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DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Parts 1728 and 1755

Standards and Specifications for Timber Products Acceptable for Use by Rural Utilities Service Electric and Telecommunications Borrowers; Correction

AGENCY: Rural Utilities Service, USDA.

ACTION: Final rule; technical correction.

SUMMARY: The Rural Utilities Service, a Rural Development agency in the United States Department of Agriculture, published a final rule on October 14, 2021, effective date of publication, amending its regulations on Electric and Telecommunications Standards and Specifications for Materials, Equipment and Construction to keep RUS standards current with the technology advances and consistent with the industry practice. This document corrects inadvertent errors that were published in that final rule, replaces an incorporated standard inadvertently removed from the centralized index section, and updates the incorporation by reference of RUS Bulletin 1728F–700, RUS Specification for Wood Poles, Stubs and Anchor Logs.

DATES: Effective May 6, 2022.

Incorporation by Reference: The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of May 6, 2022. The incorporation by reference of certain other publications listed in this rule was approved by the Director of the Federal Register as of June 18, 2019 and October 14, 2021.

ADDRESSES: The material incorporated by reference is available at: *https://www.rd.usda.gov/resources/regulations/bulletins.*

FOR FURTHER INFORMATION CONTACT: Chendi Zhang, Mechanical Engineer Engineering Standards Branch, Electric Programs | Rural Utilities Service | Rural Development U.S. Department of Agriculture, 1400 Independence Ave. SW | Washington, DC 20250–1567 | Phone: 202–690–9032 | email: *Chendi.Zhang@usda.gov.*

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This final rule is exempt from the Office of Management and Budget (OMB) review for purposes of Executive Order 12866 and, therefore, has not been reviewed by OMB.

Executive Order 12372

This final rule is excluded from the scope of Executive Order 12372, Intergovernmental Consultation, which may require consultation with State and local officials. A notice of final rule entitled ''Department Programs and Activities Excluded from Executive Order 12372,'' (50 FR 47034) exempted the Rural Utilities Service loans and loan guarantees from coverage under this order.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. The Rural Utilities Service has determined that this rule meets the applicable standards provided in section 3 of the Executive Order. In addition, all state and local laws and regulations that are in conflict with this final rule will be preempted. No retroactive effect will be given to this final rule and in accordance with section 212(e) of the Department of Agriculture Reorganization Act of 1994 (7 U.S.C. 6912(e)) administrative appeal procedures, if any, must be exhausted before an action against the Department or its agencies may be initiated.

Executive Order 13132

This final rule 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. Under Executive Order 13132, this final rule does not have sufficient federalism implications to require preparation of a Federalism Assessment.

Regulatory Flexibility Act Certification

The Rural Utilities Service has determined that the Regulatory Flexibility Act is not applicable to this final rule since USDA Rural Utilities Service is not required by 5 U.S.C. 551 *et seq.* or any other provision of the law to publish a notice of proposed rulemaking with request to the subject matter of this rule.

Information Collection and Recordkeeping Requirements

This final rule contains no new reporting or recordkeeping burdens under OMB control number 0572–0076 that would require approval under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

Assistance Listings

The program described by this final rule is listed in the Assistance Listings (formerly the Catalog of Federal Domestic Assistance Programs) as No. 10.850, Rural Electrification Loans and Loan Guarantees. These Federal assistance program listings are available at the following *Sam.gov* website: *https://sam.gov/content/assistance-listing/federal.*

Unfunded Mandates

This final rule contains no Federal Mandates (under the regulatory provision of title II of the Unfunded Mandates Reform Act of 1995 [2 U.S.C. Chapter 25]) for State, local, and tribal governments, or the private sector. Thus, this final rule is not subject to the requirements of sections 202 and 205 of the Unfunded Mandates Reform Act of 1995.

National Environmental Policy Act

In accordance with the National Environmental Policy Act of 1969, Public Law 91–190, this final rule has been reviewed in accordance with 7 CFR part 1970 (''Environmental Policies and Procedures''). The Agency has determined that (i) this action meets the criteria established in 7 CFR 1970.53(f); (ii) no extraordinary circumstances exist; and (iii) the action is not ''connected'' to other actions with potentially significant impacts, is not considered a ''cumulative action'' and is not precluded by 40 CFR 1506.1. Therefore, the Agency has determined that the action does not have a significant effect on the human environment, and therefore neither an Environmental Assessment nor an Environmental Impact Statement is required.

USDA Non-Discrimination Statement

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Background

I. General Discussion

The Rural Utilities Service maintains bulletins that contain construction standards and specifications for materials and equipment and provide regulated specifications to RUS Electric Program borrowers for procurement of electric transmission and distribution line wood materials. These standards and specifications apply to systems constructed by electric and telecommunications borrowers in accordance with the loan contract, and contain standard construction units, materials, and equipment units used on electric and telecommunications borrowers' systems. The following bulletins establish standards for the manufacture and inspection of wood utility poles, crossarms and pole keys: Bulletin 1728F–700 ''RUS Specification for Wood Poles, Stubs and Anchor Logs'', incorporated by reference at § 1728.97; Bulletin 1728H–701, ''Specification for Wood Crossarms (Solid and Laminate), Transmission Timbers, and Pole Keys'', codified at 7 CFR 1728.201; and Bulletin 1728H–702, ''Specification for Quality Control and Inspection of Timber Products'', codified at 7 CFR 1728.202.

II. Purpose of the Regulatory Action

This Final rule; technical correction corrects inadvertent errors in the Final rule; response to comments published in the **Federal Register** (86 FR 57015) on October 14, 2021 (October final rule).

III. Summary of Corrections

The updates and corrections to the October final rule are as follows:

A. Bulletin 1728F–700 ''RUS Specification for Wood Poles, Stubs and Anchor Logs'' (Incorporated by Reference at § 1728.97)

(The update and corrections detailed below describe changes to the text of the Bulletin, which does not appear in this Final rule; technical corrections, since the Bulletin is incorporated by reference.)

- Update the current date of issuance date.
- In paragraph 5(b), remove the incorrect entry of 2 years and replacing it with 1 year that no material treated with creosote, pentachlorophenol, DCOI or copper naphthenate shall be shipped for use on a RUS borrower's system later than 1 year following the original treatment date branded on the material; and
- Correct the requirements for Copper Naphthenate retentions in Table 8 in Appendix A.

B. Bulletin 1728H–702, ''Specification for Quality Control and Inspection of Timber Products'' (Codified at 7 CFR 1728.202)

- Add the annual requirement of submitting the lab certificate from the amendatory language, that was discussed in the Summary of Changes but inadvertently omitted from the amendatory language for § 1728.202 in the October final rule.

C. Corresponding and Miscellaneous CFR Amendments

- Update the date of issuance for Bulletin 1728F–700, ''RUS Specification for Wood Poles, Stubs and Anchor Logs'', in § 1728.97 and 1755.97.
- Update the date of issuance for Bulletin 1728H–702, ''Specification for Quality Control and Inspection of Timber Products'', in § 1755.98.
- Add AWPA M3–16, ''Standard for the Quality Control of Preservative Treated Products for Industrial'' back into § 1728.97, from which it was inadvertently deleted.

Incorporation by Reference

Bulletin 1728F–700, RUS Specification for Wood Poles, Stubs and Anchor Logs. This specification describes the minimum acceptable quality of wood poles, stubs, telephone pedestal stubs, and anchor logs (hereinafter called poles, except where specifically referred to as stubs or anchor logs) purchased by or for RUS borrowers. The requirements of this specification implement contractual provisions between RUS and borrowers receiving financial assistance from RUS.

RUS provides free online public access to view and download copies of Bulletin 1728–F 700. The RUS website to view and download this bulletin is: *http://www.rd.usda.gov/resources/regulations/bulletins.*

The following standards were previously approved for incorporation by reference and their use continues unchanged: AWPA A6, AWPA A9, and AWPA A83.

List of Subjects

7 CFR Part 1728

Electric power, Incorporation by reference, Loan programs-energy, Reporting and recordkeeping requirements, Rural areas.

7 CFR Part 1755

Incorporation by reference, Loan programs-communications, Reporting and recordkeeping requirements, Rural areas, Telephone.

For reasons set forth in the preamble, chapter XVII of title 7 of the Code of Federal Regulations is amended as follows:

PART 1728—ELECTRIC STANDARDS AND SPECIFICATIONS FOR MATERIALS AND CONSTRUCTION

■ 1. The authority citation for part 1728 continues to read as follows:

Authority: 7 U.S.C. 901 *et seq.,* 1921 *et seq.,* and 6941 *et seq.*

■ 2. Amend § 1728.97 by:

■ a. Revising paragraph (a)(21); and
■ b. Redesignating paragraphs (e)(10) and (11) as paragraphs (e)(11) and (12) and adding new paragraph (e)(10).

The revision and addition read as follows:

§ 1728.97 Incorporation by reference of electric standards and specifications.

* * * * *

(a) * * *

(21) Bulletin 1728F–700, RUS Specification for Wood Poles, Stubs and Anchor Logs (April 18, 2022), incorporation approved for §§ 1728.98 and 1728.202.

* * * * *

(e) * * *

(10) AWPA M3–16, Standard for the Quality Control of Preservative Treated Products for Industrial Use, Revised 2016, incorporation by reference approved for §§ 1728.201 and 1728.202.

* * * * *

■ 3. Amend § 1728.202 by:
■ a. Removing paragraph (b)(10) introductory text;
■ b. Adding paragraph (b)(10)(i);
■ c. Revising the heading for table 1 to paragraph (b)(10) and revising the heading for note 1 to paragraph (b)(10); and
■ d. Adding paragraphs (b)(10)(ii) and (iii).

The additions and revisions read as follows:

§ 1728.202 Bulletin 1728H–702, Specification for Quality Control and Inspection of Timber Products

* * * * *

(b) * * *

(10)(i) Inspection agencies shall maintain their own properly equipped laboratory that, at a minimum, is able to run the referee methods listed in table 1 to this paragraph (b)(10) for retention analysis for all preservatives being inspected. This laboratory shall be independent from any treating plant laboratory. Inspection Agencies may use one central laboratory. All XRF units maintained by third party inspection agencies as part of their RUS required laboratories shall be calibrated at least quarterly by said agency utilizing the referee method for each preservative treatment being analyzed or via comparison with a set of graduated treated wood standards. Each agency shall keep an up-to-date written record of these quarterly calibration results.

Table 1 to Paragraph (b)(10)(i)

* * * * *

Note 1 to table 1 to paragraph (b)(10)(i): * * *

(ii) Inspection agencies shall, on an annual basis, provide RUS Technical Standards Committee ''A'' with proof that the agency does have the required, fully equipped laboratory capable of running each of the referee methods of analysis as illustrated in table 1 to paragraph (b)(10)(i) of this section. AWPA A83 or AWPA A9 (both incorporated by reference at § 1728.97) shall be followed for Pentachlorophenol testing.

(iii) AWPA A30 (incorporated by reference at § 1728.97) or AWPA A9 shall be followed for DCOI testing. AWPA A6 (incorporated by reference at § 1728.97) shall be followed for Creosote testing and AWPA A9 shall be followed for XRF, as illustrated in table 1 to paragraph (b)(10)(i) of this section.

* * * * *

PART 1755—TELECOMMUNICATIONS STANDARDS AND SPECIFICATIONS FOR MATERIALS, EQUIPMENT AND CONSTRUCTION

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

Authority: 7 U.S.C. 901 *et seq.,*1921 *et seq.,* and 6941 *et seq.*

■ 5. Amend § 1755.97 by revising paragraphs (a)(1) and (b)(13) to read as follows:

§ 1755.97 Telephone standards and specifications.

(a)(1) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the Rural Utilities Service (RUS) and at the National Archives and Records Administration (NARA). Contact the RUS at: 1400 Independence Ave. SW, Washington, DC, 202–692–0042; email: *comments@usda.gov;* Telephone number: 202–692–0042; *https://www.rd.usda.gov/resources/regulations/bulletins.* For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.* The material may be obtained from the following source(s):

* * * * *

(b) * * *

(13) Bulletin 1728F–700, RUS Specification for Wood Poles, Stubs and Anchor Logs, April 18, 2022.

* * * * *

■ 6. Amend § 1755.98 by revising paragraph (a) to read as follows:

§ 1755.98 List of telecommunications specifications included in other 7 CFR parts.

* * * * *

Section	Issue date	Title
(a) 1728.202	4.18.2022	RUS Specification for Quality Control and Inspection of Timber Products.
*	*	* * * * *

Christopher A. McLean,

Acting Administrator, Rural Utilities Service.

[FR Doc. 2022–09606 Filed 5–5–22; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0685; Project Identifier AD–2021–00432–T; Amendment 39–22015; AD 2022–08–12]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2020–21–17, which applied to all The Boeing Company Model 757 airplanes. AD 2020–21–17 required repetitive inspections for skin cracking and shim migration at the upper link drag fittings, diagonal brace cracking, and fastener looseness; and applicable on-condition actions. This AD was prompted by reports of bolt rotation in the engine drag fitting joint and fastener heads and cracks found in the skin of the fastener holes, and the need to reduce the compliance time for certain groups. This AD retains the requirements of AD 2020–21–17 with reduced compliance times for certain airplane groups. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 10, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 10, 2022.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0685.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0685; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: David Truong, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5224; email: *david.truong@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2020–21–17, Amendment 39–21290 (85 FR 79418, December 10, 2020) (AD 2020–21–17). AD 2020–21–17 applied to all The Boeing Company Model 757 airplanes. The NPRM published in the **Federal Register** on September 9, 2021 (86 FR 50485). The NPRM was prompted by reports of bolt rotation in the engine drag fitting joint and fastener heads and cracks found in the skin of the fastener holes, and the need to reduce the compliance time for certain groups. In the NPRM, the FAA proposed to retain the requirements of AD 2020–21–17 with reduced compliance times for certain airplane groups. The FAA is issuing this AD to address cracking in the wing upper skin and forward drag fittings, which could lead to a compromised upper link and reduced structural integrity of the engine strut, and possible separation of a strut and engine from the airplane during flight.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from the Air Line Pilots Association, International (ALPA), Boeing, and FedEx who supported the NPRM without change.

The FAA received additional comments from three commenters, including Aviation Partners Boeing (APB), United Airlines (UAL), and United Parcel Service (UPS). The following presents the comments received on the NPRM and the FAA's response to each comment.

Effect of Winglets on Accomplishment of the Proposed Actions

APB stated that accomplishing Supplemental Type Certificate (STC) ST01518SE does not affect the actions specified in the proposed AD.

The FAA concurs with the commenter. The FAA has redesignated paragraph (c) of the proposed AD as paragraph (c)(1) of this AD and added paragraph (c)(2) to this AD to state that installation of STC ST01518SE does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01518SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

Request To Clarify Certain Figures in the Service Information

UAL requested clarification of Figures 21 and 22 for an open-hole high frequency eddy current (HFEC) inspection as specified in Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 2, dated March 1, 2021. UAL stated that in note (a) of Figures 21 and 22, it specifies to ''Do an open-hole HFEC inspection for any crack in accordance with 757 NDT [Non-Destructive Test] Manual Part 6, 51–00–16,'' at the ''Fastener Holes and Drag Fitting.'' UAL also stated that this is different than the inspection specified in note (a) of Figures 7 and 8 which specifies to ''Do an open-hole HFEC inspection for any crack of the holes of loose fasteners only in accordance with 757 NDT Manual Part 6, 51–00–16'' at the ''Fastener Holes.''

UAL stated that the NDT manual references are the same in Figures 7 and 8, and Figures 21 and 22. UAL commented that Figures 7 and 8 are used in Part 4 inspections (only at loose fastener hole locations found at locations 11 through 18) of the service information; and Figures 21 and 22 are used in Part 8 inspections (inspections of all fastener locations 11 through 18) of the service information. UAL commented that it is not clear what the intent is of making step 1 in Figures 21 and 22 specify ''Fastener Holes'' and ''Drag Fitting,'' (listed as two separate items) and if these are different inspections of the fastener holes.

The FAA agrees to provide clarification. Part 4 inspections use Figures 7 and 8 of the service information to inspect for any cracking, and are an on-condition action required only for any fastener holes that are found (during Part 2 inspections) to have loose fasteners in the wing upper skin. Part 8 inspections use Figures 21 and 22 to inspect for any cracking in the fastener holes of the upper wing skin and drag fitting, and are required for all airplanes. Accomplishing an open hole

HFEC inspection as a result of Condition 5 (which requires accomplishing figures 7 and 8), meets the requirement of the open hole HFEC inspection of fastener holes 11 through 18 for only the fastener hole(s) inspected (as specified in note (a) of Tables 4 and 7 in the Accomplishment Instructions of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 2, dated March 1, 2021). The open hole HFEC inspection for any cracking of fastener holes 11 through 18 specified in Figures 7 and 8 and Figures 21 and 22 are the same, however the ''Drag Fitting'' specified in Figures 21 and 22 is emphasized so the drag fitting fastener holes are not missed when performing the open hole HFEC inspection through the fastener hole shared between the upper wing skin and drag fitting. Part 4 and Part 8 have different compliance times and repetitive inspection intervals. The FAA has not changed this AD in this regard.

Request To Include Previously Approved AMOCs

UPS requested that the FAA include previously approved AMOCs in the proposed AD for AD 2018–16–05, Amendment 39–19345 (83 FR 38250, August 6, 2018) (AD 2018–16–05), which was superseded by AD 2020–21–17.

The FAA agrees with the request. AMOCs for AD 2018–16–05 that are still applicable to the corresponding provisions of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 2, dated March 1, 2021, which are required by paragraph (g) of this AD, are approved as AMOCs for this AD. The FAA has added paragraph (j)(5) to this AD to include AMOCs approved for AD 2018–16–05.

Conclusion

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 2, dated March 1, 2021. This service information specifies procedures for repetitive general visual and detailed inspections for loose fasteners, skin cracking, and shim migration at the upper link drag fittings, and for cracking in the diagonal brace and diagonal brace fittings; repetitive open-hole high frequency eddy current inspections for cracking of the fastener holes and loose bolt holes; and applicable on-condition actions. On-condition actions include installing the upper link and upper link pins; replacing drag fittings; installing bolts, washers, and nuts; performing a torque check of fasteners on the affected shims; trimming affected shims and applying chemical conversion coating on the shims, fillet seal, and drag fittings; and repairing cracks, migrated shims, mistorqued bolts, and loose fasteners.

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

Costs of Compliance

The FAA estimates that this AD would affect 450 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Repetitive HFEC inspections	85 work-hours × $85 per hour = $7,225 per inspection cycle.	$0	$7,225 per inspection cycle ..	$3,251,250 per inspection cycle.

The FAA has received no definitive data on which to base the cost estimates for the on-condition actions specified in this AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2020–21–17, Amendment 39–21290 (85 FR 79418, December 10, 2020); and

■ b. Adding the following new AD:

2022–08–12 The Boeing Company: Amendment 39–22015; Docket No.

FAA–2021–0685; Project Identifier AD–2021–00432–T.

(a) Effective Date

This airworthiness directive (AD) is effective June 10, 2022.

(b) Affected ADs

This AD replaces AD 2020–21–17, Amendment 39–21290 (85 FR 79418, December 10, 2020) (AD 2020–21–17).

(c) Applicability

(1) This AD applies to all The Boeing Company Model 757–200, –200PF, –200CB, and –300 series airplanes, certificated in any category.

(2) Installation of Supplemental Type Certificate (STC) ST01518SE does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01518SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by reports of bolt rotation in the engine drag fitting joint and fastener heads and cracks found in the skin of the fastener holes, and the need to reduce the compliance time for certain groups. The FAA is issuing this AD to address cracking in the wing upper skin and forward drag fittings, which could lead to a compromised upper link and reduced structural integrity of the engine strut, and possible separation of a strut and engine from the airplane during flight.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 2, dated March 1, 2021, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 2, dated March 1, 2021.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 757–57A0073, Revision 2, dated March 1, 2021, which is referred to in Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 2, dated March 1, 2021.

(h) Exceptions to Service Information Specifications

(1) Where Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 2, dated March 1, 2021, uses the phrase ''the Original Issue date of Requirements Bulletin 757–57A0073 RB,'' this AD requires using September 10, 2018 (the effective date of AD 2018–16–05, Amendment 39–19345 (83 FR 38250, August 6, 2018)).

(2) Where the Compliance Time columns of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 2, dated March 1, 2021, uses the phrase ''the Revision 1 date of Requirements Bulletin 757–57A0073 RB date of this service bulletin,'' this AD requires using January 14, 2021 (the effective date of AD 2020–21–17).

(3) Where the Condition and Compliance Time columns of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 2, dated March 1, 2021, uses the phrase ''the Revision 2 date of Requirements Bulletin 757–57A0073 RB,'' this AD requires using the effective date of this AD.

