539.506. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 6. Add § 539.507 to read as follows:

§ 539.507 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 539.507. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 541—ZIMBABWE SANCTIONS REGULATIONS

■ 7. The authority citation for part 541 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13288, 68 FR 11457, 3 CFR, 2003 Comp., p. 186; E.O. 13391, 70 FR 71201, 3 CFR, 2005 Comp., p. 206; E.O. 13469, 73 FR 43841, 3 CFR, 2008 Comp., p. 1025.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 8. Add § 541.512 to subpart E to read as follows:

§ 541.512 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 541.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 9. Add § 541.513 to subpart E to read as follows:

§ 541.513 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 541.513. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 544—WEAPONS OF MASS DESTRUCTION PROLIFERATORS SANCTIONS REGULATIONS

■ 10. The authority citation for part 544 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13094, 63 FR 40803, 3 CFR, 1998 Comp., p. 200; E.O. 13382, 70 FR 38567, 3 CFR, 2005 Comp., p. 170.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 11. Add § 544.512 to subpart E to read as follows:

§ 544.512 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 544.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 12. Add § 544.513 to subpart E to read as follows:

§ 544.513 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 544.513. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 546—DARFUR SANCTIONS REGULATIONS

■ 13. The authority citation for part 546 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; 22 U.S.C. 287c; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13067, 62 FR 59989, 3 CFR, 1997 Comp., p. 230; E.O. 13400, 71 FR 25483, 3 CFR, 2006 Comp., p. 220.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 14. Add § 546.511 to subpart E to read as follows:

§ 546.511 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of

this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 546.511. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 15. Add § 546.512 to subpart E to read as follows:

§ 546.512 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 546.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 547—DEMOCRATIC REPUBLIC OF THE CONGO SANCTIONS REGULATIONS

■ 16. The authority citation for part 547 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; 22 U.S.C. 287c; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13413, 71 FR 64105, 3 CFR, 2006 Comp., p. 247; E.O. 13671, 79 FR 39949, 3 CFR, 2015 Comp., p. 280.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 17. Add § 547.512 to subpart E to read as follows:

§ 547.512 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation

and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 547.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 18. Add § 547.513 to subpart E to read as follows:

§ 547.513 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 547.513. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 548—BELARUS SANCTIONS REGULATIONS

■ 19. The authority citation for part 548 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13405, 71 FR 35485, 3 CFR, 2006 Comp., p. 231.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 20. Add § 548.511 to subpart E to read as follows:

§ 548.511 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 548.511. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 21. Add § 548.512 to subpart E to read as follows:

§ 548.512 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical

devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 548.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 549—LEBANON SANCTIONS REGULATIONS

■ 22. The authority citation for part 549 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13441, 72 FR 43499, 3 CFR, 2008 Comp., p. 232.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 23. Add § 549.511 to subpart E to read as follows:

§ 549.511 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 549.511. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 24. Add § 549.512 to subpart E to read as follows:

§ 549.512 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 549.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 551—SOMALIA SANCTIONS REGULATIONS

■ 25. The authority citation for part 551 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; 22 U.S.C. 287c; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13536, 75 FR 19869, 3 CFR, 2010 Comp., p. 203; E.O. 13620, 77 FR 43483, 3 CFR, 2012 Comp., p. 281.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 26. Add § 551.512 to subpart E to read as follows:

§ 551.512 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 551.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 27. Add § 551.513 to subpart E to read as follows:

§ 551.513 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 551.513. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 552—YEMEN SANCTIONS REGULATIONS

■ 28. The authority citation for part 552 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13611, 77 FR 29533, 3 CFR, 2012 Comp., p. 260.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 29. Add § 552.512 to subpart E to read as follows:

§ 552.512 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 552.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 30. Add § 552.513 to subpart E to read as follows:

§ 552.513 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 552.513. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 553—CENTRAL AFRICAN REPUBLIC SANCTIONS REGULATIONS

■ 31. The authority citation for part 553 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; 22 U.S.C. 287c; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13667, 79 FR 28387, 3 CFR, 2014 Comp., p. 243.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 32. Add § 553.512 to subpart E to read as follows:

§ 553.512 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed

with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 553.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 33. Add § 553.513 to subpart E to read as follows:

§ 553.513 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 553.513. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 555—MALI SANCTIONS REGULATIONS

■ 34. The authority citation for part 555 continues to read as follows:

Authority: 25 U.S.C. 396 *et seq.,* 396a *et seq.,* 2101 *et seq.;* 30 U.S.C. 181 *et seq.,* 351 *et seq.,* 1001 *et seq.,* 1701 *et seq.;* 43 U.S.C. 1301 *et seq.,* 1331 *et seq.,* 1801 *et seq.*

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 35. Add § 555.511 to subpart E to read as follows:

§ 555.511 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 555.511. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 36. Add § 555.512 to subpart E read as follows:

§ 555.512 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 555.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 558—SOUTH SUDAN SANCTIONS REGULATIONS

■ 37. The authority citation for part 558 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 110–96, 121 Stat. 1011 (50 U.S.C. 1705 note); E.O. 13664, 79 FR 19283, April 7, 2014.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 38. Add § 558.511 to subpart E to read as follows:

§ 558.511 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 558.511. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 39. Add § 558.512 to subpart E to read as follows:

§ 558.512 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 558.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 562—IRANIAN SECTOR AND HUMAN RIGHTS ABUSES SANCTIONS REGULATIONS

■ 40. The authority citation for part 562 continues to read as follows:

Authority: 3 U.S.C. 301; 18 U.S.C. 2332d; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 110–96, 121 Stat. 1011 (50 U.S.C. 1705 note); Pub. L. 111–195, 124 Stat. 1312 (22 U.S.C. 8501–8551); E.O. 12957, 60 FR 14615, 3 CFR, 1995 Comp., p. 332; E.O. 13553, 75 FR 60567, October 1, 2010; E.O. 13871, 84 FR 20761, May 10, 2019.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 41. Add § 562.510 to subpart E to read as follows:

§ 562.510 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 562.510. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 42. Add § 562.511 to subpart E to read as follows:

§ 562.511 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 562.511. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 569—SYRIA–RELATED SANCTIONS REGULATIONS

■ 43. The authority citation for part 569 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; 28 U.S.C. 2461 note; 50 U.S.C. 1705 note; E.O. 13894, 84 FR 55851, October 17, 2019.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 44. Add § 569.511 to subpart E to read as follows:

§ 569.511 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 569.511. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 45. Add § 569.512 to subpart E to read as follows:

§ 569.512 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 569.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 570—LIBYAN SANCTIONS REGULATIONS

■ 46. The authority citation for part 570 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; 22 U.S.C. 287c; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13566, 76 FR 11315, 3 CFR, 2011 Comp., p. 222; E.O. 13726, 81 FR 23559, 3 CFR, 2016 Comp., p. 454.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 47. Add § 570.517 to subpart E to read as follows:

§ 570.517 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to

engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 570.517. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 48. Add § 570.518 to subpart E to read as follows:

§ 570.518 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 570.518. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 576—IRAQ STABILIZATION AND INSURGENCY SANCTIONS REGULATIONS

49. The authority citation for part 576 continues to read as follows:

Authority: 3 U.S.C. 301; 22 U.S.C. 287c; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13303, 68 FR 31931, 3 CFR, 2003 Comp., p. 227; E.O. 13315, 68 FR 52315, 3 CFR, 2003 Comp., p. 252; E.O. 13350, 69 FR 46055, 3 CFR, 2004 Comp., p. 196; E.O. 13364, 69 FR 70177, 3 CFR, 2004 Comp., p. 236; E.O. 13438, 72 FR 39719, 3 CFR, 2007 Comp., p. 224; E.O. 13668, 79 FR 31019, 3 CFR, 2014 Comp., p. 248.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 50. Add § 576.515 to subpart E to read as follows:

§ 576.515 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 576.515. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 51. Add § 576.516 to subpart E to read as follows:

§ 576.516 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 576.516. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 578—CYBER–RELATED SANCTIONS REGULATIONS

■ 52. The authority citation for part 578 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); Pub. L. 115–44, 131 Stat. 886 (codified in scattered sections of 22 U.S.C.); E.O. 13694, 80 FR 18077, 3 CFR 2015 Comp., p. 297; E.O. 13757, 82 FR 1, 3 CFR 2016 Comp., p. 659.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 53. Add § 578.512 to subpart E to read as follows:

§ 578.512 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 578.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 54. Add § 578.513 to subpart E to read as follows:

§ 578.513 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 578.513. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 579—FOREIGN INTERFERENCE IN U.S. ELECTIONS SANCTIONS REGULATIONS

■ 55. The authority citation for part 579 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L.

101–410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 110–96, 121 Stat. 1011 (50 U.S.C. 1705 note); E.O. 13848, 83 FR 46843, September 12, 2018.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 56. Add § 579.511 to subpart E to read as follows:

§ 579.511 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 579.511. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 57. Add § 579.512 to subpart E to read as follows:

§ 579.512 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 579.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 582—NICARAGUA SANCTIONS REGULATIONS

■ 58. The authority citation for part 582 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; 28 U.S.C. 2461 note; 50 U.S.C. 1705 note; 50 U.S.C. 1701 note; E.O. 13851, 83 FR 61505, 3 CFR, 2018 Comp., p. 884.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 59. Add § 582.511 to subpart E to read as follows:

§ 582.511 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to

information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 582.511. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 60. Add § 582.512 to subpart E to read as follows:

§ 582.512 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 582.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 583—GLOBAL MAGNITSKY SANCTIONS REGULATIONS

■ 61. The authority citation for part 583 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); Pub. L. 114–328, Div. A, Title XII, Subt. F, 130 Stat. 2533 (22 U.S.C. 2656 note); E.O. 13818, 82 FR 60839, 3 CFR, 2017 Comp., p. 399.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 62. Add § 583.511 to subpart E to read as follows:

§ 583.511 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development

projects directly benefiting the civilian population.

Note 1 to § 583.511. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 63. Add § 583.512 to subpart E to read as follows:

§ 583.512 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 583.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 584—MAGNITSKY ACT SANCTIONS REGULATIONS

■ 64. The authority citation for part 584 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); Pub. L. 112–208, Title IV, 126 Stat. 1502 (22 U.S.C. 5811 note).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 65. Add § 584.512 to subpart E to read as follows:

§ 584.512 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 584.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 66. Add § 584.513 to subpart E to read as follows:

§ 584.513 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled

drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 584.513. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 585—HONG KONG–RELATED SANCTIONS REGULATIONS

■ 67. The authority citation for part 585 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); E.O. 13936, 85 FR 43413, July 17, 2020.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 68. Add § 585.511 to subpart E to read as follows:

§ 585.511 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 585.511. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 69. Add § 585.512 to subpart E to read as follows:

§ 585.512 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 585.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 588—WESTERN BALKANS STABILIZATION REGULATIONS

■ 70. The authority citation for part 588 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13219, 66 FR 34777, 3 CFR, 2001 Comp., p. 778; E.O. 13304, 68 FR 32315, 3 CFR, 2004 Comp. p. 229; E.O. 14033, 86 FR 43905.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 71. Add § 588.511 to subpart E to read as follows:

§ 588.511 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions

prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 588.511. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 72. Add § 588.512 to subpart E to read as follows:

§ 588.512 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 588.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 590—TRANSNATIONAL CRIMINAL ORGANIZATIONS SANCTIONS REGULATIONS

■ 73. The authority citation for part 590 continues to read as follows:

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 13581, 76 FR 44757, 3 CFR, 2011 Comp., p. 260; E.O. 13863, 84 FR 10255, 3 CFR, 2019 Comp., p. 267.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 74. Add § 590.512 to subpart E to read as follows:

§ 590.512 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 590.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 75. Add § 590.513 to subpart E to read as follows:

§ 590.513 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 590.513. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 594—GLOBAL TERRORISM SANCTIONS REGULATIONS