(4) Where Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 2, dated March 1, 2021, specifies contacting Boeing for repair instructions: This AD requires doing the repair using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(i) Credit for Previous Actions

(1) This paragraph provides credit for the actions specified in paragraph (g) of this AD, except for the open-hole high frequency eddy current inspections at fastener locations 11–18, if those actions were performed before the effective date of this AD using Boeing Alert Requirements Bulletin 757–57A0073 RB, dated July 14, 2017.

(2) This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 1, dated August 1, 2019. This service information is not incorporated by reference in this AD.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in Related Information. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(4) AMOCs approved for AD 2020–21–17 are approved as AMOCs for the corresponding provisions of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 2, dated March 1, 2021, that are required by paragraph (g) of this AD.

(5) AMOCs approved for AD 2018–16–05, Amendment 39–19345 (83 FR 38250, August 6, 2018) are approved as AMOCs for the corresponding provisions of Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 2, dated March 1, 2021, that are required by paragraph (g) of this AD.

(k) Related Information

(1) For more information about this AD, contact David Truong, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5224; email: *david.truong@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (l)(3) and (4) of this AD.

(l) Material Incorporated by Reference

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

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

(i) Boeing Alert Requirements Bulletin 757–57A0073 RB, Revision 2, dated March 1, 2021.

(ii) [Reserved]

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on April 7, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–09663 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0512; Project Identifier AD–2022–00367–E; Amendment 39–22042; AD 2022–10–04]

RIN 2120–AA64

Airworthiness Directives; Engine Alliance Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Engine Alliance (EA) GP7270, GP7272, and GP7277 model turbofan engines. This AD was prompted by a manufacturer investigation that revealed certain stages 7–9 compressor rotor spools were manufactured from a billet of material suspected of having foreign material embedded. This AD requires the replacement of the affected stages 7–9 compressor rotor spool. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 23, 2022.

The FAA must receive comments on this AD by June 21, 2022.

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

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

For service information identified in this final rule, contact Engine Alliance, 411 Silver Lane, East Hartford, CT 06118; phone: (800) 565–0140; email: *help24@pw.utc.com;* website: *www.enginealliianceportal.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0512; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Stephen Elwin, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7236; email: *Stephen.L.Elwin@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA was notified by the manufacturer of a powder metal material contamination discovered in a part manufactured from the same billet material used to manufacture the EA GP7270, GP7272, and GP7277 high-pressure compressor (HPC) stage 8 rotor disk. Subsequent investigation by the manufacturer determined that the HPC stage 8 rotor disk, which is welded into the stages 7–9 compressor rotor spool, was manufactured from billets suspected of having foreign material embedded. The presence of foreign material in the billet may lead to crack formations and premature failure of the HPC stage 8 rotor disk. This condition, if not addressed, could result in failure of the HPC stage 8 rotor disk, uncontained release of the HPC stage 8 rotor disk, damage to the engine, and damage to the airplane. The FAA is issuing this AD to address the unsafe condition on these products.

FAA's Determination

The FAA is issuing this AD because the agency has determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Related Service Information

The FAA reviewed Engine Alliance Service Bulletin (SB) EAGP7–72–449, Original Issue, dated December 9, 2021. The SB describes procedures for removing and replacing the affected stages 7–9 compressor rotor spool.

AD Requirements

This AD requires the replacement of the affected stages 7–9 compressor rotor spool.

Interim Action

The FAA considers this AD to be an interim action. This issue is still under investigation by the manufacturer and, depending on the results of that investigation, the FAA may consider further rulemaking action.

Justification for Immediate Adoption and Determination of the Effective Date

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

The FAA justifies waiving notice and comment prior to adoption of this rule because no domestic operators use this product. It is unlikely that the FAA will receive any adverse comments or useful information about this AD from any U.S. operator. Accordingly, notice and opportunity for prior public comment are unnecessary, pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the foregoing reason(s), the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0512 and Project Identifier AD–2022–00367–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and

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

Regulatory Flexibility Act

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

Costs of Compliance

The FAA estimates that this AD affects 0 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace stages 7–9 compressor rotor spool ..	8 work-hours × $85 per hour = $680	$853,400	$854,080	$0

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2022–10–04 Engine Alliance: Amendment 39–22042; Docket No. FAA–2022–0512; Project Identifier AD–2022–00367–E.

(a) Effective Date

This airworthiness directive (AD) is effective May 23, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Engine Alliance (EA) GP7270, GP7272, and GP7277 model turbofan engines with an installed:

(1) Stages 7–9 compressor rotor spool, part number (P/N) 2031M90G05, having serial number (S/N) GWN0R7R3; or

(2) Stages 7–9 compressor rotor spool, P/N 2031M90G07, having S/N GWN0R9R3, GWN0R9TC, GWN0R9TM, GWN0RCT5, or GWN0RCT6.

(d) Subject

Joint Aircraft System Component (JASC) Code 7230, Turbine Engine Compressor Section.

(e) Unsafe Condition

This AD was prompted by a manufacturer investigation that revealed certain stages 7–9 compressor rotor spools were manufactured from a billet of material suspected of having foreign material embedded. The FAA is issuing this AD to prevent failure of the high-pressure compressor (HPC) stage 8 rotor disk. The unsafe condition, if not addressed, could result in uncontained release of the HPC stage 8 rotor disk, damage to the engine, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

Within 500 flight cycles (FCs) after the effective date of this AD, remove the affected stages 7–9 compressor rotor spool from service and replace with a part eligible for installation.

(h) Definition

For the purpose of this AD, a ''part eligible for installation'' is any stages 7–9 compressor rotor spool with an S/N that is not identified in paragraph (c)(1) or (2) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

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

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

(j) Related Information

For more information about this AD, contact Stephen Elwin, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7236; email: *Stephen.L.Elwin@faa.gov*.

(k) Material Incorporated by Reference

None.

Issued on April 30, 2022.

Gaetano A. Sciortino,

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

[FR Doc. 2022–09631 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0506; Project Identifier MCAI–2022–00507–G; Amendment 39–22037; AD 2022–09–17]

RIN 2120–AA64

Airworthiness Directives; Scheibe-Aircraft-GmbH Gliders

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Scheibe-Aircraft-GmbH Model SF 25 C gliders. This AD was prompted by mandatory continuing airworthiness information (MCAI) issued by the aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as severe corrosion on the inner surface of the control stick tube. This AD requires inspecting the left-hand (LH) and right-hand (RH) control sticks for corrosion and, if corrosion is found, replacing the affected control stick. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective May 23, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 23, 2022.

The FAA must receive comments on this AD by June 21, 2022.

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

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

For service information identified in this final rule, contact Scheibe Aircraft GmbH, Am Flugplatz 5, Heubach, D–73540, Germany; phone: +49 07173 184286; email: *info@scheibe-aircraft.de;* website: *https://scheibe-aircraft.de/*. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0506.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0506; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the MCAI, any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4165; email: *jim.rutherford@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Emergency AD 2022–0066–E, dated April 11, 2022 (referred to after this as ''the MCAI''), to address an unsafe condition on Scheibe-Aircraft-GmbH (formerly Sportavia-Pützer GmbH & Co. KG and Scheibe Flugzeugbau GmbH) Model SF 25-series sailplanes (gliders). The MCAI states:

> An occurrence was reported of finding fracture in a RH control stick of a powered sailplane, located above the weld seam at the transfer joint. Subsequent investigation determined that the fracture was a result of severe corrosion phenomena affecting the inner surface of the control stick tube due to water ingress.
>
> This condition, if not detected and corrected, could lead to a rupture of an affected part, possibly resulting in reduced control, or loss of control, of the powered sailplane.
>
> To address this unsafe condition, Scheibe issued the original issue of [service bulletin] TM/SB 653–96 to provide inspection and replacement instructions.
>
> Consequently, EASA issued Emergency AD 2022–0043–E (later revised) to require repetitive inspections of each affected part to detect corrosion and replacement of each affected part with a serviceable part.
>
> Since EASA AD 2022–0043R1 was issued, it was identified that powered sailplanes on which Scheibe mod[ification] 653C–41–S10.1 is embodied are also affected by this unsafe condition.
>
> For the reason described above, this [EASA] AD retains the requirements of EASA AD 2022–0043R1, which is superseded, and expands the Applicability.

You may examine the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0506.

FAA's Determination

The FAA is issuing this AD because the agency has determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Scheibe Aircraft GmbH Service Bulletin 653–96/1, dated April 4, 2022. This service information specifies procedures for repetitive inspections for corrosion on the LH and RH control sticks and replacement instructions for when corrosion is found. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Other Related Service Information

The FAA also reviewed Scheibe Aircraft GmbH Service Bulletin 653–96, dated March 2, 2022. This service information specifies procedures for repetitive inspections for corrosion on the LH and RH control sticks and replacement instructions for when corrosion is found.

FAA's Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service

information referenced above. The FAA is issuing this AD because it has determined the unsafe condition described previously is likely to exist or develop on other products of the same type design.

AD Requirements

This AD requires accomplishing the actions specified in the service information already described, except as discussed under ''Differences Between this AD and the MCAI.''

Differences Between This AD and the MCAI

The MCAI applies to serial numbers (S/N) 44147 through S/N 44159 inclusive, and this AD does not because those gliders are not eligible for import into the United States.

The MCAI applies to Model SF 25 E and SF 25 K gliders, and this AD does not because they do not have an FAA type certificate.

The MCAI allows for a 30-day compliance time tolerance for the repetitive inspections to coincide with other maintenance tasks, and this AD does not.

The MCAI allows the pilot-owner to do the inspections, and this AD does not.

The MCAI specifies a 20-month modification requirement. The FAA is considering requiring this modification; however, the planned compliance time for this modification would allow enough time to provide notice and opportunity for prior public comment on the merits of this modification. The FAA may require that modification in a future AD action.

Justification for Immediate Adoption and Determination of the Effective Date

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

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because the amount of time moisture has accumulated in the control sticks and caused corrosion to develop is unknown. Therefore, the initial inspection must be accomplished before further flight. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

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

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0506 and Project Identifier MCAI–2022–00507–G'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

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

Costs of Compliance

The FAA estimates that this AD affects 1 glider of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per glider	Cost on U.S. operators
Inspect LH and RH control sticks	4 work-hours × $85 per hour = $340	Not Applicable	$340	$340

The FAA estimates the following costs to replace a single control stick, if required based on the results of the inspection:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per glider
Replace single control stick	4 work-hours × $85 per hour = $340	$500	$840

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2022–09–17 Scheibe-Aircraft-GmbH: Amendment 39–22037; Docket No. FAA–2022–0506; Project Identifier MCAI–2022–00507–G.

(a) Effective Date

This airworthiness directive (AD) is effective May 23, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Scheibe-Aircraft-GmbH Model SF 25 C gliders, certificated in any category, that have Scheibe Modification 653E.41–S10 or 653C–41–S10.1 installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 2700, Flight Control System.

(e) Unsafe Condition

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as severe corrosion on the inner surface of the control stick tube. The FAA is issuing this AD to detect corrosion on the left-hand (LH) and right-hand (RH) control sticks, which, if not corrected, could lead to failure of the control stick tube and loss of control of the glider.

(f) Compliance

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

(g) Inspection and Replacement

(1) Before further flight after the effective date of this AD and thereafter at intervals not to exceed 12 months or 100 hours time-in-service, whichever occurs first, inspect all control sticks (other than part number (P/N) 20093, P/N 20093/G, P/N 20094, and P/N 20094/G) for corrosion by following Action 1, step 1.4, in Scheibe Aircraft GmbH Service Bulletin 653–96/1, dated April 4, 2022 (SB 653–96/1), except you may use a borescope instead of an endoscope. If there is any corrosion, before further flight, replace the affected control stick with a LH control stick P/N 20093 or P/N 20093/G; or a RH control stick P/N 20094 or P/N 20094/G by following Action 3 (all steps) in SB 653–96/1.

(2) Replacing a control stick with LH control stick P/N 20093 or P/N 20093/G; or RH control stick P/N 20094 or P/N 20094/G, terminates the repetitive inspection for that control stick side only. Replacing both control sticks with LH control stick P/N 20093 or P/N 20093/G and RH control stick P/N 20094 or P/N 20094/G terminates the repetitive inspection for both sides.

(3) As of the effective date of this AD, do not install on any glider a control stick that has a P/N other than LH control stick P/N 20093 or P/N 20093/G; or RH control stick P/N 20094 or P/N 20094/G.

(h) Credit for Previous Actions

You may take credit for the action required by paragraph (g)(1) of this AD if you performed those actions before the effective date of this AD using Scheibe Aircraft GmbH Service Bulletin 653–96, dated March 2, 2022.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (j)(1) of this AD and email to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(j) Related Information

(1) For more information about this AD, contact Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4165; email: *jim.rutherford@faa.gov.*

(2) Refer to European Union Aviation Safety Agency (EASA) Emergency AD 2022–0066–E, dated April 11, 2022, for more information. You may examine the EASA AD in the AD docket at *https://www.regulations.gov* by searching for and locating it in Docket No. FAA–2022–0506.

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (k)(3) and (4) of this AD.

(k) Material Incorporated by Reference

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

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

(i) Scheibe Aircraft GmbH Service Bulletin 653–96/1, dated April 4, 2022.

Note 1 to paragraph (k)(2)(i): Page 4 of this service information is identified as 653–95.

Note 2 to paragraph (k)(2)(i): This service information contains German to English translation. EASA used the English translation in referencing the document from Scheibe Aircraft GmbH. For enforceability purposes, the FAA will cite the service information in English as it appears on the document.

(ii) [Reserved]

(3) For service information identified in this AD, contact Scheibe Aircraft GmbH, Am Flugplatz 5, Heubach, D–73540, Germany; phone: +49 07173 184286; email: *info@scheibe-aircraft.de;* website: *https://scheibe-aircraft.de/.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on April 22, 2022.

Gaetano A. Sciortino,

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

[FR Doc. 2022–09890 Filed 5–4–22; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1173; Project Identifier AD–2021–00917–T; Amendment 39–22017; AD 2022–08–14]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all The Boeing Company Model 747–8F series airplanes. This AD was prompted by reports of fuselage crown stringer cracking between station (STA) 740 and STA 1000, stringer (S)–7 to S–12. This AD requires repetitive detailed inspections for cracking of fuselage crown stringers and applicable on-condition actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 10, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 10, 2022.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1173.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1173; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Stefanie Roesli, Aerospace Engineer, Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3964; email: *stefanie.n.roesli@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all The Boeing Company Model 747–8F series airplanes. The NPRM published in the **Federal Register** on January 31, 2022 (87 FR 4826). The NPRM was prompted by reports of fuselage crown stringer cracking between STA 740 and STA 1000, S–7 to S–12. In the NPRM, the FAA proposed to require repetitive detailed inspections for cracking of fuselage crown stringers and applicable on-condition actions. The FAA is issuing this AD to address cracking in fuselage crown stringers. This condition, if not addressed, could result in the inability of a structural element to sustain limit load, and could adversely affect the structural integrity of the airplane.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from Boeing, who supported the NPRM without change.

Conclusion

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 747–53A2906 RB, dated July 16, 2021. This service information specifies procedures for repetitive detailed inspections for cracking of fuselage crown stringers, repair of cracks, and a high frequency eddy current (HFEC) inspection for cracking of repaired areas. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES.**

Costs of Compliance

The FAA estimates that this AD affects 33 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Repetitive detailed inspections.	84 work-hours × $85 per hour = $7,140 per inspection cycle.	$0	$7,140 per inspection cycle.	$235,620 per inspection cycle.

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
HFEC inspection	1 work-hour × $85 per hour = $85	$0	$85.
Repair	Up to 550 work-hours × $85 per hour = $46,750 (per repaired area)	2,400	Up to $49,150.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2022–08–14 The Boeing Company: Amendment 39–22017; Docket No. FAA–2021–1173; Project Identifier AD–2021–00917–T.

(a) Effective Date

This airworthiness directive (AD) is effective June 10, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 747–8F series airplanes, certificated in any category.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports of fuselage crown stringer cracking between station (STA) 740 and STA 1000, stringer (S)–7 to S–12. The FAA is issuing this AD to address cracking in fuselage crown stringers. This condition, if not addressed, could result in the inability of a structural element to sustain limit load, and could adversely affect the structural integrity of the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 747–53A2906 RB, dated July 16, 2021, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 747–53A2906 RB, dated July 16, 2021.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 747–53A2906, dated July 16, 2021, which is referred to in Boeing Alert Requirements Bulletin 747–53A2906 RB, dated July 16, 2021.

(h) Exception to Service Information Specifications

Where the Compliance Time columns of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 747–53A2906 RB, dated July 16, 2021, use the phrase ''the original issue date of Requirements Bulletin 747–53A2906 RB,'' this AD requires using ''the effective date of this AD.''

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector,

or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(j) Related Information

For more information about this AD, contact Stefanie Roesli, Aerospace Engineer, Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3964; email: *stefanie.n.roesli@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) Boeing Alert Requirements Bulletin 747–53A2906 RB, dated July 16, 2021.

(ii) [Reserved]

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, *fr.inspection@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on April 7, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–09662 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1141; Airspace Docket No. 21–AGL–34]

RIN 2120–AA66

Amendment of Class E Airspace; La Porte, IN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at La Porte, IN. This action is the result of an airspace review caused by the decommissioning of the La Porte non-directional beacon (NDB) and the La Porte Localizer (LOC).

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Rebecca Shelby, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5857.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E airspace extending upward from 700 feet above the surface at La Porte Municipal, La Porte, IN, to support instrument flight rule operations at this airport and removing the Class E airspace extending upward from 700 feet above the surface at La Porte Hospital Heliport, La Porte, IN as the instrument procedures are cancelled and the airspace is no longer required.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 8991; February 17, 2022) for Docket No. FAA–2021–1141 to amend the Class E airspace at La Porte, IN. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

The geographic coordinates of the airport will remain the same as in the current order. The NPRM inadvertently stated that the geographic coordinates would be updated to coincide with the FAA's aeronautical database.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 amends the Class E airspace extending upward from 700 feet above the surface to within 6.5-mile (decreased from a 7.3-mile) radius of La Porte Municipal Airport, La Porte, IN, by removing the La Porte NDB and associated extension and removing the La Porte Hospital Heliport point in space and associated airspace from the airspace legal description.

This action is necessary due to an airspace review caused by the decommissioning of the La Porte NDB and the La Porte LOC which provided navigation information for the instrument procedures at this airport.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is

published yearly and effective on September 15.

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL IN E5 La Porte, IN [Amended]

La Porte Municipal Airport, IN
(Lat. 41°34′21″ N, long. 86°44′04″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of La Porte Municipal Airport.

Issued in Fort Worth, Texas, on April 28, 2022.

Martin A. Skinner,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–09642 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0057; Airspace Docket No. 21–AWA–3]

RIN 2120–AA66

Amendment of Class B Airspace Description; Atlanta, GA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, technical amendment.

SUMMARY: This action amends the description of the Hartsfield-Jackson Atlanta International Airport, GA, Class B airspace area by changing the reference for defining the center point of the airspace from the ''Atlanta VORTAC'' to a ''Point of Origin.'' This action is required because the Atlanta VORTAC is scheduled for decommissioning. The Point of Origin is based on the same geographical coordinates as the Atlanta VORTAC; therefore, the change is editorial only and does not alter the currently charted boundaries, or altitudes, or the air traffic control (ATC) procedures for the Atlanta Class B airspace area.

DATES: Effective date 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it makes editorial changes to an existing Class B airspace description to maintain accuracy.

History

The Atlanta, GA, Class B airspace area was established as a ''Terminal Control Area (TCA)'' on June 15, 1970 (35 FR 7784, May 21, 1970). In 1993, as part of the Airspace Reclassification Final Rule (56 FR 65638, December 17, 1991), the term ''terminal control area'' was replaced by ''Class B airspace area.'' The Atlanta Class B airspace area was last modified on March 3, 2013 (78 FR 1742, January 9, 2013). Currently, the Atlanta VORTAC serves as the reference point for defining the center of the Class B airspace area. The Atlanta VORTAC is also used in defining the boundaries of seven of the ten subareas that make up the Class B airspace area. The Atlanta VORTAC is scheduled to be decommissioned, so the FAA is establishing a ''Point of Origin'' to replace references to the Atlanta VORTAC in the Atlanta Class B description. The Point of Origin has the same latitude and longitude coordinates as the Atlanta VORTAC therefore, there is no change to the existing charted boundaries of the Atlanta Class B airspace area. All references to the Atlanta VORTAC in the Atlanta Class B airspace description (as published in FAA Order JO 7400.11F) are replaced by ''Point of Origin.'' This practice is consistent with other Class B airspace

locations that do not have a suitable navigation aid located on the airport.