■ 76. The authority citation for part 594 continues to read as follows:

Authority: 3 U.S.C. 301; 22 U.S.C. 287c; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); Pub. L. 114–102, 129 Stat. 2205, as amended (50 U.S.C. 1701 note); Pub. L. 115–44, 131 Stat 886 (codified in scattered sections of 22 U.S.C.); Pub. L. 115–348, 132 Stat. 5055 (50 U.S.C. 1701 note); E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; E.O. 13268, 67 FR 44751, 3 CFR 2002 Comp., p. 240; E.O. 13284, 68 FR 4075, 3 CFR, 2003 Comp., p. 161; E.O. 13372, 70 FR 8499, 3 CFR, 2006 Comp., p. 159; E.O. 13886, 84 FR 48041, 3 CFR, 2019 Comp., p. 356.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 77. Add § 594.520 to subpart E to read as follows:

§ 594.520 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 594.520. This section does not relieve any person authorized thereunder

from complying with any other applicable laws or regulations.

■ 78. Add § 590.521 to subpart E to read as follows:

§ 594.521 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 594.521. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 597—FOREIGN TERRORIST ORGANIZATIONS SANCTIONS REGULATIONS

■ 79. The authority citation for part 597 continues to read as follows:

Authority: 8 U.S.C. 1189; 18 U.S.C. 2339B; 31 U.S.C. 321(b); Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 80. Add § 597.516 to subpart E to read as follows:

§ 597.516 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 597.516. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 81. Add § 597.517 to subpart E to read as follows:

§ 597.517 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos,

and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 597.517. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 598—FOREIGN NARCOTICS KINGPIN SANCTIONS REGULATIONS

■ 82. The authority citation for part 598 continues to read as follows:

Authority: 3 U.S.C. 301; 21 U.S.C. 1901–1908; 31 U.S.C. 321(b); Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 83. Add § 598.515 to subpart E to read as follows:

§ 598.515 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a specially designated narcotics trafficker.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a specially designated narcotics trafficker, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 598.515. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 84. Add § 598.516 to subpart E to read as follows:

§ 598.516 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual who is a specially designated narcotics trafficker are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 598.516. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

PART 599—ILLICIT DRUG TRADE SANCTIONS REGULATIONS

■ 85. The authority citation for part 599 continues to read as follows:

Authority: 3 U.S.C. 301; 21 U.S.C. 2301 *et seq.;* 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 14059, 86 FR 71549, December 15, 2021.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 86. Add § 599.512 to subpart E to read as follows:

§ 599.512 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities.

(a) Except as provided in paragraph (c) of this section, all transactions prohibited by this part that are ordinarily incident and necessary to the activities described in paragraph (b) of this section by a nongovernmental organization are authorized, provided that the nongovernmental organization is not a person whose property or

interests in property are blocked pursuant to this part.

(b) The activities referenced in paragraph (a) of this section are non-commercial activities designed to directly benefit the civilian population that fall into one of the following categories:

(1) Activities to support humanitarian projects to meet basic human needs, including disaster, drought, or flood relief; food, nutrition, or medicine distribution; the provision of health services; assistance for vulnerable or displaced populations, including individuals with disabilities and the elderly; and environmental programs;

(2) Activities to support democracy building, including activities to support rule of law, citizen participation, government accountability and transparency, human rights and fundamental freedoms, access to information, and civil society development projects;

(3) Activities to support education, including combating illiteracy, increasing access to education, international exchanges, and assisting education reform projects;

(4) Activities to support non-commercial development projects directly benefiting civilians, including those related to health, food security, and water and sanitation;

(5) Activities to support environmental and natural resource protection, including the preservation and protection of threatened or endangered species, responsible and transparent management of natural resources, and the remediation of pollution or other environmental damage; and

(6) Activities to support disarmament, demobilization, and reintegration (DDR) programs and peacebuilding, conflict prevention, and conflict resolution programs.