Class B airspace areas are published in paragraph 3000 of FAA Order JO 7400.11F dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class B airspace area listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by editing the description of the Atlanta, GA, Class B airspace area (as published in FAA Order JO 7400.11F) to replace references to the ''Atlanta VORTAC'' with a ''Point of Origin.'' This action is necessary because the Atlanta VORTAC is scheduled to be decommissioned. The ''Point of Origin'' uses the same latitude/longitude position as the current Atlanta VORTAC location. The descriptions of the following seven Atlanta Class B airspace subareas are affected by the change: A, B, F, G, H, I, and J. The FAA is taking this action so that the currently charted boundaries of the Atlanta Class B airspace area are not affected by the decommissioning of the Atlanta VORTAC and for accuracy.

Because this action is an editorial change that does not alter the currently charted boundaries and altitudes, or the ATC procedures for the Hartsfield-Jackson Atlanta International Airport, notice and public procedure under 5 U.S.C. § 553(b) are unnecessary and contrary to the public interest.

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

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action of amending the description of the Hartsfield-Jackson Atlanta International Airport, GA, Class B airspace area by changing the reference for defining the center point of the airspace from the ''Atlanta VORTAC'' to a ''Point of Origin'', qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). As such, this action is an editorial change that is not expected to cause any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, signed August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 3000 Subpart B Class B Airspace.

* * * * *

ASO GA B Atlanta, GA

Hartsfield-Jackson Atlanta International Airport (Primary Airport)
(Lat. 33°38′12″ N, long. 84°25′40″ W)
Point of Origin
(Lat. 33°37′45″ N, long. 84°26′06″ W)

Boundaries

Area A. That airspace extending upward from the surface to and including 12,500 feet MSL, bounded on the east and west by a 7-mile radius of the Point of Origin, on the south by a line 4 miles south of and parallel to the Runway 10/28 localizer courses, and on the north by a line 4 miles north of and parallel to the Runway 08L/26R localizer courses; excluding the Atlanta Fulton County Airport-Brown Field, GA, Class D airspace area.

Area B. That airspace extending upward from 2,500 feet MSL to and including 12,500 feet MSL, bounded on the east and west by a 12-mile radius of the Point of Origin, on the south by a line 4 miles south of and parallel to the Runway 10/28 localizer courses, and on the north by a line 4 miles north of and parallel to the Runway 08L/26R localizer courses; excluding the Atlanta Fulton County Airport-Brown Field, GA, Class D airspace area and that airspace contained in Area A.

Area C. That airspace extending upward from 3,000 feet MSL to and including 12,500 feet MSL, bounded on the east by long. 84°00′32″ W, on the west by long. 84°51′38″ W, on the south by a line 8 miles south of and parallel to the Runway 10/28 localizer courses, and on the north by a line 4 miles north of and parallel to the Runway 08L/26R localizer courses; excluding that airspace contained in Areas A and B.

Area D. That airspace extending upward from 3,500 feet MSL to and including 12,500 feet MSL, bounded on the east by long. 84°00′32″ W, on the west by long. 84°51′38″ W, on the south by a line 4 miles north of and parallel to the Runway 08L/26R localizer courses, and on the north by a line 8 miles north of and parallel to the Runway 08L/26R localizer courses.

Area E. That airspace extending upward from 4,000 feet MSL to and including 12,500 feet MSL, bounded on the east by long.

83°54′04″ W, on the west by long. 84°57′41″ W, on the south by a line 12 miles south of and parallel to the Runway 10/28 localizer courses and on the north by a line 8 miles north of and parallel to the Runway 08L/26R localizer courses; excluding that airspace contained in Areas A, B, C, and D.

Area F. That airspace extending upward from 5,000 feet MSL to and including 12,500 feet MSL, within a 30-mile radius of the Point of Origin and bounded on the east by long. 83°54′04″ W, on the south by a line 8 miles north of and parallel to the Runway 08L/26R localizer courses, on the west by long. 84°57′41″ W, and on the north by a line 12 miles north of and parallel to the Runway 08L/26R localizer courses.

Area G. That airspace extending upward from 6,000 feet MSL to and including 12,500 feet MSL bounded on the north by a line 12 miles south of and parallel to the Runway 10/28 localizer courses, on the east by a line from lat. 33°25′21″ N, long. 84°16′49″ W direct to lat. 33°15′33″ N, long. 84°01′55″ W, on the south by a 30-mile radius of the Point of Origin, and on the west by a line from lat. 33°25′25″ N, long. 84°33′32″ W direct to lat. 33°18′26″ N, long. 84°42′56″ W and thence south via long. 84°42′56″ W.

Area H. That airspace extending upward from 5,000 feet MSL to and including 12,500 feet MSL, within a 30-mile radius of the Point of Origin south of a line 12 miles south of and parallel to the Runway 10/28 localizer courses, bounded on the west by long. 84°57′41″ W and on the east by long. 83°54′04″ W. excluding that airspace within the lateral limits of area G.

Area I. That airspace extending upward from 7,000 feet MSL to and including 12,500 feet MSL bounded on the north by the 30-mile radius of the Point of Origin, on the east by a line from lat. 33°50′59″ N, long. 84°16′38″ W direct to lat. 34°04′20″ N, long. 84°09′24″ W, on the south by a line 12 miles north of and parallel to the Runway 08L/26R localizer courses, and on the west by a line from lat. 33°50′59″ N, long. 84°34′14″ W direct to lat. 34°01′40″ N, long. 84°47′55″ W.

Area J. That airspace extending upward from 6,000 feet MSL to and including 12,500 feet MSL bounded on the north by a 30-mile radius of the Point of Origin, on the east by long. 83°54′04″ W, on the south by a line 12 miles north of and parallel to the Runway 08L/26R localizer courses, and on the west by long. 84°57′41″ W, excluding that airspace within the lateral limits of area I.

* * * * *

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–09241 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0131; Airspace Docket No. 22–ACE–4]

RIN 2120–AA66

Amendment of Class D and Class E Airspace; Joplin, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class D and Class E airspace at Joplin, MO. This action as the result of an airspace review conducted as part of the decommissioning of the Neosho very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program. The geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class D airspace, the Class E surface airspace, and the Class E airspace extending upward from 700 feet above the surface at Joplin Regional Airport, Joplin, MO, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 11362; March 1, 2022) for Docket No. FAA–2022–0131 to amend the Class D and Class E airspace at Joplin, MO. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One comment was received supporting the proposal. No response is provided.

Class D and E airspace designations are published in paragraphs 5000, 6002, and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71:

Amends the Class D airspace at Joplin Regional Airport, Joplin, MO, by updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database; and updates the outdated term ''Airport/Facility Directory'' with ''Chart Supplement'';

Amends the Class E surface airspace at Joplin Regional Airport by updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database; and updates the outdated term ''Airport/Facility Directory'' with ''Chart Supplement'';

And amends the Class E airspace extending upward from 700 feet above the at Joplin Regional Airport by removing the LUNNS LOM and associated extension from the airspace

legal description as they are no longer required; adds an extension 2.4 miles each side of the 182° bearing from the airport extending from the 6.8-mile radius of the airport to 7.1 miles south of the airport; adds an extension 3.8 miles each side of the 318° bearing from the airport extending from the 6.8-mile radius of the airport to 12.5 miles northwest of the airport; and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is necessary due to an airspace review conducted as part of the decommissioning of the Neosho VOR, which provided navigation information for the instrument procedures this airport, as part of the VOR MON Program.

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

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ACE MO D Joplin, MO [Amended]

Joplin Regional Airport, MO
(Lat. 37°09′11″ N, long. 94°29′56″ W)

That airspace extending upward from the surface to and including 3,500 feet MSL within a 4.3-mile radius of Joplin Regional Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective dates and times will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.

* * * * *

ACE MO E2 Joplin, MO [Amended]

Joplin Regional Airport, MO
(Lat. 37°09′11″ N, long. 94°29′56″ W)

Within a 4.3-mile radius of Joplin Regional Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective dates and times will thereafter be continuously published in the Chart Supplement.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ACE MO E5 Joplin, MO [Amended]

Joplin Regional Airport, MO
(Lat. 37°09′11″ N, long. 94°29′56″ W)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of Joplin Regional Airport, and within 2.4 miles each side of the 182° bearing from the airport extending from the 6.8-mile radius to 7.1 miles south of the airport, and within 3.8 miles each side of the 318° bearing from the airport extending from the 6.8-mile radius to 12.5 miles northwest of the airport.

Issued in Fort Worth, Texas, on May 2, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–09672 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1048; Airspace Docket No. 21–ASO–13]

RIN 2120–AA66

Amendment of VOR Federal Airways V–7, V–9, and V–11; Eastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies VHF Omnidirectional Range (VOR) Federal airway V–11. This action is necessary due to the planned decommissioning of the Dyersburg, TN, (DYR); and the Holly Springs, MS (HLI) VOR Tactical Air Navigation (VORTAC) facilities, under the FAA's VOR Minimum Operational Network (MON) program, which provide navigation guidance for segments of the routes. The FAA originally proposed to amend V–7 and V–9 with this rule but these routes require further review and are being delayed to a later date.

DATES: Effective date 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA JO Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

History

The FAA published a notice of proposed rulemaking (NPRM) for Docket No. FAA–2021–1048 in the **Federal Register** (86 FR 70992; December 14, 2021), modifying VOR Federal airways V–7, V–9, and V–11. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

VOR Federal airways are published in paragraph 6010(a) of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airway routes listed in this document will be published subsequently in FAA Order JO 7400.11F.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Differences From the NPRM

VOR Federal airways V–7 and V–9 are removed from this docket action for further planning and coordination purposes. They are delayed to a later date. Only the amendments to V–11 are implemented by this rule.

Additionally, the description of V–11 published in the NPRM is incorrect. The NPRM stated that V–11 extends ''between Magnolia, MS, and the intersection of the Fort Wayne, IN, 038° and the Flag City, OH, 308° radials.'' This was due to an editorial error by the writer because the rule to implement that version of the description had been previously withdrawn. The correct, current, description of V–11 reads: ''From Brookley, AL; Greene County, MS; INT Greene County 315° and Magnolia, MS, 133° radials; Magnolia; Sidon, MS; Holly Springs, MS; Dyersburg, TN; Cunningham, KY; Pocket City, IN; Brickyard, IN; Marion, IN; Fort Wayne, IN; to INT Fort Wayne 038° and Flag City, OH, 308° radials.''

This latter description is the one that is currently depicted on the IFR En Route charts, and is being modified by this rule as described below.

The Rule

The FAA is amending 14 CFR part 71 by modifying VOR Federal airway V–11 in the eastern United States due to the planned decommissioning of the Dyersburg, TN, (DYR) VORTAC; and the Holly Springs, MS, (HLI) VORTAC as part of the FAA VOR MON program.

V–11: V–11 currently extends between Brookley, AL, and the intersection of the Fort Wayne, IN, 038°, and the Flag City, OH, 308° radials. This action removes the segments from Sidon, MS; to Holly Springs, MS; to Dyersburg, TN. As amended, V–11 consists of two parts: ''From Brookley, AL; Greene County, MS; INT Greene County 315° and Magnolia, MS 133° radials, to Magnolia, MS. From Cunningham, KY; Pocket City, IN; Brickyard, IN; Marion, IN; Fort Wayne, IN; to INT Fort Wayne 038°, and the Flag City, OH, 308° radials.'',

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

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action of modifying VOR Federal airway V–11, in support of the FAA VOR MON Project, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points); and paragraph 5–6.5b, which categorically excludes from further environmental impact review ''Actions regarding establishment of jet routes and Federal airways (see 14 CFR 71.15, *Designation of jet routes and VOR Federal airways*) . . .''. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F,

Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–11 [Amended]

From Brookley, AL; Greene County, MS; INT Greene County 315° and Magnolia, MS, 133° radials; to Magnolia. From Cunningham, KY; Pocket City, IN; Brickyard, IN; Marion, IN; Fort Wayne, IN; to INT Fort Wayne 038° and Flag City, OH, 308° radials.

* * * * *

Issued in Washington, DC, on April 28, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–09439 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0048; Airspace Docket No. 22–ASO–01]

RIN 2120–AA66

Amendment of Class D Airspace and Class E Airspace; Gulf Shores, AL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class D airspace and Class E airspace extending upward from 700 feet above the surface for Gulf Shores International Airport/Jack Edwards Field, Gulf Shores, AL, (formerly Jack Edwards National Airport), by updating the airport's name, and adding necessary verbiage to the descriptions. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783.

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends airspace in the Gulf Shores, AL, area, to support IFR operations in the area.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 10994, February 28, 2022) for Docket No. FAA–2022–0048 to amend Class D airspace and Class E airspace extending upward from 700 feet above the surface for Gulf Shores International Airport/Jack Edwards Field (formerly Jack Edwards National Airport), Gulf Shores, AL, by updating the airport's name, and amending the descriptions, by adding 'when active' in reference to Restricted Area R–2908.

Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class D and Class E airspace designations are published in Paragraphs 5000 and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11F.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic routes, and reporting points.

The Rule

The FAA is amending 14 CFR part 71 by amending Class D airspace and Class E airspace extending upward from 700 feet above the surface for Gulf Shores International Airport/Jack Edwards Field (formerly Jack Edwards National Airport), Gulf Shores, AL, by updating the airport's name, and amending the descriptions, by adding 'when active' in reference to Restricted Area R–2908.

Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

Class D and Class E airspace designations are published in Paragraphs 5000 and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11. FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially

significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO AL D Gulf Shores, AL [Amended]

Gulf Shores International Airport/Jack Edwards Field, AL
(Lat. 30°17′23′ W″N, long. 87°40′18″ W)

That airspace extending upward from the surface to and including 2,000 feet MSL, within a 4.3-mile radius of Gulf Shores International Airport/Jack Edwards Field, excluding that airspace within Restricted Area R–2908, when active. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO AL E5 Gulf Shores, AL [Amended]

Gulf Shores International Airport/Jack Edwards Field, AL
(Lat. 30°17′23′ W″N, long. 87°40′18″ W)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of Gulf Shores International Airport/Jack Edwards Field, excluding that airspace within Restricted Area R–2908, when active.

Issued in College Park, Georgia, on April 28, 2022.

Andreese C. Davis,

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

[FR Doc. 2022–09520 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1031; Airspace Docket No. 21–ASO–14]

RIN 2120–AA66

Amendment and Removal of VOR Federal Airways V–18, V–115, V–222, V–241, V–245, V–311, V–321, V–325, V–333, V–415, V–417, and V–463 in the Southeastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends five VHF Omnidirectional Radar (VOR) Federal airways, V–18, V–222, V–245, V–325, and V–417 in association with the VOR Minimum Operation Network (MON) project in the southeastern United States. This action is necessary due to the planned decommissioning of the following ground-based NAVAIDs: Atlanta, GA, (ATL) VOR Tactical Air Navigational System (VORTAC); Crimson, AL, (LDK) VORTAC; and Macon, GA, (MCN) VORTAC. The following airways are removed from this docket and will be addressed in a subsequent docket action at a later date: V–115, V–241, V–311, V–321, V–333, V–415, and V–463.

DATES: Effective date 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2021–1031 in the **Federal Register** (86 FR 70989, December 14, 2021), to amend seven VOR Federal airways and remove five airways in the southeastern United States. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

Domestic VOR Federal airways are published in paragraph 6010(a) of FAA Order JO 7400.11F, dated August 10, 2021 and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airways listed in this document will be subsequently published in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Differences From the NPRM

This rule includes changes to the VOR Federal airways proposed in the NPRM to enable ongoing review by the Department of Defense. So as to avoid the premature removal of route

segments, only those structural changes necessary due to the scheduled decommissioning of the Atlanta, GA, (ATL); Crimson, AL, (LDK), and Macon, GA, (MCN) VORs are included in this rule.

The following routes are removed from this rule: V–115, V–421, V–311, V–321, V–333, V–415, and V–463. These routes will be addressed in a subsequent docket action at a later date. The NPRM proposed the removal of V–325 and V–417. Instead, these routes will be retained and amended in this rule. V–245 is amended as proposed in the NPRM. The following are changes from NPRM:

V–18: The NPRM proposed to remove the segments from the Crimson, AL, (LDK) VORTAC to Vulcan, AL, and the segment from Colliers, SC, to Charleston, SC. The FAA has decided to retain the segment From Colliers, SC, to Charleston, SC.

V–222: The NPRM proposed to terminate V–222 at Montgomery, AL. Instead, the FAA has decided to terminate V–222 at the TIROE intersection, as currently charted.

V–325: V–325 currently extends from the Columbia, SC, (CAE) VORTAC, to the Muscle Shoals, AL, (MSL) VORTAC. The NPRM proposed to remove the entire route. The FAA has decided to retain V–325 and amend it as follows: From Columbia, SC, to Athens, GA; and From INT Gadsden, AL, 091° and Rome, GA, 133° radials; to INT Vulcan, AL, 013° and Gadsden 302° radials.

V–417: V–417 currently extends from the Meridian, MS, (MEI) VORTAC to the Charleston, SC, (CHS) VORTAC. The NPRM proposed to remove the entire route. The FAA has decided to retain V–417 and amend it as follows: From Vulcan, AL; Rome, GA; to INT Rome 060° and Hinch Mountain, TN, 160° radials. From Athens, GA; Colliers, SC; Allendale, SC; to Charleston, SC.

The Rule

This action amends 14 CFR part 71 by modifying V–18, V–222, V–245, V–325, and V–417.

V–18: V–18 is amended by removing the segment between Crimson, AL, and Vulcan, AL. The amended route extends between Belcher, LA and Meridian, MS; and between Colliers, SC, and Charleston, SC.

V–222: V–222 is amended by removing the segments from the intersection of the Foothills, SC, and the Harris, GA, radials to Lynchburg, VA. The amended route extends from El Paso, TX to the intersection of the La Grange, GA, 048° and the Rome, GA, 166° radials (the charted TIROE Intersection).

V–325: V–325 is amended to extend from Columbia, SC to Athens, GA; and from the intersection of the Gadsden, AL 091° and the Rome, GA 133° radials; to the intersection of the Vulcan, AL, 013° and the Gadsden 302° radials.

V–417: V–417 is amended by removing the segments from Meridian, MS, to Crimson, AL. The amended route consists of two parts: From Vulcan, AL, to the intersection of the Rome, GA, 060°, and the Hinch Mountain, TN, 160° radials (the charted NELLO intersection); and From Athens, GA, to Charleston, SC.

Full route descriptions of the above routes are listed in ''The Amendment'' section of this rule.

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

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action of amending five VOR Federal airways, in the southeastern United States qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points); and paragraph 5–6.5b, which categorically excludes from further environmental impact review ''Actions regarding establishment of jet routes and Federal airways (see 14 CFR 71.15, *Designation of jet routes and VOR Federal airways*) . . .''. As such, this action is not expected to cause any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–18 [Amended]

From Belcher, LA; Monroe, LA; Magnolia, MS; to Meridian, MS. From Colliers, SC; to Charleston, SC

* * * * *

V–222 [Amended]

From El Paso, TX, via Salt Flat, TX; Fort Stockton, TX; 20 miles, 116 miles, 55 MSL, Junction, TX; Stonewall, TX; INT Stonewall 113° and Industry, TX, 267° radials; Industry; INT Industry 101° and Humble 259° radials; Humble; Beaumont, TX; Lake Charles, LA; McComb, MS; Eaton, MS; Monroeville, AL; Montgomery, AL; LaGrange, GA; to INT LaGrange 048° and Rome, GA, 166° radials .

* * * * *

V–245 [Amended]

From Alexandria, LA, via Natchez, MS; Magnolia, MS; to Bigbee, MS.

* * * * *

V–325 [Amended]

From Columbia, SC to Athens, GA. From INT Gadsden, AL, 091° and Rome, GA, 133° radials; Gadsden; to INT Vulcan, AL 013° and Gadsden 302° radials.

* * * * *

V–417 [Amended]

From Vulcan, AL; Rome, GA; to INT Rome 060° and Hinch Mountain, TN, 160° radials. From Athens, GA; Colliers, SC; Allendale, SC; to Charleston, SC.

* * * * *

Issued in Washington, DC, on April 28, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–09440 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0128; Airspace Docket No. 22–AGL–7]

RIN 2120–AA66

Amendment of Class E Airspace; Worthington, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Worthington, MN. This action as the result of an airspace review conducted as part of the decommissioning of the Worthington very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program. The geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E surface airspace and the Class E airspace extending upward from 700 feet above the surface at Worthington Municipal Airport, Worthington, MN, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 11359; March 1, 2022) for Docket No. FAA–2022–0128 to amend the Class E airspace at Worthington, MN. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraphs 6002 and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71:

Amends the Class E surface airspace to within a 4.1-mile (decreased from a 7-mile) radius of Worthington Municipal Airport, Worthington, MN; updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database; and updates the outdated term ''Airport/Facility Directory'' with ''Chart Supplement'';

And amends the Class E airspace extending upward from 700 feet above the surface to within a 6.6-mile (decreased from a 7-mile) radius of Worthington Municipal Airport; amends the extension to the north to extending from the 6.6-mile (decreased from a 7-mile) radius of the airport to 10.8 (decrease from 11.6) miles north of the airport; and amends the extension to the south to 1 (decreased from 2) mile each side of the 180° (previously 176°) bearing from the airport extending from the 6.6-mile (decreased from 7-mile) radius of the airport to 11.2 (increased from 11.1) miles south of the airport.

This action is due to an airspace review conducted as part of the decommissioning of the Worthington VOR, which provided navigation information for the instrument procedures at this airport, as part of the VOR MON Program.

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

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6002. Class E Airspace Areas Designated as a Surface Area.

* * * * *

AGL MN E2 Worthington, MN [Amended]

Worthington Municipal Airport, MN
(Lat. 43°39′18″ N, long. 95°34′45″ W)

Within a 4.1-mile radius of Worthington Municipal Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL MN E5 Worthington, MN [Amended]

Worthington Municipal Airport, MN
(Lat. 43°39′18″ N, long. 95°34′45″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Worthington Municipal Airport, and within 2 miles each side of the 000° bearing from the airport extending from the 6.6-mile radius to 10.8 miles north of the airport, and within 1 mile each side of the 180° bearing from the airport extending from the 6.6-mile radius to 11.2 miles south of the airport.

Issued in Fort Worth, Texas, on May 2, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–09673 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0043; Airspace Docket No. 22–ACE–2]

RIN 2120–AA66

Amendment of Class E Airspace; Emmetsburg, IA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Emmetsburg, IA. This action as the result of an airspace review caused by the decommissioning of the Emmetsburg non-directional beacon (NDB). The geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E airspace extending upward from 700 feet above the surface at Emmetsburg Municipal Airport, Emmetsburg, IA, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 7776; February 10, 2022) for Docket No. FAA–2022–0043 to amend the Class E airspace at Emmetsburg, IA. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 amends the Class E airspace extending upward from 700 feet above the surface at Emmetsburg Municipal Airport, Emmetsburg, IA, by removing the Emmetsburg NDB and associated extension from the airspace legal description; and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is necessary due to an airspace review caused by the decommissioning of the Emmetsburg NDB which provided navigation

information for the instrument procedures this airport.

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

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ACE IA E5 Emmetsburg, IA [Amended]

Emmetsburg Municipal Airport, IA
(Lat. 43°06′07″ N, long. 94°42′16″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Emmetsburg Municipal Airport, and within 3.8 miles each side of the 316° bearing from the airport extending from the 6.5-mile radius to 10.3 miles northwest of the airport.

Issued in Fort Worth, Texas, on April 28, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–09427 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0821; Airspace Docket No. 21–ASW–1]

RIN 2120–AA66

Amendment, Establishment, and Revocation of Multiple Air Traffic Service (ATS) Routes in the Vicinity of Borger, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Jet Route J–8 and VHF Omnidirectional Range (VOR) Federal airway V–272; establishes Area Navigation (RNAV) route T–420; and removes Jet Route J–142 and VOR Federal airways V–304 and V–390. The FAA is taking this action due to the planned decommissioning of the VOR portion of the Borger, TX, VOR/Tactical Air Navigation (VORTAC) navigational aid (NAVAID). The Borger VOR is being decommissioned in support of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Effective date 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/*. For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

History

The FAA published a notice of proposed rulemaking (NPRM) for Docket No. FAA–2021–0821 in the **Federal Register** (86 FR 60418; November 2, 2021), amending Jet Route J–8 and VOR Federal airway V–272; establishing RNAV route T–420; and removing Jet Route J–142 and VOR Federal airways V–304 and V–390. The proposed amendment actions were due to the planned decommissioning of the VOR portion of the Borger, TX, VORTAC NAVAID. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

Subsequent to the NPRM, the FAA published a rule for Docket No. FAA–2021–0632 in the **Federal Register** (87 FR 24860; April 27, 2022), amending J–8 by removing the airway segment overlying the Kingfisher, OK, VORTAC between the Borger, TX, VORTAC and the Springfield, MO, VORTAC. That airway amendment is effective July 14, 2022, also and is included in this rule.

Jet Routes are published in paragraph 2004, VOR Federal airways are published in paragraph 6010(a), and United States RNAV T-routes are published in paragraph 6011 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The ATS routes listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by modifying Jet Route J–8 and VOR Federal airway V–272; establishing RNAV route T–420; and removing Jet Route J–142 and VOR Federal airways V–304 and V–390 due to the planned decommissioning of the Borger, TX, VOR. The ATS route actions are described below.

J–8: J–8 extends between the Needles, CA, VORTAC and the Borger, TX, VORTAC; and between the Springfield, MO, VORTAC and the Casanova, VA, VORTAC. The route segment between the Fort Union, NM, VORTAC and the Borger, TX, VORTAC is removed. The unaffected portions of the existing airway remain as charted.

J–142: J–142 extends between the Socorro, NM, VORTAC and the Borger, TX, VORTAC. The route segment between the Anton Chico, NM, VORTAC and the Borger VORTAC is removed due to the planned decommissioning of the Borger VOR. Additionally, the remaining route segment between the Socorro VORTAC and the Anton Chico VORTAC is also removed due to the distance between the VORTACs being within NAVAID service volumes and pilots can file direct. As a result, the route is removed in its entirety.

V–272: V–272 extends between the Dalhart, TX, VORTAC and the Will Rogers, OK, VORTAC. The airway segment overlying the Borger, TX, VORTAC between the Dalhart VORTAC and the Burns Flat, OK, VORTAC is removed. The unaffected portions of the existing airway remain as charted.

V–304: V–304 extends between the Panhandle, TX, VORTAC and the Lamar, CO, VOR/Distance Measuring Equipment (VOR/DME). The airway segment between the Panhandle VORTAC and Liberal, KS, VORTAC is removed due to the planned decommissioning of the Borger VOR. Additionally, the remaining airway segment between the Liberal VORTAC and the Lamar VOR/DME is removed due to it overlying V–210 which will remain available for use by NAS users. As a result, the airway is removed in its entirety.

V–390: V–390 extends between the Tucumcari, NM, VORTAC and the Mitbee, OK, VORTAC. The airway is removed in its entirety.

T–420: T–420 is a new route that extends between the Dalhart, TX, VORTAC and the Will Rogers, OK, VORTAC. This T-route mitigates the removal of the V–272 airway segment between the Dalhart, TX, VORTAC and the Burns Flat, OK, VORTAC (noted above), as well as provides RNAV routing capability between the Dalhart, TX, area and the Oklahoma City, OK, area.

The NAVAID radials listed in the Jet Route description below are unchanged and stated in True degrees.

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

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action of modifying Jet Route J–8 and VOR Federal airway V–272; establishing RNAV route T–420; and removing Jet Route J–142 and VOR Federal airways V–304 and V–390, due to the planned decommissioning of the Borger, TX, VOR NAVAID, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J–8 [Amended]

From Needles, CA; Flagstaff, AZ; Gallup, NM; to Fort Union, NM. From Springfield, MO; St Louis, MO; Louisville, KY;

Charleston, WV; INT Charleston 092° and Casanova, VA, 253° radials; to Casanova.

* * * * *

J–142 [Removed]

* * * * *

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–272 [Amended]

From Burns Flat, OK; to Will Rogers, OK.

* * * * *

V–304 [Removed]

* * * * *

V–390 [Removed]

* * * * *

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–420 Dalhart, TX (DHT) to Will Rogers, OK (IRW) [New]

Dalhart, TX (DHT)	VORTAC	(Lat. 36°05′29.24″ N, long. 102°32′40.71″ W)
Burns Flat, OK (BFV)	VORTAC	(Lat. 35°14′13.00″ N, long. 099°12′22.20″ W)
Will Rogers, OK (IRW)	VORTAC	(Lat. 35°21′30.95″ N, long. 097°36′33.22″ W)

Issued in Washington, DC, on April 28, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–09509 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2020–1053; Airspace Docket No. 20–ANM–32]

RIN 2120–AA66

Amendment of Restricted Area R–7001C and Establishment of Restricted Areas, R–7001D, R–7002A, R–7002B, and R–7002C; Guernsey, WY

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

ACTION: Final rule.

SUMMARY: This action amends restricted area R–7001C and establishes four restricted areas, R–7001D, R–7002A, R–7002B, and R–7002C. The Wyoming Army National Guard (WYARNG) requested the establishment of the new restricted areas to support its air-to-ground firing from helicopters and long range artillery training. This additional airspace allows for the segregation of hazardous activities from non-participating air traffic.

DATES: Effective date 0901 UTC, July 14, 2022.

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2020–1053 in the **Federal Register** (86 FR 12552; March 4, 2021) to amend restricted area R–7001C and establish four restricted areas, R–7001D, R–7002A, R–7002B, and R–7002C. The current restricted area was made public on February 14, 1962 (27 FR 1355). Since R–7001 was established, increased activities, and advancements in technologies require amendments to R–7001 and the establishment of new restricted areas to ensure non-participating aircraft are protected from hazardous activity in the National Airspace System (NAS). Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. No comments were received.

Differences From the NPRM

In the NPRM published in the **Federal Register** (86 FR 12552; March 4, 2021), some of the coordinates defining restricted area R–7002B are inaccurately annotated. The first latitude specifies ''42°22′24″ N'' and should read as ''42°22′25″ N''. The third set of coordinates show the longitude as ''04°43′17″ W'' and should read ''104°43′17″ W''. This rule corrects these errors.

The Rule

This action amends 14 CFR part 73 by amending R–7001C and establishing R–7001D, R–7002A, R–7002B, and R–7002C at Guernsey, WY. The amended and new restricted areas will support the Army's more advanced technology weapons systems and provide further safety of the NAS for general aviation pilots. The restricted area descriptions are as follows:

R–7001C: R–7001C retain the current boundaries, but the floor of the restricted area will begin at 23,501 feet mean sea level (MSL). No other changes are made to the legal description.

R–7001D: R–7001D is established above R–7001C and has the same boundaries as the existing restricted area. The altitudes are from 30,001 to 45,000 feet MSL. Operations are limited to 20 days a year.

R–7002A: R–7002A is established north of, and shares its southern boundary with R–7001A, R–7001B, and R–7001C. The altitudes are from the surface to 23,500 feet MSL. Operations are limited to 20 days a year.

R–7002B: R–7002B is established on the southeast border, and shares its northern boundary with R–7001A, R–7001B, and R–7001C. The altitudes are from the surface to 23,500 feet MSL. Operations are limited to 20 days a year.

R–7002C: R–7002C is established west of, and shares its eastern border with R–7001A, R–7001B, and R–7001C. The altitudes are from the surface to 23,500 feet MSL. Operations are limited to 20 days a year

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not

warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this rulemaking action of amending restricted area R–7001C and establishing four restricted areas, R–7001D, R–7002A, R–7002B, and R–7002C, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). As such, this rulemaking action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. For this rulemaking action, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study. On February 2, 2022, and in accordance with FAA Order 1050.1F, paragraph 8–2—*Adoption of Other Agencies' NEPA Documents,* the FAA adopted WYARNG's Supplemental Environmental Assessment (SEA) and Finding of No Significant Impact/Record of Decision (FONSI) for the establishment of R–7001D, at Camp Guernsey, Guernsey, Wyoming. WYARNG finalized its SEA in November 2021, and signed the FONSI on December 28, 2021.

Lists of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for part 73 continues to read as follows:

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

§ 73.70 Wyoming [Amended]

■ 2. Section 73.70 is amended as follows:

* * * * *

R–7001C Guernsey, WY [Amended]

Boundaries: Beginning at lat. 42°27′30″ N, long. 104°52′32″ W; to lat. 42°27′30″ N, long. 104°42′32″ W; to lat. 42°22′30″ N, long. 104°42′32″ W; to lat. 42°20′00″ N, long. 104°52′32″ W; to the point of beginning.

Designated Altitudes: 23,501 feet MSL to 30,000 feet MSL.

Time of Designation: Intermittent, 24 hours in advance by NOTAM.

Controlling agency: FAA, Denver ARTCC.

Using agency: Adjutant General, State of Wyoming.

R–7001D Guernsey, WY [New]

Boundaries: Beginning at lat. 42°27′30″ N, long. 104°52′32″ W; to lat. 42°27′30″ N, long. 104°42′32″ W; to lat. 42°22′30″ N, long. 104°42′32″ W; to lat. 42°20′00″ N, long. 104°52′32″ W; to the point of beginning.

Designated Altitudes: 30,001 feet MSL to 45,000 feet MSL.

Time of Designation: By NOTAM, at least 24 hours in advance.

Controlling Agency: FAA, Denver ARTCC.

Using Agency: Adjutant General, State of Wyoming.

R–7002A Guernsey, WY [New]

Boundaries: Beginning at lat. 42°27′55″ N, long. 104°52′33″ W; to lat. 42°27′55″ N, long. 104°51′46″ W; to lat. 42°28′21″ N, long. 104°51′45″ W; to lat. 42°28′21″ N, long. 104°48′46″ W; to lat. 42°27′56″ N, long. 104°48′46″ W; to lat. 42°27′55″ N, long. 104°47′28″ W; to lat. 42°27′30″ N, long. 104°46′43″ W; to lat. 42°27′30″ N, long. 104°52′32″ W; to the point of beginning.

Designated Altitudes: Surface to 23,500 feet MSL.

Time of Designation: By NOTAM, at least 24 hours in advance.

Controlling Agency: FAA, Denver ARTCC.

Using Agency: Adjutant General, State of Wyoming.

R–7002B Guernsey, WY [New]

Boundaries: Beginning at lat. 42°22′25″ N, long. 104°42′54″ W; to lat. 42°21′41″ N, long. 104°42′52″ W; to lat. 42°21′11″ N, long. 104°43′17″ W; to lat. 42°21′12″ N, long. 104°47′16″ W; to lat. 42°21′19″ N, long. 104°47′16″ W; to the point of beginning.

Designated Altitudes: Surface to 23,500 feet MSL.

Time of Designation: By NOTAM, at least 24 hours in advance.

Controlling Agency: FAA, Denver ARTCC.

Using Agency: Adjutant General, State of Wyoming.

R–7002C Guernsey, WY [New]

Boundaries: Beginning at lat. 42°27′03″ N, long. 104°53′54″ W; to lat. 42°27′03″ N, long. 104°52′32″ W; to lat. 42°20′00″ N, long. 104°52′32″ W; to lat. 42°20′18″ N, long. 104°51′19″ W; to lat. 42°19′42″ N, long. 104°51′17″ W; to lat. 42°19′43″ N, long. 104°53′03″ W; to lat. 42°20′49″ N, long. 104°54′38″ W; to lat. 42°22′43″ N, long. 104°54′38″ W; to lat. 42°22′48″ N, long. 104°53′22″ W; to lat. 42°23′39″ N, long. 104°53′23″ W; to lat. 42°23′40″ N, long. 104°53′58″ W; to the point of beginning; excluding that airspace 500 feet AGL and below ¼ mile either side of the BNSF railroad.

Designated Altitudes: Surface to 23,500 feet MSL.

Time of Designation: By NOTAM, at least 24 hours in advance.

Controlling Agency: FAA, Denver ARTCC.

Using Agency: Adjutant General, State of Wyoming.

* * * * *

Issued in Washington, DC, May 2, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–09692 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 641

[Docket No. ETA–2022–0002]

RIN 1205–AC04

Senior Community Service Employment Program Conforming Changes to the Supporting Older Americans Act of 2020—Updated Guidance on Priority of Service, Durational Limits, and State Plan Submissions

AGENCY: Employment and Training Administration, Labor Department.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: On February 14, 2022, the Department of Labor (Department) concurrently published both a direct final rule (DFR) and proposed rule putting forth guidance on priority service, durational limits, and State Plan submissions regarding a State's Senior Community Service Employment Program, or SCSEP. Because the Department did not receive any significant adverse comments within the scope of the rulemaking, the Department is implementing the DFR as published.

DATES: As of May 6, 2022, the Department is confirming the effective date of the rule published February 14, 2022 at 87 FR 8186 as April 15, 2022.

FOR FURTHER INFORMATION CONTACT: Steven Rietzke, Chief, Division of National Programs, Tools and Technical Assistance, Office of Workforce Investment, at 202–693–3980 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The DFR published at 87 FR 8186 on February 14, 2022, became effective on April 15, 2022. In the DFR, the Department stated that the DFR would become effective April 15, 2022 without further action, unless significant adverse comments were submitted by March 16, 2022 (the end of the public comment period), and the Department would publish a timely withdrawal of the proposed rule. In the same issue of the **Federal Register** in which this notice is published, the Department is publishing a withdrawal of the proposed rule, which was also published on February 14, 2022.

The Department received seven comments on this rulemaking. Several of these comments were supportive of the provisions this rulemaking proposed to implement. While other comments could be characterized as negative or adverse, none of those comments were significant or within the scope of this rulemaking. One commenter was opposed to the time limit; however, that time limit is set forth in the Supporting Older Americans Act of 2020, and is, therefore, a statutory requirement beyond the purview of the rulemaking. The remaining comments were outside the scope of the rulemaking. The comments are publicly available as part of the rulemaking docket at *https://www.regulations.gov/docket/ETA-2022-0002/comments.*

The Department has determined that none of the adverse comments are significant and within the scope of the rulemaking. Therefore, the DFR published at 87 FR 8186 on February 14, 2022, became effective on April 15, 2022.

Angela Hanks,

Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2022–09491 Filed 5–5–22; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2022–N–0289]

Medical Devices; Cardiovascular Devices; Classification of the Reverse Central Venous Recanalization System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the reverse central venous recanalization system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the reverse central venous recanalization system's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective May 6, 2022. The classification was applicable on February 10, 2020.

FOR FURTHER INFORMATION CONTACT: Finn Donaldson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2568, Silver Spring, MD 20993–0002, 301–796–9579, *Finn.Donaldson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the reverse central venous recanalization system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2) of the FD&C Act.

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically

placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application (PMA) to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

For this device, FDA issued an order on March 21, 2016, finding the Surfacer Inside-Out Access Catheter System not substantially equivalent to a predicate not subject to PMA. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

On August 15, 2019, FDA received Bluegrass Vascular Technologies, Inc.'s request for De Novo classification of the Surfacer Inside-Out Access Catheter System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 10, 2020, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 870.1342.[1] We have named the generic type of device reverse central venous recanalization system, and it is identified as a prescription device for obtaining central venous access to facilitate catheter insertion into the central venous system. Reverse recanalization involves the initiation of an access path from within the vein and then progressing to the skin for patients with upper body venous occlusions or other conditions that preclude central venous access by other methods.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—REVERSE CENTRAL VENOUS RECANALIZATION SYSTEM RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Infection	Sterilization validation, Shelf life testing, and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.
Embolization caused by component fracture	Clinical performance testing, and Non-clinical performance testing.
Death, bleeding, damage to non-target tissue and organs, blood vessel perforation or rupture, hematoma; or delays to therapy from failure to achieve central venous access.	Clinical performance testing, Non-clinical performance testing, and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, reverse central venous recanalization systems are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information 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 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 870

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the **Federal Register** Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 870.1342 to subpart B to read as follows:

§ 870.1342 Reverse central venous recanalization system.

(a) *Identification.* A reverse central venous recanalization system is a prescription device for obtaining central venous access to facilitate catheter insertion into the central venous system. Reverse recanalization involves the initiation of an access path from within the vein and then progressing to the skin for patients with upper body venous occlusions or other conditions that preclude central venous access by other methods.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must fulfill the following:

(i) Demonstrate the ability to safely deliver, deploy, and remove the device; and

(ii) Evaluate all adverse events including death, bleeding, damage to non-target tissue and organs, blood vessel perforation or rupture, and hematoma.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Simulated-use testing in a clinically relevant bench anatomic model to assess the delivery, deployment, and retrieval of the system;

(ii) Compatibility with other devices labeled for use with the device;

(iii) Tensile strengths of joints and components;

(iv) Kink resistance of system components;

(v) Radiopacity of components used to monitor procedure under fluoroscopy;

(vi) Characterization and verification of all dimensions; and

(vii) Leakage of air or fluid.

(3) All patient contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device components intended to be provided sterile.

(5) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(6) Labeling for the device must include:

(i) Instructions for use, including a description of compatible devices;

(ii) A detailed summary of the clinical testing conducted and;

(iii) Shelf life and storage conditions.

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09745 Filed 5–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2022–N–0141]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Magnetically Maneuvered Capsule Endoscopy System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the magnetically maneuvered capsule endoscopy system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the magnetically maneuvered capsule endoscopy system's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective May 6, 2022. The classification was applicable on May 22, 2020.