(c) This section does not authorize funds transfers initiated or processed with knowledge or reason to know that the intended beneficiary of such transfers is a person blocked pursuant to this part, other than for the purpose of effecting the payment of taxes, fees, or import duties, or the purchase or receipt of permits, licenses, or public utility services.

(d) Specific licenses may be issued on a case-by-case basis to authorize nongovernmental or other entities to engage in other activities designed to directly benefit the civilian population, including support for the removal of landmines and economic development projects directly benefiting the civilian population.

Note 1 to § 599.512. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

■ 87. Add § 599.513 to subpart E to read as follows:

§ 599.513 Transactions related to the provision of agricultural commodities, medicine, medical devices, replacement parts and components, or software updates for personal, non-commercial use.

(a) All transactions prohibited by this part that are related to the provision, directly or indirectly, of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to an individual whose property and interests in property are blocked pursuant to this part are authorized, provided the items are in quantities consistent with personal, non-commercial use.

(b) For the purposes of this section, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) That are intended for ultimate use as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this section, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Note 1 to § 599.513. This section does not relieve any person authorized thereunder from complying with any other applicable laws or regulations.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

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FEDERAL REGISTER

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No. 244 December 21, 2022

Part VIII

The President

Proclamation 10508—Wright Brothers Day, 2022

Federal Register
Vol. 87, No. 244
Wednesday, December 21, 2022

Presidential Documents

Title 3—

The President

Proclamation 10508 of December 16, 2022

Wright Brothers Day, 2022

By the President of the United States of America

A Proclamation

On Wright Brothers Day, we celebrate the ingenuity and perseverance of Orville and Wilbur Wright, whose aircraft expanded the limits of human discovery and lifted this Nation to new heights.

From their home in Dayton, Ohio, the Wright Brothers were captivated—''afflicted,'' in Wilbur's words—by the belief that humans could fly. They researched and experimented, redesigned and repaired, and braved dangerous early trials. When their Wright Flyer finally took to the skies over Kitty Hawk, North Carolina, on December 17, 1903, they launched the future of aviation and helped define the American spirit: bold, daring, innovative, and always asking what is next.

That same spirit has delivered ground-breaking discoveries in American air and space technology for almost 120 years. America has broken the sound barrier, put a man on the moon, collaborated to create the International Space Station, and achieved powered flight on Mars. Just last year, we launched the most powerful deep-space telescope ever sent into space and gained a new window into the history of our universe.

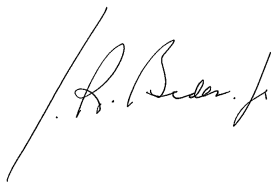
We are also carrying on the Wright Brothers' legacy by always striving for better safety and comfort in air travel. Our Bipartisan Infrastructure Law is investing $25 billion to renovate airport terminals; upgrade air traffic control facilities; and improve runways, taxiways, and other vital infrastructure that make flying easier and more secure. We have pushed airlines to rebook travelers' tickets for free when flights are significantly delayed or canceled, and to disclose fees, like for checked baggage, clearly and up front. And we are exploring new technologies that can decrease carbon emissions coming from airplanes.

As inheritors of game-changing innovations and torch-bearers of the spirit of American ingenuity, we have so much to be proud of and so much to look forward to. We can lead the world in the technologies of tomorrow, change the course of human health and disease, tackle the climate crisis, and continue shaping a fairer, more equitable planet. With shared purpose, unyielding faith in our future, and a drive to make the impossible possible, there is nothing beyond our capacity. I have never been more optimistic about our Nation's future—especially in our skies and in space.

The Congress, by a joint resolution approved December 17, 1963, as amended (77 Stat. 402; 36 U.S.C. 143), has designated December 17 of each year as ''Wright Brothers Day'' and has authorized and requested the President to issue annually a proclamation inviting the people of the United States to observe that day with appropriate ceremonies and activities.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, do hereby proclaim December 17, 2022, as Wright Brothers Day.

IN WITNESS WHEREOF, I have hereunto set my hand this sixteenth day of December, in the year of our Lord two thousand twenty-two, and of the Independence of the United States of America the two hundred and forty-seventh.



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Wednesday, December 21, 2022

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LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

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