FOR FURTHER INFORMATION CONTACT: Stephanie Cole, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2536, Silver Spring, MD 20993–0002, 301–796–8587, *Stephanie.Cole@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the magnetically maneuvered capsule endoscopy system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2) of the FD&C Act.

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a

classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On August 13, 2019, FDA received AnX Robotica, Inc.'s request for De Novo classification of the NaviCam Capsule Endoscope System with NaviCam Stomach Capsule. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on May 22, 2020, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 876.1310.[1] We have named the generic type of device magnetically maneuvered capsule endoscopy system, and it is identified as consisting of an ingestible capsule and magnetic controller and is used for visualization of the stomach and duodenum. The ingestible capsule contains a camera that wirelessly captures images of the mucosa. The magnetic controller is used outside of the patient and is magnetically coupled with the capsule to control its location and viewing direction.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—MAGNETICALLY MANEUVERED CAPSULE ENDOSCOPY SYSTEM RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Infection	Reprocessing validation, Sterilization validation, and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.
Aspiration of capsule leading to injury	Labeling.
Tissue damage	Clinical performance testing, and Labeling.
Equipment malfunction leading to injury	Electrical, thermal, and mechanical safety testing; Software validation, verification, and hazard analysis; Human factors testing; Non-clinical performance testing; Shelf life testing; and Labeling.
Interference with other devices (*e.g.,* interference with image acquisition, patient information compromised, and ferromagnetic implants in users and patients).	Electromagnetic compatibility testing; Software validation, verification, and hazard analysis; Non-clinical performance testing; and Labeling.
Failure to visualize areas of the stomach and duodenum leading to inadequate treatment.	Clinical performance testing, Non-clinical performance testing, and Labeling.
Failure to excrete the capsule due to an obstruction resulting in abdominal pain, nausea, and vomiting.	Clinical performance testing, and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

While this final order contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this final order. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 876.1310 to subpart B to read as follows:

§ 876.1310 Magnetically maneuvered capsule endoscopy system.

(a) *Identification.* A magnetically maneuvered capsule endoscopy system consists of an ingestible capsule and magnetic controller and is used for visualization of the stomach and duodenum. The ingestible capsule contains a camera that wirelessly captures images of the mucosa. The magnetic controller is used outside of the patient and is magnetically coupled with the capsule to control its location and viewing direction.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing with the device under anticipated conditions of use must evaluate visualization of the intended region and document the adverse event profile.

(2) Non-clinical testing data must demonstrate the optical, mechanical, and functional integrity of the device under physically stressed conditions. The following performance characteristics must be tested, and detailed protocols must be provided for each test:

(i) A bite test must be performed to ensure that the capsule can withstand extreme cases of biting;

(ii) A pH resistance test must be performed to evaluate integrity of the capsule when exposed to a physiological relevant range of pH values;

(iii) A battery life test must be performed to demonstrate that the capsule's operating time is not constrained by the battery capacity;

(iv) A shelf life test must be performed to demonstrate that the device performs as intended at the proposed shelf life date;

(v) Optical testing must be performed to evaluate fundamental image quality characteristics such as resolution, field of view, depth of field, geometric distortion, signal to noise ratio, dynamic range, and image intensity uniformity;

(vi) A color performance test must be performed to compare the color differences between the input scene and output image;

(vii) A photobiological safety analysis must be performed based on maximum (worst-case) light exposure to internal gastrointestinal mucosa, and covering ultraviolet, visible, and near-infrared ranges, as appropriate. A mitigation analysis must be provided;

(viii) Performance testing must demonstrate that the viewing software clearly presents the current frame rate, which is either adjustable manually by the user or automatically by the device. Testing must demonstrate that the viewing software alerts the user when the video quality is reduced from nominal due to imaging data communication or computation problems;

(ix) A data transmission test must be performed to verify the robustness of the data transmission between the capsule and the receiver. This test must include controlled signal attenuation for simulating a non-ideal environment; and

(x) Magnetic field strength testing characterization must be performed to identify the distances from the magnet that are safe for patients and users with ferromagnetic implants, devices, or objects.

(3) Software validation, verification, and hazard analysis must be provided.

(4) Electrical safety, thermal safety, mechanical safety, and electromagnetic compatibility testing must be performed.

(5) The patient-contacting components of the device must be demonstrated to be biocompatible.

(6) Performance data must validate the reprocessing instructions for the reusable components of the device.

(7) Performance data must demonstrate the sterility of any device components labeled sterile.

(8) Human factors testing must demonstrate that the intended users can safely and correctly use the device, based solely on reading the instructions for use.

(9) Clinician labeling must include:

(i) Specific instructions and the clinical and technical expertise needed for the safe use of the device;

(ii) A detailed summary of the clinical testing pertinent to use of the device, including information on effectiveness and device- and procedure-related complications;

(iii) The patient preparation procedure;

(iv) A detailed summary of the device technical parameters;

(v) Magnetic field safe zones;

(vi) A screening checklist to ensure that all patients and operating staff are screened from bringing ferromagnetic implants, devices, or objects near the external magnet;

(vii) Reprocessing instructions for reusable components;

(viii) Shelf life for single use components; and

(ix) Use life for reusable components.

(10) Patient labeling must include:

(i) An explanation of the device and the mechanism of operation;

(ii) The patient preparation procedure;

(iii) A brief summary of the clinical study; and

(iv) A summary of the device- and procedure-related complications pertinent to use of the device.

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09735 Filed 5–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2022–N–0175]

Medical Devices; General and Plastic Surgery Devices; Classification of the Mountable Electromechanical Surgical System for Transluminal Approaches

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the mountable electromechanical surgical system for transluminal approaches into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the mountable electromechanical surgical system for transluminal approaches'

classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective May 6, 2022. The classification was applicable on February 26, 2021.

FOR FURTHER INFORMATION CONTACT: Virag Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4609, Silver Spring, MD 20993–0002, 301–796–0452, *Virag.Patel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the mountable electromechanical surgical system for transluminal approaches as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On April 17, 2019, FDA received Memic Innovative Surgery Ltd.'s request for De Novo classification of the Hominis Surgical System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 26, 2021, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 878.4961.[1] We have named the generic type of device mountable electromechanical surgical system for transluminal approaches, and it is identified as a software-controlled, patient bed- and/or operating table-mounted electromechanical surgical system with human/device interfaces that allows a qualified user to perform transluminal endoscopic or laparoscopic surgical procedures using surgical instruments attached to an electromechanical arm.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

TABLE 1—MOUNTABLE ELECTROMECHANICAL SURGICAL SYSTEM FOR TRANSLUMINAL APPROACHES RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Thermal, electrical, or mechanical fault, or system malfunction resulting in tissue perforation or injury to patient or user.	Non-clinical performance testing; Electrical safety testing; Electromagnetic compatibility (EMC) testing; Software verification, validation, and hazard analysis; Human factors assessment; Clinical performance testing; Annual reporting; and Labeling.
Use error resulting in patient injury: ..... • Dehiscence or delayed healing at the device access site. • Hemorrhage. • Thromboembolism. • Transluminal risks.	Non-clinical performance testing; Human factors assessment; Training; Clinical performance testing; Post-market surveillance; Annual reporting; Control on distribution; and Labeling.
Adverse tissue reaction	Biocompatibility evaluation, and Pyrogenicity testing.
Infection	Biocompatibility evaluation; Pyrogenicity testing; Sterilization validation; Reprocessing validation; Shelf-life testing; Clinical performance testing; and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

While this final order contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this final order. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 822, regarding postmarket surveillance of medical devices, have been approved under OMB control number 0910–0449; the collections of information in 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 878.4961 to subpart E to read as follows:

§ 878.4961 Mountable electromechanical surgical system for transluminal approaches.

(a) *Identification.* A mountable electromechanical surgical system for transluminal approaches is a software-controlled, patient bed- and/or operating table-mounted electromechanical surgical system with human/device interfaces that allows a qualified user to perform transluminal endoscopic or laparoscopic surgical procedures using surgical instruments attached to an electromechanical arm.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The device manufacturer must develop, and update as necessary, a device-specific use training program that ensures proper device setup/use/shutdown, accurate control of instruments to perform the intended surgical procedures, troubleshooting and handling during unexpected events or emergencies, and safe practices to mitigate use error.

(2) The device manufacturer may only distribute the device to facilities that implement and maintain the device-specific use training program and ensure that users of the device have completed the device-specific use training program.

(3) The device manufacturer must conduct and complete post-market surveillance, including an impact of the training program on user learning, behavior, and performance, in accordance with an FDA-agreed-upon protocol. The device manufacturer must submit post-market surveillance reports that contain current data and findings in accordance with the FDA-agreed-upon protocol.

(4) The device manufacturer must submit a report to FDA annually on the anniversary of initial marketing authorization for the device, until such time as FDA may terminate such reporting, which comprises the following information:

(i) Cumulative summary, by year, of complaints and adverse events since date of initial marketing authorization; and

(ii) Identification and rationale for changes made to the device, labeling or device-specific use training program, which did not require submission of a premarket notification during the reporting period.

(5) Labeling must include:

(i) A detailed summary of clinical performance testing conducted with the device, including study population, results, adverse events, and comparisons to any comparator groups identified;

(ii) A statement in the labeling that the safety and effectiveness of the device has not been evaluated for outcomes related to the treatment or prevention of cancer, including but not limited to risk reduction, overall survival, disease-free survival and local recurrence, unless FDA determines that it can be removed or modified based on clinical performance data submitted to FDA;

(iii) Identification of compatible devices;

(iv) The list of surgical procedures for which the device has been determined to be safe with clinical justification;

(v) Reprocessing instructions for reusable components;

(vi) A shelf life for any sterile components;

(vii) A description of the device-specific use training program;

(viii) A statement that the device is only for distribution to facilities that implement and maintain the device-specific use training program and ensure that users of the device have completed the device-specific use training program; and

(ix) A detailed summary of the post-market surveillance data collected under paragraph (b)(3) of this section and any necessary modifications to the labeling to accurately reflect outcomes based upon the post-market surveillance data collected under paragraph (b)(3) of this section.

(6) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use.

(7) Human factors validation testing must be performed and must demonstrate that the user interfaces of the system support safe use in an operating room environment.

(8) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must include:

(i) Device motion accuracy and precision;

(ii) System testing;

(iii) Instrument reliability;

(iv) Thermal effects on tissue;

(v) Human-device interface;

(vi) Mounting hardware testing;

(vii) Workspace access testing; and

(viii) Performance testing with compatible devices.

(9) Software verification, validation, and hazard analysis must be performed. Software documentation must include an assessment of the impact of threats and vulnerabilities on device functionality and end users/patients as part of cybersecurity review.

(10) Electromagnetic compatibility and electrical, thermal, and mechanical safety testing must be performed.

(11) Performance data must demonstrate the sterility of all patient-contacting device components.

(12) Performance data must support the shelf life of the device components provided sterile by demonstrating continued sterility and package integrity over the labeled shelf life.

(13) Performance data must validate the reprocessing instructions for the reusable components of the device.

(14) Performance data must demonstrate that all patient-contacting components of the device are biocompatible.

(15) Performance data must demonstrate that all patient-contacting components of the device are non-pyrogenic.

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09749 Filed 5–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2022–0227]

Special Local Regulation; Crystal Pier Outrigger Race, San Diego, CA

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Crystal Pier Outrigger Race special local regulations on the waters of Mission Bay, California, on May 7, 2022. These special local regulations are necessary to provide for the safety of the participants, crew, spectators, sponsor vessels, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area unless authorized by the Captain of the Port, or his designated representative.

DATES: The regulations in 33 CFR 100.1101 will be enforced from 7 a.m. through 5 p.m. on May 7, 2022, for the locations described in Item No. 14 in Table 1 to § 100.1101.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander John Santorum, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone 619–278–7656, email *MarineEventsSD@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in 33 CFR 100.1101 for the Crystal Pier Outrigger Race in Mission Bay, CA in 33 CFR 100.1101, for the locations described in Item No. 14 in Table 1 to that section from 7 a.m. until 5 p.m. on May 7, 2022. This enforcement action is being taken to provide for the safety of life on navigable waterways during the event. The Coast Guard's regulation for recurring marine events in the San Diego Captain of the Port Zone identifies the regulated entities and area for this event. Under the provisions of 33 CFR 100.1101, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area, unless authorized by the Captain of the Port, or his designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

In addition to this document in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners, marine information broadcasts, and local advertising by the event sponsor.

If the Captain of the Port Sector San Diego or his designated representative determines that the regulated area need not be enforced for the full duration stated on this document, he or she may use a Broadcast Notice to Mariners or other communications coordinated with the event sponsor to grant general permission to enter the regulated area.

Dated: May 2, 2022.

T.J. Barelli,

Captain, U.S. Coast Guard, Captain of the Port San Diego.

[FR Doc. 2022–09722 Filed 5–5–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0190]

RIN 1625–AA00

Safety Zone; Sabine River, Orange, TX

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters of the Sabine

River, extending the entire width of the river, adjacent to the public boat ramp located in Orange, TX. The safety zone is necessary to protect persons and vessels from hazards associated with a high-speed boat race competition in Orange, TX. Entry of vessels or persons into this zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Port Arthur or a designated representative.

DATES: This rule is effective from 9 a.m. on May 21, 2022 through 6 p.m. on May 22, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0190 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Scott Whalen, Marine Safety Unit Port Arthur, U.S. Coast Guard; telephone 409–719–5086, email *Scott.K.Whalen@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

On March 9, 2022, the City of Orange, TX notified the Coast Guard that it would be sponsoring high speed boat races from 9 a.m. through 6 p.m. on May 21 and 22, 2022, adjacent to the public boat ramp in Orange, TX. The Captain of the Port Marine Safety Unit Port Arthur (COTP) has determined that potential hazards associated with high speed boat races would be a safety concern for spectator craft and vessels in the vicinity of these race events. In response, on March 29, 2022, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Special Local Regulation, Sabine River, Orange, TX (87 FR 18338). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this marine event. During the comment period that ended April 29, 2022, we received no comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. High speed boat races are scheduled to occur on the Sabine River on May 21 and 22, 2022. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with high speed boat races on a narrow waterway.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Port Arthur (COTP) has determined that potential hazards associated with high speed boat races will be a safety concern for spectator craft and vessels in the vicinity of these race events.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments regarding the establishment of this safety zone on our NPRM published March 29, 2022. We mistakenly referred to the rule as a special local regulation in some places in the NPRM. However, as we noted in the first sentence of the summary in the NPRM, we were proposing to establish a temporary safety zone. We made one change to the regulatory text to replace the reference to special local regulations with safety zone in paragraph (d)(4). There are no substantive changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from 9 a.m. through 6 p.m. daily on May 21, 2022 and May 22, 2022. The safety zone will cover all navigable waters of the Sabine River, extending the entire width of the river, adjacent to the public boat ramp located in Orange, TX bounded to the north by the Orange Public Wharf and latitude 30°05′50″ N and to the south at latitude 30°05′33″ N. The duration of the zone is intended to protect participants, spectators, and other persons and vessels, in the navigable waters of the Sabine River during high-speed boat races and will include breaks and opportunity for vessels to transit through the regulated area.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the proposed size, location and duration of the rule. The safety zone will encompass a less than half-mile stretch of the Sabine River for 8-hours on each of two days. The Coast Guard will notify the public by issuing Local Notice to Mariners (LNM), and/or Marine Safety Information Bulletin (MSIB) and Broadcast Notice to Mariners via VHF–FM radio and the rule will allow vessels to seek permission to enter the zone during scheduled breaks.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business

Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone that will last 8-hours on each of two days and that would prohibit entry on less than a half-mile stretch of the Sabine River in Orange, TX. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREA AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T08–0190 to read as follows:

§ 165.T08–0190 Safety Zone; Sabine River, Orange, Texas

(a) *Location.* The following area is a safety zone: All navigable waters of the Sabine River, extending the entire width of the river, adjacent to the public boat ramp located in Orange, TX bounded to the north by the Orange Public Wharf and latitude 30°05′50″ N and to the south at latitude 30°05′33″ N. The duration of the safety zone is intended to protect participants, spectators, and other persons and vessels, in the navigable waters of the Sabine River during high-speed boat races and will include breaks and opportunity for vessels to transit through the regulated area.

(b) *Effective period.* This section is effective from 9 a.m.on May 21, 2022 through 6 p.m. on May 22, 2022.

(c) *Enforcement periods.* This section will be enforced from 9 a.m. through 6 p.m. daily.

(d) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry of vessels or persons into this zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Port Arthur (COTP) or a designated representative. They may be contacted on VHF–FM channel 13 or 16, or by phone at by telephone at 409–719–5070.

(2) The COTP or a designated representative may forbid and control the movement of all vessels in the regulated area. When hailed or signaled by an official patrol vessel, a vessel shall come to an immediate stop and comply with the directions given. Failure to do so may result in expulsion from the area, citation for failure to comply, or both.

(3) The COTP or a designated representative may terminate the event or the operation of any vessel at any time it is deemed necessary for the protection of life or property.

(4) The COTP or a designated representative will terminate enforcement of the safety zone of this section at the conclusion of the event.

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

Dated: May 3, 2022.

Molly. A. Wike,

Captain, U.S. Coast Guard, Captain of the Port, Marine Safety Zone Port Arthur.

[FR Doc. 2022–09753 Filed 5–5–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2022–0096]

Safety Zone; Four Seasons Hotel Fireworks Display Event, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a temporary safety zone for a fireworks display located on the navigable waters of the Lower Mississippi River (LMR) between Mile Marker (MM) 94.5 and MM 95.5 Above Head of Passes (AHP). This action is needed to provide for the safety of life on these navigable waterways during the event. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Captain of the Port or designated representative.

DATES: The regulations in 33 CFR 165.845 will be enforced from 8:45 p.m. to 10 p.m. on May 18, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Commander William Stewart, Sector New Orleans, U.S. Coast Guard; telephone 504–365–2246, email *William.A.Stewart@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce safety zone located in 33 CFR 165.845 for the Four Seasons Hotel Fireworks Display event. The regulations will be enforced from 8:45 p.m. through 10 p.m. on May 18, 2022. This action is being taken to provide for the safety of life on navigable waterways during this event, which will be located between MM 94.5 and MM 95.5 AHP, LMR, LA. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Captain of the Port or designated representative.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via Marine Safety Information Bulletins (MSIBs), Local Notice to Mariners (LNMs), and/or Broadcast Notice to Mariners (BNMs).

Dated: May 2, 2022.

K.K. Denning,

Captain, U.S. Coast Guard, Captain of the Port Sector New Orleans.

[FR Doc. 2022–09788 Filed 5–5–22; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2021–0785; FRL–9591–02–R1]

Air Plan Approval; New Hampshire; Env-A 800 Testing and Monitoring Procedures, Env-A 619.03 PSD Program Requirements, and Env-A 1200 VOC RACT

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving State Implementation Plan (SIP) revisions submitted by the State of New Hampshire. These revisions amend Testing and Monitoring Procedures for sources of air pollution; revise New Hampshire's Prevention of Significant Deterioration (PSD) permitting program with respect to requirements for air quality modeling; fully approve certain infrastructure SIP requirements as they related to PSD permitting requirements for the 2015 Ozone and 2012 fine particle matter ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS); and amend Volatile Organic Compounds (VOCs) Reasonably Available Control Technology (RACT). This action is being taken under the Clean Air Act (CAA).

DATES: This rule is effective on June 6, 2022.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R01–OAR–2021–0785. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that, if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays and facility closures due to COVID–19.

FOR FURTHER INFORMATION CONTACT: John Creilson, Air Quality Branch, U.S. Environmental Protection Agency, EPA Region 1, 5 Post Office Square—Suite 100, (Mail code 05–2), Boston, MA 02109, tel. (617) 918–1688, email *creilson.john@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

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I. Background and Purpose
a. Env-A 800 Testing and Monitoring Procedures
b. Env-A 619.03 PSD Program Requirements
c. Env-A 1200 VOC RACT
II. Final Action
III. Incorporation by Reference
IV. Statutory and Executive Order Reviews

I. Background and Purpose

On March 3, 2022 (87 FR 12016), EPA published a notice of proposed rulemaking (NPRM) for the State of New Hampshire proposing to approve several SIP revisions submitted by the State. Information about the proposed SIP revisions are as follows.

a. Env-A 800 Testing and Monitoring Procedures

On August 19, and subsequently on December 20, 2021, the New Hampshire Department of Environmental Services (NH DES) submitted a revision to its State Implementation Plan (SIP). The submittal consisted of revisions to an existing rule, Env-A 800, Testing and Monitoring Procedures, that was previously approved into the New Hampshire SIP. Env-A 800 establishes testing and monitoring procedures, calculation procedures, standards, and requirements used to determine compliance with Federal and state air pollution regulations.

b. Env-A 619.03 PSD Program Requirements

On September 16, 2021, NH DES submitted a revision to its SIP-approved regulation Part Env-A 619.03, the State's CAA PSD permitting program, updating the reference date for 40 CFR 52.21 to incorporate EPA's current ''Guideline on Air Quality Models'' in appendix W of 40 CFR part 51. The revision also addressed issues related to EPA's conditional approvals to the State's PSD program for purposes of the 2015 Ozone and 2012 $PM_{2.5}$ NAAQS infrastructure SIP requirements. Specifically, EPA conditionally approved infrastructure SIP elements associated with CAA sections 110(a)(2)(C), 110(a)(2)(D)(i)(II), 110(a)(2)(J), and 110(a)(2)(K). *See* 85 FR 67651 (October 26, 2020). EPA proposed

to approve the revision to the New Hampshire SIP and convert these conditional approvals to full approvals.

c. Env-A 1200 VOC RACT

On July 15, 2021, the NH DES submitted a revision to its SIP, which consisted of amendments to an existing rule, Env-A 1200, Volatile Organic Compounds (VOC) Reasonably Available Control Technology (RACT), that was previously approved into the New Hampshire SIP. Env-A 1200 establishes requirements for the implementation of RACT on certain stationary sources located in New Hampshire that emit VOCs.

The rationale for EPA's proposed actions for these revisions is explained in the NPRM and will not be restated here. There were no public comments received on the NPRM.

II. Final Action

EPA is approving New Hampshire's SIP revisions pertaining to Env-A 800 Testing and Monitoring Procedures, Env-A 619.03 PSD Program Requirements, and Env-A 1200 VOC RACT, as described in Section I. EPA is also converting to full approval the 2015 Ozone and 2012 $PM_{2.5}$ NAAQS infrastructure SIP requirements for CAA sections 110(a)(2)(C), 110(a)(2)(D)(i)(II), 110(a)(2)(J), and 110(a)(2)(K).

III. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of New Hampshire regulations (1) Env-A 800 as adopted on May 1, 2019, with the exception of section 801.02(b) and (d) and section 810; (2) Env-A 619.03 as adopted on March 16, 2021; and (3) Env-A 1200 as adopted on October 17, 2019, described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents generally available through *https://www.regulations.gov* and at the EPA Region 1 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the State Implementation Plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[1]

IV. Statutory and Executive Order Reviews

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

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

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 5, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: April 28, 2022.

David Cash,

Regional Administrator, EPA Region 1.

Part 52 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

[1] 62 FR 27968 (May 22, 1997).

Subpart EE—New Hampshire

■ 2. In § 52.1520:
■ a. In the table in paragraph (c):
■ i. Revise the fourth table heading and the entries for ''Env-A 600,'' ''Env-A 800,'' and ''Env-A 1200''; and
■ ii. Add footnote 1; and
■ b. In the table in paragraph (e), revise the entries for ''Submittals to meet Section 110(a)(2) Infrastructure Requirements for the 2012 $PM_{2.5}$ NAAQS'' and ''Submittal to meet Section 110(a)(2) Infrastructure Requirements for the 2015 Ozone NAAQS''.

The revisions and addition read as follows:

§ 52.1520 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED NEW HAMPSHIRE REGULATIONS

State citation	Title/subject	State effective date	EPA approval date [1]	Explanations
*	*	*	*	*
Env-A 600	Statewide Permit System	4/20/2021	5/6/2022 [Insert **Federal Register** citation].	Revisions to Env-A 619.13 to incorporate updated reference date to the ambient air quality modeling guidelines at 40 CFR part 51, Appendix W.
Env-A 800	Testing and Monitoring Procedures	4/30/2019	5/6/2022 [Insert **Federal Register** citation].	Minor revisions to the previously approved Env-A 800 rule be incorporated into the State's SIP, except for Env-A 801.02(b) and (d) that relate to trading, and Env-A 810.
*	*	*	*	*
Env-A 1200	Volatile Organic Compounds (VOCs) Reasonably Available Control Technology (RACT).	10/17/2019	5/6/2022 [Insert **Federal Register** citation].	
*	*	*	*	*

[1] In order to determine the EPA effective date for a specific provision listed in this table, consult the **Federal Register** document cited in this column for the particular provision.

* * * * *

(e) * * *

NEW HAMPSHIRE NON-REGULATORY

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approved date	Explanations
*	*	*	*	*
Submittals to meet Section 110(a)(2) Infrastructure Requirements for the 2012 $PM_{2.5}$ NAAQS.	Statewide	12/22/2015; supplement submitted 6/8/2016.	12/4/2018, 83 FR 62464	These submittals are approved with respect to the following CAA requirements: 110(a)(2)(A), (B), (C), (D), (E), (F), (G), (H), (J), (L), and (M).
		12/22/2015	10/26/2020, 85 FR 67651	This submittal is conditionally approved with respect to provisions of CAA 110(a)(2)(K). The following previously approved items are corrected and changed from approval to conditional approval: 110(a)(C) (PSD only), (D)(i)(II) (prong 3 only), and (J) (PSD only).
		4/20/2021	5/6/2022 [Insert **Federal Register** citation].	Items that were conditionally approved on 10/26/2020 are now fully approved.
*	*	*	*	*
Submittal to meet Section 110(a)(2) Infrastructure Requirements for the 2015 Ozone NAAQS.	Statewide	4/20/2021	5/6/2022 [Insert **Federal Register** citation].	Items that were conditionally approved on 10/26/2020 are now fully approved.
*	*	*	*	*

* * * * *

[FR Doc. 2022–09514 Filed 5–5–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2020–0560; FRL–7546–02–OAR]

RIN 2060–AU59

National Emission Standards for Hazardous Air Pollutants: Mercury Cell Chlor-Alkali Plants Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action finalizes the residual risk and technology review (RTR) conducted for the Mercury Cell Chlor-Alkali Plants source category regulated under national emission standards for hazardous air pollutants (NESHAP). In addition, this action finalizes the beyond-the-floor determination that EPA performed in response to a petition for reconsideration of the 2003 NESHAP. These final amendments prohibit mercury emissions from existing mercury cell chlor-alkali plants based on the results of our technology review and our beyond-the-floor maximum achievable control technology (MACT) determination. The compliance date for this requirement is three years. Since mercury emissions will be eliminated as a result of the final rule standards, any adverse health or environmental effects from mercury emissions from the source category will also be eliminated in that three-year time frame. Furthermore, the EPA is finalizing work practice standards and instrumental monitoring of mercury to minimize fugitive mercury emissions from the cell rooms during the period of time before emissions are eventually eliminated. In addition, the EPA is finalizing work practice standards to minimize fugitive chlorine emissions from mercury cell chlor-alkali plants, which were not previously regulated under the NESHAP. The EPA is also finalizing revisions related to emissions during periods of startup, shutdown, and malfunction (SSM) and amendments to correct a few minor errors in compliance provisions in the 2003 rule.

DATES: This final rule is effective on May 6, 2022.

ADDRESSES: The U.S. Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA–HQ–OAR–2020–0560. 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 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. Hand Deliveries and couriers may be received by scheduled appointment only. For further information and updates on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Phil Mulrine, Sector Policies and Programs Division (D243–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5289; fax number: (919) 541–4991; and email address: *mulrine.phil@epa.gov.* For specific information regarding the risk modeling methodology, contact James Hirtz, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0881; fax number: (919) 541–0840; and email address: *hirtz.james@epa.gov.*

SUPPLEMENTARY INFORMATION:

Preamble acronyms and abbreviations. We use multiple acronyms and terms in this preamble. Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, it is intended to refer to the EPA. 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:

AEGL acute exposure guideline level two
CAA Clean Air Act
CFR Code of Federal Regulations
Cl_2 Chlorine
CRA Congressional Review Act
EPA Environmental Protection Agency
ERT Electronic Reporting Tool
HAP hazardous air pollutants(s)
HCl hydrochloric acid
Hg mercury
HI hazard index
HQ hazard quotient
MACT maximum achievable control technology
MATS Mercury and Air Toxics Standards
NAIC North American Industry Classification System
NESHAP national emission standards for hazardous air pollutants
NTTAA National Technology Transfer and Advancement Act
NOCS Notification of Compliance Status report
NRDC Natural Resources Defense Council
OMB Office of Management and Budget
PB–HAP HAPs known to be persistent and bioaccumulative in the environment
PDF portable document format
PM particulate matter
ppm parts per million
ppmv parts per million by volume
PRA Paperwork Reduction Act
REL reference exposure limit
RTR risk and technology review
SSM startup, shutdown, and malfunction
SV screening value
TOSHI target organ-specific hazard index
tpy tons per year
UMRA Unfunded Mandates Reform Act

Background information. On January 8, 2021, the EPA proposed revisions to the 2003 Mercury Cell Chlor-Alkali Plants NESHAP, 40 CFR part 63, subpart IIIII, based on our RTR and MACT beyond-the-floor analyses (86 FR 1362, January 8, 2021). In this action, we are finalizing decisions and revisions for the rule. We summarize the comments we timely received regarding the proposed rule and provide our responses in this preamble. A ''track changes'' version of the regulatory language that incorporates the changes in this action is available in the docket.

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

I. General Information
A. Does this action apply to me?
B. Where can I get a copy of this document and other related information?
C. Judicial Review and Administrative Reconsideration
II. Background
A. What is the statutory authority for this action?
B. What is the Mercury Cell Chlor-Alkali Plants source category and how does the NESHAP regulate HAP emissions from the source category?
C. What changes did we propose for the Mercury Cell Chlor-Alkali Plants source category in our January 8, 2021 proposal?
III. What is included in this final rule?
A. What are the final rule amendments based on the risk review for the Mercury Cell Chlor-Alkali Plants source category?
B. What are the final rule amendments related to a non-mercury option for the Mercury Cell Chlor-Alkali Plants Source Category pursuant to CAA sections 112(d)(2), (3), and (6)?
C. What are the final rule amendments based on the technology review for the

Mercury Cell Chlor-Alkali Plants source category?
D. What are the final rule amendments pursuant to sections 112(d)(2) and (3) and (h) for the Mercury Cell Chlor-Alkali Plants source category?
E. What are the final rule amendments addressing emissions during periods of startup, shutdown, and malfunction?
F. What are the effective and compliance dates of the standards?
IV. What is the rationale for our final decisions and amendments for the Mercury Cell Chlor-Alkali Plants source category?
A. Residual Risk Review for the Mercury Cell Chlor-Alkali Plants Source Category
B. Non-Mercury Option for the Mercury Cell Chlor-Alkali Plants Source Category
C. Technology Review for the Mercury Cell Chlor-Alkali Plants Source Category
D. Amendments Pursuant to Sections 112(d)(2) and (3) and (h) for the Mercury Cell Chlor-Alkali Plants Source Category
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F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act (NTTAA)
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
K. Congressional Review Act (CRA)

I. General Information

A. 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
Mercury Cell Chlor-Alkali Plants	325180

[1] North America 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.

B. 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/mercury-cell-chloralkali-plants-national-emissions-standards.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version and key technical documents at this same website.

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.

C. 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 (the Court) by July 5, 2022. Under CAA section 307(b)(2), the requirements established by this final rule 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

A. What is the statutory authority for this action?

Section 112 of the CAA establishes a two-stage regulatory process to address emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, we must identify categories of sources emitting one or more of the HAP listed in CAA section 112(b) and then promulgate technology-based NESHAP for those sources. ''Major sources'' are those that emit, or have the potential to emit, any single HAP at a rate of 10 tons per year (tpy) or more, or 25 tpy or more of any combination of HAP. For major sources, these standards are commonly referred to as MACT standards and must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). In developing MACT standards, CAA section 112(d)(2) directs the EPA to consider the application of measures, processes, methods, systems, or techniques, including, but not limited to, those that reduce the volume of or eliminate HAP emissions through process changes, substitution of materials, or other modifications; enclose systems or processes to eliminate emissions; collect, capture, or treat HAP when released from a process, stack, storage, or fugitive emissions point; are design, equipment, work

practice, or operational standards; or any combination of the above.

For these MACT standards, the statute specifies certain minimum stringency requirements, which are referred to as MACT floor requirements, and which may not be based on cost considerations. See CAA section 112(d)(3). For new sources, the MACT floor cannot be less stringent than the emission control achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than floors for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, we must also consider control options that are more stringent than the floor under CAA section 112(d)(2). We may establish standards more stringent than the floor, based on the consideration of the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements.

In the second stage of the regulatory process, the CAA requires the EPA to undertake two different analyses, which we refer to as the technology review and the residual risk review. Under the technology review, we must review the technology-based standards and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less frequently than every 8 years, pursuant to CAA section 112(d)(6). In conducting this review, the EPA is not required to recalculate the MACT floors that were established in earlier rulemakings. *Natural Resources Defense Council* v. *EPA,* 529 F.3d 1077, 1084 (D.C. Cir. 2008) (*NRDC*). *Association of Battery Recyclers, Inc.* v. *EPA,* 716 F.3d 667 (D.C. Cir. 2013). The EPA may consider cost in deciding whether to revise the standards pursuant to CAA section 112(d)(6). The EPA is required to address regulatory gaps, such as missing standards for listed air toxics known to be emitted from the source category, and any new MACT standards must be established under CAA sections 112(d)(2) and (3), or, in specific circumstances, CAA sections 112(d)(4) or (h). *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020) (*LEAN*). Under the residual risk review, we must evaluate the risk to public health remaining after application of the technology-based standards and revise the standards, if necessary, to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. The residual risk review is required within 8 years after promulgation of the technology-based standards, pursuant to CAA section 112(f). In conducting the residual risk review, if the EPA determines that the current standards provide an ample margin of safety to protect public health, it is not necessary to revise the MACT standards pursuant to CAA section 112(f).[1] For more information on the statutory authority for this rule, see *https://www.federalregister.gov/documents/2021/01/08/2021-00174/national-emission-standards-for-hazardous-air-pollutants-mercury-cell-chlor-alkali-plants-residual.*

B. What is the Mercury Cell Chlor-Alkali Plants source category and how does the NESHAP regulate HAP emissions from the source category?

The EPA promulgated the Mercury Cell Chlor-Alkali Plants NESHAP on December 19, 2003 (68 FR 70904). The standards are codified at 40 CFR part 63, subpart IIIII. The mercury cell chlor-alkali industry consists of facilities that use mercury cells to manufacture product chlorine, product caustic, and by-product hydrogen via an electrolytic process. The source category covered by these MACT standards currently includes one operating facility, Westlake located in West Virginia.

Subpart IIIII covers both major and area sources. The single remaining operational mercury cell-chlor-alkali plant in the category is located at a major source site. In addition to subpart IIII, processes at this major source site are subject to subparts ZZZZ (Reciprocating Internal Combustion Engine NESHAP) and DDDDD (Industrial/Commercial/Institutional Boilers and Process Heaters). The mercury cell chlor-alkali NESHAP includes standards for mercury emissions from two types of affected sources at plant sites where chlorine and caustic are produced in mercury cells: Mercury cell chlor-alkali production facility affected sources and mercury recovery facility affected sources. The 2003 rule prohibited mercury emissions from new and reconstructed mercury cell chlor-alkali production affected sources. 40 CFR 63.8190(a)(1). For existing mercury cell chlor-alkali production affected sources, the 2003 standards included emission limitations for mercury emissions from process vents (including emissions from end-box ventilation systems and hydrogen systems) and work practices for fugitive mercury emissions from the cell room. 40 CFR 63.8190(a)(2), 63.8192(a) through (f).

For new, reconstructed, and existing mercury recovery facilities, the 2003 NESHAP included emission limitations for mercury emissions from oven type thermal recovery unit vents and non-oven type thermal recovery unit vents. 40 CFR 63.8190(a)(3). Note that the single remaining operational facility does not operate a mercury recovery facility, so there are no operating mercury recovery facilities subject to subpart IIIII.

The 2003 rule did not promulgate standards for chlorine (Cl_2) or hydrochloric acid (HCl), citing the authority of section 112(d)(4) of the CAA (68 FR 70906). In its 2003 action (68 FR 70904), the EPA promulgated the initial Mercury Cell Chlor-Alkali Plants NESHAP pursuant to CAA section 112(d)(2) and (3) and added the source category to the EPA's Source Category List under CAA sections 112(c)(1), as well as under (c)(3), (c)(6) and (k)(3)(B), in each case because of the mercury emissions.

Following promulgation of the 2003 Mercury Cell Chlor-Alkali Plants NESHAP, the EPA received a petition to reconsider several aspects of the rule from the Natural Resources Defense Council (NRDC). NRDC also filed a petition for judicial review of the rule in the U.S. Court of Appeals for the District of Columbia Circuit. In a letter dated April 8, 2004, the EPA granted NRDC's petition for reconsideration and on July 20, 2004, the court placed the petition for judicial review in abeyance pending the EPA's action on reconsideration.

The EPA issued proposed revisions to the 2003 rule on June 11, 2008 (73 FR 33258) and on March 14, 2011 (76 FR 13852), to respond to the reconsideration petition. This final action completes EPA's rulemaking following those two proposals and the third action proposed on January 8, 2021 (86 FR 1362), and completes the EPA's action in response to the 2004 petition for reconsideration of the 2003 rule.

[1] The Court has affirmed this approach of implementing CAA section 112(f)(2)(A): *NRDC,* 529 F.3d at 1083 (''If EPA determines that the existing technology-based standards provide an 'ample margin of safety,' then the Agency is free to readopt those standards during the residual risk rulemaking.'').

C. What changes did we propose for the Mercury Cell Chlor-Alkali Plants source category in our January 8, 2021, proposal?

On January 8, 2021, the EPA published a proposed rule in the **Federal Register** for the Mercury Cell Chlor-Alkali Plants NESHAP, 40 CFR part 63, subpart IIIII, that took into consideration the RTR analyses and the MACT beyond-the-floor analysis. In the proposed rule, we proposed: (1) The determination that risks due to emissions of HAP are acceptable from the Mercury Cell Chlor-Alkali Plants source category and that the 2003 NESHAP provides an ample margin of safety to protect public health; (2) to amend the requirements for cell room fugitive mercury emissions to require work practice standards for the cell rooms plus instrumental monitoring of cell room fugitive mercury emissions under the technology review; (3) work practice standards for fugitive chlorine emissions from mercury cell chlor-alkali plants, which were not previously regulated under the NESHAP; (4) revisions related to emissions during periods of startup, shutdown and malfunction (SSM), which had also been addressed in the 2011 proposed rule; (5) provisions for electronic submission of performance test results, compliance reports, and Notification of Compliance Status (NOCS) reports; and (6) amendments to correct minor errors and improve the compliance provisions of the rule, which had also been addressed in the 2008 and 2011 proposals.

With regard to our technology review and an overdue beyond-the-floor determination, as explained in the January 2021 document (86 FR 1362, January 8, 2021), we evaluated two options: (1) Improved cell room mercury monitoring and work practices to minimize emissions; and (2) the elimination of Hg emissions by requiring the conversion to a non-Hg technology.

Based on this evaluation, we proposed option 1, as mentioned above, however we also described option 2 (mercury elimination) in detail in the January 2021 notice and solicited comments. Specifically, we explained that based on consideration of the updated costs and cost effectiveness and uncertainties, and given the passage of time, and the fact that the cost-effectiveness data and analysis done in 2011 were based on two facilities that are no longer operating, we questioned at that time whether those 2011 analyses would still be transferable to the one remaining operating facility. Consequently, we did not propose to require the elimination of mercury in the January 2021 document. However, we solicited comments, data, and other information regarding this proposed decision, including data and information regarding the capital and annual costs, cost effectiveness, non-air impacts, and other relevant information that would be relevant for the remaining facility regarding whether the NESHAP should include a zero-mercury standard as a beyond-the-floor MACT standard. We also stated that we intend to consider any such submitted data and information, in addition to the data and information contained in the records for the 2008 and 2011 proposals and in the 2021 proposal, in reaching final conclusions regarding a zero-mercury standard (see 86 FR 1362, January 8, 2021).

III. What is included in this final rule?

This action finalizes the EPA's determinations pursuant to the RTR and MACT provisions of CAA section 112 for the Mercury Cell Chlor-Alkali Plants source category and amends the Mercury Cell Chlor-Alkali Plants NESHAP based on those determinations.

A. What are the final rule amendments based on the risk review for the Mercury Cell Chlor-Alkali Plants source category?

No changes to the Mercury Cell Chlor-Alkali Plants NESHAP are being promulgated to meet the requirements of CAA section 112(f). Under this action, for purposes of section 112(f), we are finalizing the risk assessments and our determination that the risks from the Mercury Cell Chlor-Alkali Plants source category are acceptable, the 2003 standards provide an ample margin of safety to protect public health, and more stringent standards are not necessary to prevent an adverse environmental effect.

B. What are the final rule amendments related to a non-mercury option for the Mercury Cell Chlor-Alkali Plants Source Category pursuant to sections 112(d)(2), (3), and (6)?

To satisfy the requirements of CAA sections 112(d)(2), (d)(3), and (6), including to respond to the petition for reconsideration of the 2003 rule by completing our MACT beyond-the-floor analysis, we are revising the MACT standards to prohibit mercury emissions from existing mercury cell chlor-alkali plants. Specifically, these amendments prohibit mercury emissions from existing mercury chlor-alkali production facility affected sources. This makes the mercury standard for existing sources the same as the standard for new and reconstructed sources that has been in the NESHAP since 2003. Since we conclude that it is improbable that a mercury cell chlor-alkali plant can be operated without mercury emissions, we expect this revision will effectively require the lone remaining mercury cell chlor-alkali plant in operation in the U.S. to cease production of chlorine with their single mercury cell production unit. We anticipate the facility will continue to produce chlorine through its other, higher-volume non-mercury chlorine production units located at the Westlake facility and may convert the mercury cell unit to a membrane cell or other non-mercury chlorine production process. There are no mercury recovery facilities still in operation in the U.S. This final rule provides a three-year period to comply with the requirement to eliminate mercury emissions from the single remaining existing affected source. To demonstrate compliance, the owner or operator will need to submit a notification certifying that all mercury emissions have been eliminated permanently no later than 120 days after the compliance date.

C. What are the final rule amendments based on the technology review for the Mercury Cell Chlor-Alkali Plants source category?

We determined that there are developments in practices, processes, and control technologies that warrant revisions to the MACT standards for this source category. As noted above, we are revising the MACT standards to include a prohibition of mercury emissions, which is based on both a section 112(d)(6) technology review and our beyond-the-floor review under section 112(d)(2) and (3) in response to NRDC's 2004 petition for reconsideration. Also based on the section 112(d)(6) technology review and in response to NRDC's 2004 petition, we are amending the requirements for cell room fugitive mercury emissions to require work practice standards for the cell rooms along with instrumental monitoring of cell room fugitive mercury emissions during the period of time before emissions are eventually eliminated. In addition, under the technology review, we identified a regulatory gap, and as discussed below, we are establishing new standards under CAA section 112(h).

D. What are the final rule amendments pursuant to sections 112(d)(2) and (3) and (h) for the Mercury Cell Chlor-Alkali Plants source category?

In addition to the requirements for mercury described above, we are also finalizing amendments pursuant to section 112(h) for chlorine emissions, similar to the standards we proposed in January 2021 (86 FR 1362), that require implementation of work practices to minimize chlorine emissions from the mercury cell chlor-alkali processes. Further details regarding these work practice standards are described in section IV.D of this document.

E. What are the final rule amendments addressing emissions during periods of startup, shutdown, and malfunction?

We are finalizing amendments related to provisions that apply during periods of SSM that the EPA proposed on January 8, 2021. Further details are provided in section IV.E of this document.

F. What are the effective and compliance dates of the standards?

The revisions to the MACT standards being promulgated in this action are effective on May 6, 2022. The compliance date for existing mercury cell chlor-alkali plants to eliminate mercury emissions is May 6, 2025.

These final amendments will essentially require that the single remaining operating mercury cell chlor-alkali facility either convert its one mercury cell unit to a non-mercury technology (its other units are already using non-mercury technology) or close that mercury cell unit and thereafter rely solely on its other non-mercury units for chlorine production. Either of these options will require significant time for the company to reach a decision and to develop and implement a plan of action. For example, it is expected that it could take between six months and one year to develop an engineering design and plan for conversion. The facility would then need to solicit bids for the conversion, which could take up to six months. Construction could then take up to two years. In addition, arrangements will need to be made to dismantle the mercury cell facility, to store the elemental mercury removed from the cells and to dispose of the mercury-contaminated wastes. The most recent conversion in the U.S. was the facility in Ashtabula, Ohio. This Ashtabula facility was, like the West Virginia, facility, one of the smaller capacity mercury cell units in the U.S. (less than 75,000 tons of chlorine per year). It was also of similar age (Ashtabula constructed in 1963 and West Virginia in 1958) and was located in a neighboring state. The company announced the plans to convert their mercury cell process to membrane cells in 2014. They broke ground in 2017 and the conversion was complete in 2020. In conclusion, six years elapsed between the time the decision to convert was made and the conversion was completed, which included three full years for the dismantling/construction. Therefore, we conclude that the full three-year compliance period allowed by section 112(i)(3) of the CAA to meet new or revised emission standards is warranted. Moreover, as discussed further below, this period will provide ample time for the United States, via the elimination of mercury emissions from the plant, to meet its obligations to eliminate mercury emissions from this source category under the international treaty known as the Minamata Convention.

For existing sources, in 2021, we proposed two changes to the work practice standards. One of these changes was the requirement to operate a cell-room mercury monitoring program in addition to mercury work practices. This change was proposed in both 2008 and 2011. The second proposed change is a program to require work practices to reduce fugitive chlorine emissions. While these proposed work practice standards were based on the practices in place at the single facility in the source category, they will require some modifications to the procedures currently employed at the facility. Specifically, they will need to develop and implement a recordkeeping system to record and maintain the records required for the mercury cell and fugitive chlorine work practices and to incorporate the required material in the requisite reports. As proposed, we are providing 180 days for the facility to modify their current procedures. Therefore, the mercury and chlorine work practice standards being promulgated in this action require compliance on November 2, 2022.

We also proposed in January 2021, a change to the SSM requirements to remove the exemption from the requirements to meet the standards during SSM periods and to remove the requirement to develop and implement an SSM plan. This change was also proposed in 2008 and 2011. Our experience with similar industries shows that this sort of regulated facility generally requires a time period of 6 months to read and understand the amended rule requirements; to evaluate their operations to ensure that they can meet the standards during periods of startup and shutdown as defined in the rule and make any necessary adjustments; and to update their operation, maintenance, and monitoring plans to reflect the revised requirements. As proposed, we are providing 180 days for the facility to comply with the revised SSM requirements. As such, these revisions require compliance by November 2, 2022.

IV. What is the rationale for our final decisions and amendments for the Mercury Cell Chlor-Alkali Plants source category?

For each issue, this section provides a description of what we addressed in the proposed rules for the source category and what we are finalizing for the issue, the EPA's rationale for the final decisions and amendments, and the comments and responses.

A. Residual Risk Review for the Mercury Cell Chlor-Alkali Plants Source Category

1. What did we propose pursuant to CAA Section 112(f) for the Mercury Cell Chlor-Alkali Plants source category?

We proposed that health risks due to emissions of HAP from the Mercury Cell Chlor-Alkali Plants source category are acceptable, that the 2003 NESHAP provides an ample margin of safety to protect public health, and that no additional standards are necessary to prevent an adverse environmental effect.

A two-step evaluation approach was used, similar to the approach applied in the Benzene NESHAP, to determine whether or not risks are acceptable and to determine whether the 2003 standards provide an ample margin of safety to protect public health or needed to be revised to meet this goal. We considered health risk and other health information; information and additional factors relating to the appropriate level of control were also considered—*e.g.,* cost and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors.

Table 2 below provides a summary of the results of the inhalation risk assessment for the source category conducted for the January 2021 proposal. More detailed information on the risk assessment can be found in the *National Emission Standards for Hazardous Air Pollutants: Mercury Cell*

Chlor-Alkali Plants Residual Risk and Technology Review supporting document, available in the docket for this action (Docket No.: EPA–HQ–OAR–2020–0560–0014).

TABLE 2—INHALATION RISK ASSESSMENT SUMMARY FOR THE MERCURY CELL CHLOR-ALKALI PLANTS [1]

[Source category]

Risk assessment	Number of facilities [2]	Maximum individual cancer risk (1-in-1million) [3]	Estimated population at increased risk of cancer ≥1-in-1 million	Estimated annual cancer incidence (cases per year)	Maximum chronic noncancer TOSHI [4]	Maximum screening acute noncancer HQ [5]
Baseline Actual Emissions						
Source Category	2	0.004	0	0.0000003	0.05 (respiratory)	2 (REL) 7E–4 (AEGL2).
Facility-Wide	2	0.3	0	0.0001	0.05 (respiratory).	
Baseline Allowable Emissions						
Source Category	2	0.004	0	0.0000003	0.05 (respiratory).	

[1] Based on actual and allowable emissions.
[2] When the risk assessment was completed in mid-2020, there were 2 operating facilities in the mercury cell chlor-alkali source category and both were subject to 40 CFR part 63, subpart IIIII. However, in late 2020 one of those facilities converted to a non-mercury process. Therefore, currently only one operating facility remains in the source category.
[3] Maximum individual excess lifetime cancer risk due to HAP emissions from the source category.
[4] Maximum TOSHI. The target organ with the highest TOSHI for the source category is the respiratory system.
[5] The maximum estimated acute exposure concentration was divided by available short-term threshold values to develop an array of HQ values. The acute HQ shown was based upon the lowest acute 1-hour dose-response value, the REL for mercury (elemental). When an HQ exceeds 1, we also show the HQ using the next lowest available acute dose-response value.

As shown in the table above, for the Mercury Cell Chlor-Alkali Plants source category, the maximum cancer risk to the individual most exposed is less than 1-in-1 million based on actual emissions and allowable emissions. The estimated incidence of cancer due to inhalation exposures for the source category is 0.0000003 excess cancer cases per year, or one excess case every 3 million years. No one is exposed to cancer risk greater than or equal to 1-in-1 million based upon actual and allowable emissions. We estimated that the maximum chronic noncancer TOSHI from inhalation exposure is less than 1 (0.05 [respiratory]). For both actual and allowable emissions, respiratory risks were driven by chlorine emissions from the mercury cell building.

Based on our refined screening analysis of reasonable worst-case acute exposure to actual emissions from the category, the facility exceeded an HQ of 1 (the HQ was 2), when compared to the 1-hour REL for mercury (elemental). As discussed in section III.C.3.c of the 2021 proposal preamble, we used an acute hourly multiplier of 10 for all emission processes. For this HAP, there are no AEGL–1 or ERPG–1 values for comparison, but AEGL–2 or ERPG–2 values are available. For elemental mercury, when the maximum off-site concentration is compared with the AEGL–2 and ERPG–2, the maximum acute noncancer HQ is well below 1 (0.0007). With regard to multipathway exposures, HAP known to be persistent and bioaccumulative in the environment (PB–HAP) emissions (based on estimates of actual emissions) were reported from both facilities in the source category with both exceeding the Tier 1 non-cancer screening threshold emission rate for mercury. A Tier 2 screening analysis was conducted, and the facility did not have a screening value (SV) greater than 1 for any scenario (the fisher and farmer had the highest SV at 0.4). There are no carcinogenic PB–HAP emitted from the source category, so there are no cancer SVs to report.

Considering all the health risk information and factors noted, the proposed determination was that the risks are acceptable and that no additional standards are necessary to prevent an adverse environmental effect. Under the ample margin of safety analysis, we evaluated the cost and feasibility of available control technologies and other measures that could be applied to further reduce the risks (or potential risks) due to emissions of HAP from the source category. After careful consideration of these options, since the risks due to mercury emissions were already low, we did not propose any additional standards for mercury under CAA section 112(f).

2. How did the risk review change for the Mercury Cell Chlor-Alkali Plants source category?

We made no changes to either the risk assessments or our determinations regarding risk acceptability, ample margin of safety, or adverse environmental effects for the Mercury Cell Chlor-Alkali Plants source category since the proposal was published on January 8, 2021. We are finalizing the risk review as proposed (86 FR 1362, January 8, 2021).

3. What key comments did we receive on the risk review, and what are our responses?

The only comment received regarding the risk assessment was that one commenter agreed with our assessment that emissions were low and that risks were low and at acceptable levels.

4. What is the rationale for our final approach and final decisions for the risk review?

As noted above, in 2021, we proposed that the 2003 Mercury Cell Chlor-Alkali NESHAP provides an ample margin of safety to protect public health without any revisions. Other than a general agreement with the results, there were no specific comments submitted on the risk review approach, results, or decision. Therefore, we are finalizing the proposed determination that the risks are acceptable, that the 2003 rule provides an ample margin of safety to protect public health and that no additional standards are necessary to prevent an adverse environmental effect.

B. Non-Mercury Option for the Mercury Cell Chlor-Alkali Plants Source Category

1. What did we propose related to the non-mercury option for the Mercury Cell Chlor-Alkali Plants source category?

We addressed this issue in all three of our proposed rules issued following promulgation of the 2003 rule, in response to the 2004 petition for reconsideration of the 2003 rule's consideration of section 112(d)(2) and (3) beyond-floor options and most recently as part of the technology review under section 112(d)(6). In the 2021 proposal, we further considered our two prior proposals, but did not re-propose the option to require non-mercury production technology for existing sources, which has been the requirement for new and reconstructed mercury cell chlor-alkali production sources since the rule was originally promulgated in 2003. This option was considered both as part of the technology review under the authority of section 112(d)(6) and as a ''beyond-the-floor'' option under sections 112(d)(2) and (3). As explained in the several proposed rules, selecting this option would eliminate all mercury emissions by forcing the remaining facility to either convert to a non-mercury technology or close its mercury cell chlor-alkali operations. While we did not in 2021, re-propose this option under either 112(d)(2) and (3) or (d)(6), we described this option in detail in the proposed rule's **Federal Register** (FR) notice published on January 8, 2021 (86 FR 1362), including the estimated capital costs, annualized costs and cost effectiveness if it were to be adopted, and we specifically solicited comments, data, and other information regarding this proposed decision. Furthermore, in the January 2021 FR document, we discussed and referred to the previous 2011 proposed rule in which the EPA also analyzed expected capital costs, annualized costs and cost effectiveness of the then proposed non-mercury option but for which EPA had not taken final action at the time of the 2021 proposal.

2. What changed related to the non-mercury option for the Mercury Cell Chlor-Alkali Plants source category?

After consideration of public comments received on the 2021 proposed rule and further assessment of the expected costs, we have changed our 2021 proposed decisions under sections 112(d)(2) and (3) and (6) regarding the non-mercury option and the final rule includes an amendment that prohibits mercury emissions from existing mercury cell chlor-alkali plants as was proposed in 2011 under section 112(d)(2) and (3). Existing mercury cell chlor-alkali plants will have three years to comply with this requirement.

3. What key comments did we receive on the non-mercury option, and what are our responses?

Comment: One commenter remarked that the EPA must revise MACT standards when it finds there have been developments in processes, products, or control technologies under CAA section 112(d)(6) to reduce emissions to the maximum achievable degree. They further stated that it is achievable for facilities to switch to membrane cell technology, as demonstrated by the number of facilities that have already made this switch since adoption of the 2003 rule, which would eliminate emissions of mercury. The commenter also stated that because the EPA is also responding to the 2004 petition for reconsideration in this rulemaking regarding whether eliminating mercury emissions is achievable, the EPA must either promulgate a zero-emissions standard or determine that such as standard is not achievable. The commenter added that under the CAA, the EPA cannot refuse to set such standards because it does not think they are ''reasonable,'' but it must set them at the maximum degree of reduction that is achievable.

Response: We agree that it is technically achievable for facilities to switch from mercury cell to membrane cell technology, as there are many instances of successful switches spanning the last three decades. We also agree that it is technologically achievable, as a section 112(d)(2) and (3) beyond-floor measure, to require elimination of mercury emissions from the single remaining operating existing source. However, we disagree with the commenter's assertion that the EPA must promulgate a standard solely based on technical achievability in the context of section 112(d)(6). Section 112(d)(6) requires the EPA to review and revise emission standards as necessary, considering developments in practices, processes, or control technologies, but does not require revisions for all developments that are technically achievable. Other factors are considered, including cost, economic impacts, physical limitations of the site, etc.

Nevertheless, based on consideration of public comments, and after reassessing the costs and feasibility of converting to the non-mercury technology, we have determined that the non-mercury option is technically and economically feasible and is cost effective and therefore reasonable to impose under both sections 112(d)(2) and (3) and (d)(6). As explained elsewhere in this preamble, we estimate the annualized costs to convert to a membrane process would be $2.7 million per year (2019 dollars), with cost-effectiveness of $21,500 per pound of reduced mercury emissions. This cost effectiveness is within the range of cost effectiveness values the EPA has accepted historically for mercury reduction. For example, in the 2012 Mercury and Air Toxics (MATS) final rule, the EPA finalized a beyond-the-floor standard for mercury with a cost effectiveness of $22,496 per pound (based on 2007 dollars), which would be approximately $27,500 per pound based on 2019 dollars. Furthermore, we conclude that conversion to a non-mercury process is clearly feasible, as demonstrated by the six mercury cell facilities in the U.S. that have converted to the non-mercury membrane process since the year 2000. Additionally, non-mercury chlorine production accounts for more than 98% of chlorine production in the U.S.

Comment: One commenter maintained that the EPA's vague characterizations of costs and its ignorance of current costs for the one remaining facility to switch to membrane technology did not constitute an excuse for failing to determine whether the measure is achievable. The commenter said that the Agency has had 17 years since the 2004 petition for reconsideration to gather the data it needs, and any uncertainty about costs due to the EPA's failure to gather the necessary data is not a lawful or reasonable basis for not setting a zero-emissions standard for mercury.

Response: We disagree with the commenter's characterization of our assessment of the costs of conversion. While the EPA did not commission a comprehensive detailed study to assess the costs specifically for the conversion of the West Virginia mercury cell chlor-alkali unit to convert to membrane cells, the EPA did update the previous analysis to incorporate new information to ensure that the estimated costs reflected ''current'' costs expected to be incurred for a conversion. The commenter did not mention or provide any specific comments on the updated analysis.

The foundation for the analysis was the series of evaluations conducted by the EPA in 2008 through 2010, in support of the 2008 and 2011 proposed rules. The EPA first presented our evaluation of impacts of requiring conversion of all operating mercury cell

chlor-alkali production plants to non-mercury technology in 2008. Based on comments received after the June 11, 2008, proposed amendments (73 FR 33258), we updated this analysis and released it for public review in June 2009. Comments were received on this revised analysis, and a second revision was released for public review in September 2009. The EPA received comments on this second revision of the analysis and issued another revision in April 2010. Therefore, the 2010 analysis, which was based on extensive research by the EPA, had undergone three rounds of public review by the environmental community and the industry before it was relied upon to support the 2011 proposed rule.

The 2020 update to the 2010 conversion cost analysis involved several steps to ensure that the cost estimates were current. These included converting 2010 capital cost estimates, the savings associated with compliance with the mercury cell room monitoring program, and the electricity savings, to a 2019 base year. It also included incorporation of the reported costs of the latest conversion of a mercury cell facility in the U.S., which was the Ashta facility in Ohio that completed its conversion in late 2020. In addition, the 2020 analysis considered the conversion cost estimate specifically provided for the West Virginia facility by the previous owner in public comments on the 2011 proposal and updated that estimate to base year 2019.

Comment: One commenter (the owner of the single operating mercury cell facility) noted that the facility has not revisited the cost associated with converting to a non-mercury process since 2012, but they believe it is significantly higher than the EPA's estimate of $69 million.

Response: While the EPA recognizes that the facility may not have recently performed an update of the cost to convert their mercury cell unit to membrane technology, we believe there is sufficient information available to obtain a reasonable estimate of this cost. In our 2020 analysis, we estimated the conversion costs using three approaches. One was to base the capital cost of conversion solely on the highest cost factor (dollars per ton of chlorine production capacity) from the conversions considered in the 2010 analysis (after adjusting to a 2019 base year). The second approach used the cost factor calculated from the reported cost for the most recent conversion at the Ashta facility in Ohio. The cost factor for this Ashta conversion was over 20 percent higher than the highest cost factor from the previous conversions after updating them to a 2019 base year. The third approach was to incorporate the Ashta factor into an average of all the cost factors for conversions in the U.S. since 2003. These factors, which were in units of dollars per ton of chlorine production capacity, were then applied to the site-specific production capacity of the West Virginia mercury cell unit. The resulting estimates of the capital cost of conversion of the West Virginia facility using these three approaches were approximately $76 million, $92 million, and $58 million, respectively (in 2019 dollars). Given all the site-specific factors that are inherent in the cost of conversion, we do not believe it is appropriate to base an estimate on the factor from the conversion of a single facility. So, we did not select either of the first two options described above. We also did not want to potentially bias our estimate low, so we did not select the third option (average factor for five facilities that have converted since 2003). Therefore, we calculated the average cost between the three options ($69.3 million) and selected that average as our estimated cost of conversion for our consideration for our 2021 proposal. Considering the inflation that has occurred since 2019, the updated capital cost of conversion estimate is $80.7 million (in 2021 dollars). Our confidence in this estimate was bolstered by a comparison of this result with the estimate that was specifically provided earlier in 2011 for the West Virginia facility by its previous owner. This estimate, when converted to 2019 to be consistent with the year for our cost analysis, was $69.4 million (or $80.8 million for 2021 base year). Since the commenter did not provide any updated information in response to the 2020 analysis and 2021 proposed rule, we continue to maintain that our estimate is a reasonable estimate of the capital costs of converting the West Virginia mercury cell unit to membrane cell technology.

Comment: One commenter stated that the EPA's proposal ignored the U.S. obligations under the Minamata Convention on Mercury, which is a global treaty that requires the phase-out of manufacturing processes using mercury. The commenter remarked that under Article 5(2), the phase-out date for chlor-alkali production using mercury is 2025, unless an exemption is filed. The commenter noted that an exemption was filed for these processes in the U.S., and the phase-out date is now 2030. According to the commenter, since companies are typically given three years to comply with MACT standards, a final rule requiring the phase-out of mercury would be required to be promulgated by the end of 2027 for the U.S. to meet its obligations under the Minamata Convention. The commenter stated that since a final rule in 2021 that does not require elimination of mercury would put the next 8-year review completion time at the end of 2029 at the earliest, the U.S. will then be out of compliance with the Minamata Convention. The commenter stated that the EPA must issue a new proposal explaining how the 2030 phase-out deadline will be met.

Response: We agree with the commenter's summary of the U.S. obligations under the Minamata Convention agreement. We also agree that a NESHAP standard adopted under the authority of section 112 of the CAA is a valid approach to meet this obligation. In fact, during treaty negotiations, the U.S. specifically concluded that CAA section 112 gives the EPA the authority to require elimination of mercury emissions. We also agree with the commenter's conclusions about the timing of when a NESHAP would need to be promulgated. Assuming a 3-year compliance timeframe would be needed for a final rule requirement that prohibits mercury emissions, a section 112 NESHAP would need to either be finalized as part of this review, or a separate ''out of cycle'' review would be needed prior to 2027 to meet the current phase-out date of 2030 required under the Convention. (More information regarding the Minamata Convention is available at: *https://www.mercuryconvention.org/en/about*).

Comment: One commenter remarked that the environmental impacts the EPA cites as a reason not to require a zero-emission standard for mercury are actually environmental benefits. The commenter stated that the 1,000 pounds of mercury that are discharged to the environment every year would be eliminated. The commenter also stated that the EPA ignored the fact that mercury-contaminated piping and equipment must be removed at some point, and it is just a question of when. The commenter added that the costs of storing and moving mercury to a secure location is not a new expense, as the facility made a choice to continue operations with mercury past the date the Mercury Export Ban of 2008 (Pub. L. 110–414) went into effect in 2013, and it determined at that point to assume those costs.

Response: We estimate that the non-mercury requirement would eliminate just over 125 pounds of mercury released to the atmosphere per year.

Furthermore, at proposal we stated the following: ''The EPA also examined the non-air impacts associated with switching from mercury cell to non-mercury cell processes. For 2019, the West Virginia facility reported a total of 898.1 pounds of non-air mercury releases. This consists of 9 pounds to streams/water bodies, 883.3 pounds to Resource Conservation and Recovery Act, Subtitle C Landfills, and 5.8 pounds to other offsite sources. All these releases would be eliminated with the conversion to non-mercury cell processes.'' (86 FR 1382–1383)

We also acknowledge the point made by the commenter regarding the costs associated with moving the mercury recovered from a conversion and storing it. Even without a regulatory requirement to eliminate mercury emissions from existing sources, the mercury cell unit would eventually reach the end of its useful life and be shut down or replaced. Since the standards for new and reconstructed sources in subpart IIIII prohibit mercury emissions, the owner or operator could not replace the unit with another mercury cell process. Even without this standard, which has been in place since 2003, it is reasonable to assume that a new mercury cell facility would not be built. Prior to the promulgation of subpart IIIII, the use of the outdated mercury cell technology had been declining for decades and no new mercury cell facility had been constructed since the early 1970s. Hence, we agree that the owner most likely recognized this future cost when the decision was made not to convert prior to the effective date of the mercury export ban. Therefore, we conclude that the costs of the mercury storage should not be attributed to the non-mercury option under this rulemaking.

The cost of this mercury storage was estimated to be just over $53,000 per year in our 2020 conversion cost analysis. Removing these mercury storage costs lowers the overall estimated annual cost, which includes the annualized capital cost, electricity savings and reduced compliance costs from $2.77 million to just over $2.7 million. This improves the cost effectiveness from just over $22,000 per pound of mercury released to the air to around $21,500 per pound. In addition, as noted above, it also results in the reduction of around 900 pounds of mercury releases per year to other media.

Comment: One commenter registered agreement with the EPA's proposal to not require the elimination of mercury and stated that the NESHAP should not include a zero-mercury standard at this time. The commenter added that the single operating facility operates with low mercury emissions and pointed out that risks due to mercury are already low and at acceptable levels. However, another commenter expressed support for a zero-emission policy and a switch to non-mercury polluting processes at the West Virginia facility. This commenter stated that while the current mercury emissions may be in compliance with the 2003 NESHAP's standards, effort should be made to increase sustainable industrial processes if possible. According to the commenter, considering the cost-benefit analysis, it would be more beneficial for the chlor-alkali plant to transition sooner rather than later because the plant will eventually have to transition or adopt a zero-mercury emission policy as our green infrastructure increases. The commenter added that when considering pollution, especially mercury, the goal should be zero, regardless of its economic impact. Additionally, the commenter supported policies that are more proactive in tackling pollution because accidents can happen and they're typically more of an economic burden than taking proactive measures. Further, the commenter stated that even if the data shows no benefits to human health or the environment from further reducing the mercury emissions at the West Virginia plant, it would ultimately be one step closer to the national transition to cleaner, more sustainable industry.

Response: As discussed above in section IV.A of this preamble, the first commenter is correct that our conclusion of the section 112(f) residual risk assessment was that health risks due to emissions of HAP from the Mercury Cell Chlor-Alkali Plants source category are acceptable, that the 2003 NESHAP provides an ample margin of safety to protect public health, and that no additional standards are necessary to prevent an adverse environmental effect. While the recommendations of the second commenter generally lack any statutory authority to implement measures for a ''green infrastructure'' to ''transition to cleaner, more sustainable industry,'' their point about a transition to zero mercury pollution is recognized.

The residual risk assessment conducted under the authority of section 112(f) is focused on the local impacts (within 50km) directly resulting from HAP emissions from a NESHAP affected source. This type of assessment does not necessarily capture all the potential risks or impacts associated with mercury emissions. Mercury is a highly neurotoxic contaminant that enters the food web as a methylated compound, methylmercury. The contaminant is concentrated in higher trophic levels, including fish eaten by humans. Mercury is emitted to the air from various anthropogenic and natural sources. These emissions transport through the atmosphere and eventually deposit to land or water bodies. This deposition can occur locally, regionally, or globally, depending on the form of mercury emitted and other factors such as the weather. The form of mercury emitted from the single remaining operating plant is estimated to be about 98 percent elemental and two percent divalent mercury. Gaseous elemental mercury can be transported very long distances, even globally, to regions far from the emissions source (becoming part of the global ''pool'') before deposition occurs. Inorganic ionic (divalent) mercury has a shorter atmospheric lifetime and can deposit to land or water bodies closer to the emissions source. Furthermore, elemental mercury in the atmosphere can undergo transformation into ionic mercury, providing a significant pathway for deposition of emitted elemental mercury (UNEP, Global Mercury Assessments, available at: *https://www.unep.org/resources/publication/global-mercury-assessment-2018*).

Therefore, even though the estimated risks due to the mercury emissions are low based on our residual risk assessment, and the results of the residual risk assessment do not necessitate additional regulation to meet the requirements of CAA section 112(f), we agree that there is merit in eliminating mercury emissions where it is technically and economically feasible to do so, consistent with other statutory authority and requirements. And, as the second commenter points out, this is certainly possible in this situation, and the plant would need to ultimately eliminate mercury emissions anyway in order for the United States to meet its obligations under the Minamata Convention.

4. What is the rationale for our final approach for the non-mercury option?

As noted above, we are finalizing an amendment that prohibits mercury emissions from existing mercury cell chlor-alkali plants. Our rationale for this decision is based on the following points. First, our re-evaluation of the costs and associated emission reductions reveal that the cost effectiveness is within the range considered reasonable by the EPA for mercury and based on our economic analysis, the estimated annualized costs are only about 0.04 percent of the

annual revenue of the facility's ultimate parent company in 2020 and therefore the amendment is reasonable as a beyond-floor standard under section 112(d)(2) and (3). Second, this action will also eliminate the non-air releases that occur from the remaining mercury cell plant. Third, using the authority under section 112(d) of the CAA at this time is the most effective mechanism to ensure the U.S complies with the Minamata Convention agreement by the 2030 deadline. Finally, as mentioned above, we conclude that conversion to a non-mercury process is clearly feasible and has been shown to be a development in practices, processes and control technologies under section 112(d)(6), as demonstrated by six facilities in the U.S. that have converted to the non-mercury membrane process since the year 2000. Some of these points are discussed in more detail below.

In response to a comment discussed above, we adjusted the annual costs to remove the mercury storage cost. This resulted in the cost effectiveness of the non-mercury option decreasing slightly to $21,500 per pound of mercury emission reduction. While this cost effectiveness is near the upper end of the range of cost effectiveness values the EPA has accepted historically for achievable mercury control, the EPA has previously determined that cost effectiveness values higher than this are acceptable and achievable. For example, in the 2012 MATS final rule, the EPA finalized a beyond-the-floor standard for mercury of $22,496 per pound (based on 2007 dollars), which would be about $27,500 per pound based on 2019 dollars. Therefore, we conclude that the cost effectiveness of $21,500 per pound of mercury emissions reduction is reasonable especially given the other factors described above, and we have decided to finalize the amendment to prohibit mercury emissions from existing sources as an achievable beyond-floor measure under section 112(d)(2) and (3).

As noted above, we evaluated the economic impacts of this amendment and determined that the impacts are not substantial, with the annualized costs being less than 0.04 percent of sales for the subject facility's ultimate parent company (Westlake). We determined that the environmental benefit of the non-mercury option warranted these economic impacts.

The primary reasons provided at proposal for discussing but not re-proposing the non-mercury option were related to costs, cost effectiveness, and uncertainties. For example, in the January 2021 proposal FR document, the EPA stated that ''first, mercury emissions are based on calculations and assumptions regarding the facility's emissions (no test data are available for this facility), and second, because there are uncertainties with the cost estimates from the 2011 proposal as being transferable to the remaining facility. In the 2011 proposal, the estimated cost effectiveness was $20,000 per pound for the industry (see 76 FR 13852, March 14, 2011), but this was substantially based on the studies conducted for the two no longer operating sources.'' (86 FR 1378–1379)

While no additional emissions data based on testing was submitted in response to the 2021 proposal, we point out that subpart IIIII requires that measurements of the stack emissions be taken. The estimates reported by the West Virginia facility that were used in our analyses for fugitive emissions (121.4 pounds per year) are lower than the average level of 362 pounds per year per plant found during the extensive study conducted by the EPA prior to the 2008 proposal (see description in the June 11, 2008, proposal at 73 FR 33263–33266). Therefore, if the confidence is lacking regarding these estimates, it is realistic to consider that emissions, and thus emission reductions, would likely only be higher. This would result in improved cost effectiveness values (*i.e.,* the requirements would be more cost effective), providing further justification for our decision to finalize the non-mercury option.

In the 2021 proposal we stated, ''Based on consideration of the updated costs and cost effectiveness and uncertainties, and given the passage of time, and the fact that the cost-effectiveness data and analysis done in 2011 were based on two facilities that are no longer operating, we question whether those 2011 analyses would still be transferable to the one remaining operating facility.'' (86 FR 1378) Upon additional consideration, we have determined that this point is not relevant to the decision regarding the cost effectiveness of a non-mercury standard for the West Virginia facility. In 2011, we calculated an average cost effectiveness for the conversion of the four mercury cell facilities operating at that time. The range was between $13,000 to $31,000 per pound for the four individual facilities. However, the estimated cost effectiveness values for the two facilities that closed prior to 2020 is not determinative of the estimate of the conversion cost for the West Virginia facility. Also, the cost effectiveness for these two facilities does not compel what the EPA considers a reasonable cost effectiveness level for mercury. Therefore, we now reject the two major points used as rationale in the 2021 proposal for not accepting and proposing the non-mercury option. We are confident that the mercury emissions estimates for the West Virginia facility are reliable and, if anything, are underestimated. We also have determined that the cost estimate is reasonable and applicable and could be even more cost effective than presented here due to potential underestimation of the emissions. Consequently, the non-mercury option is a reasonable beyond-floor measure under section 112(d)(2) and (3), and the fact that six mercury cell facilities have converted to non-mercury membrane technology since 2000 and only a single mercury cell source remains at a facility that already has two non-mercury chlorine production units shows that is necessary to revise our existing source standard to take into account developments in practices, processes and control technologies.

Regarding the Minamata Convention on Mercury, this is a global treaty to protect human health and the environment from the adverse effects of mercury. It was agreed at the fifth session of the Intergovernmental Negotiating Committee on mercury in Geneva, Switzerland on January 19, 2013, and adopted later that year on October 10. The Minamata Convention entered into force on August 16, 2017.

Major highlights of the Minamata Convention include a ban on new mercury mines, the phase-out of existing ones, the phase out and phase down of mercury use in a number of products and processes, control measures on emissions to air and on releases to land and water, and the regulation of the informal sector of artisanal and small-scale gold mining. The Convention also addresses interim storage of mercury and its disposal once it becomes waste, sites contaminated by mercury, and health issues.

Under the Minamata Convention, the U.S. has specifically addressed mercury cell chlor-alkali production. For example, in the registration for an extension of the mercury phase out deadline from 2025 to 2030, the U.S. stated the following:

''Pursuant to Article 6, paragraph 1 of the Minamata Convention on Mercury, the United States hereby registers for an exemption from the phase-out date listed in Annex B for the use of mercury in chlor-alkali production.'' [2] The United States also provides the

[2] *https://www.mercuryconvention.org/en/parties/exemptions.*

following statement explaining the need for the exemption:

''The United States supports the phase-out of mercury use in chlor-alkali production facilities. It has implemented domestic strategies to encourage a timely transition to mercury-free alternative technologies with a view to phasing out all mercury use in domestic chlor-alkali production facilities. New or reconstructed chlor-alkali production facilities in the United States are already effectively prohibited from using mercury under section 112 of the Clean Air Act. See 40 CFR 63.8190. Most mercury cell chlor-alkali facilities in the United States have already closed or converted. While there were 14 such facilities in 1998, only two remained as of late 2013. The United States will, pursuant to Article 6, paragraph 7, withdraw this exemption if that becomes possible prior to its expiration date.'' [3]

Therefore, the U.S. is committed to phasing out all mercury emissions in domestic chlor-alkali facilities by 2030. The EPA is not aware of any plans by the owner of the lone remaining mercury cell chlor-alkali facility in West Virginia to close or convert their mercury cell facility before 2030. Therefore, we have determined that it is necessary to require this action to ensure the facility converts or closes the mercury cell chlor-alkali production process in order to eliminate mercury emissions and section 112 of the CAA provides an appropriate regulatory mechanism to enact such a requirement to eliminate emissions. The two main options regarding timing are: (1) Promulgate a non-mercury standard at this time under section 112(d)(2) and (3) and/or section 112(d)(6); or (2) promulgate a non-mercury standard by fall 2027 (*i.e.,* before the next 8-year cycle for a technology review required by section 112(d)(6)).

As pointed out by commenters, the next 8-year review will not be required until 2030. If a non-mercury standard was promulgated in 2030 and included the 3-year compliance date allowed by CAA section 112, the phase-out would not occur in time to comply with the 2030 deadline. We do not think it is prudent to plan a separate ''out of cycle'' review to promulgate a non-mercury standard in 2027, especially since the review shows that the non-mercury standard is technologically feasible, cost effective and will not impose significant economic impacts at this time, and there is no reason to think a decision would be any different in 2027. Therefore, we concluded that the best option to ensure compliance with the Minamata Convention is to promulgate a non-mercury standard at this time.

We recognize that we did not specifically propose this option in the January 2021 proposal. However, we did include it as an option that was considered and described it in detail, we provided our analysis of this option and specifically requested comment on the option. Specifically, we stated the following:

''However, we are soliciting comments, data, and other information regarding these proposed decisions, including data and information regarding the costs, cost effectiveness, non-air, and economic impacts and other relevant information regarding whether the NESHAP should include a non-mercury standard as either a beyond-the-floor MACT standard or a revised standard under the technology review, and whether the proposed work practices for chlorine emissions and proposed amendments to the mercury work practices would be necessary if a non-mercury standard were to be adopted.''

EPA also stated that ''We intend to consider any such submitted data and information, in addition to the data and information contained in the records for the 2008 and 2011 proposals and in this proposal, in reaching final conclusions under CAA sections 112(d)(2) and (6) regarding a non-mercury standard.'' (86 FR 1383)

Furthermore, the EPA proposed the non-mercury option in 2011 and referred to this 2011 proposal in the January 2021 FR document. Therefore, we provided sufficient notice of the potential that we would finalize a non-mercury option, and we are finalizing the non-mercury requirement based on a logical outgrowth of comments on our proposal and the record that public commenters had an opportunity to review and address.

C. Technology Review for the Mercury Cell Chlor-Alkali Plants Source Category

1. What did we propose pursuant to CAA section 112(d)(6) for the Mercury Cell Chlor-Alkali Plants source category?

Pursuant to CAA section 112(d)(6), we proposed amendments to the rule that would have required the combination of both a cell room monitoring program to continuously monitor mercury vapor in the cell room and a suite of equipment standards and work practices to reduce fugitive mercury emissions. This is different from the NESHAP promulgated in 2003, which required either the equipment standards and work practices or the cell room monitoring program. As described above, we also evaluated the non-mercury option under our section 112(d)(6) technology review.

2. How did the technology review change for the Mercury Cell Chlor-Alkali Plants source category?

As discussed above in section IV.B, we changed our decision related to the non-mercury option and are promulgating a prohibition of mercury emissions from the source category. The result of this final amendment prohibiting mercury emissions will be that there will no longer be any operating mercury cell chlor-alkali plants in the U.S. after May 6, 2025.

3. What key comments did we receive on the technology review, and what are our responses?

The only comment received on our proposed technology review, other than those related to the non-mercury option discussed above in section IV.B.3, was one from the facility that clarified that the existing continuous monitor analyzers for mercury at the facility are capable of detecting mercury concentration of 0.1 $\mu g/m^3$, which would meet the EPA's proposed detection requirements.

4. What is the rationale for our final approach for the technology review?

The rationale for our final decision regarding the non-mercury option is discussed above in section IV.B.4. Regarding the cell room monitoring program and equipment and work practice standards to reduce fugitive mercury emissions, the facility complies with the fugitive mercury standards by operating a continuous cell room monitoring program in accordance with paragraph 63.8192(g) as an alternative to the equipment standards and work practices in paragraphs 63.8192(a) through (d). However, while not required to do so under the NESHAP promulgated in 2003, the facility also implements those equipment standards and work practices. Therefore, the EPA determined that the combination of implementing a cell room monitoring program and performing work practices constitutes a development in emissions control practices and is finalizing the proposed requirement that both a cell room monitoring program and equipment and work practices be implemented during the period of up to 3 years before the facility converts the mercury cell process to a non-mercury process or closes the mercury cell process.

[3] Ibid.

D. Amendments Pursuant to Sections 112(d)(2) and (3) and (h) for the Mercury Cell Chlor-Alkali Plants Source Category

1. What did we propose pursuant to CAA section 112(d)(2) and (3) and (h) for the Mercury Cell Chlor-Alkali Plants source category?

Pursuant to CAA sections 112(d)(2) and (3) and (h), in 2021 we proposed amendments to the rule that would have required a leak detection and repair program to identify chlorine equipment leaks in the cell room and throughout the other parts of the mercury cell chlor-alkali production facility affected source that handle and process the chlorine gas produced. The proposed rule would have also required that chlorine monitors be installed and operated continuously throughout the affected source and that each time one of these sensors measured a chlorine concentration of 2 ppmv or greater, a complete inspection for leaks of all equipment containing 5 percent chlorine by volume would have been required within 1 hour of detection.

In addition, we evaluated the beyond-the-floor non-mercury option under our consideration of section 112(d)(2) and (3); however, we did not propose the non-mercury standard in the January 8, 2021 proposal.

2. How did the decision related to CAA section 112(d)(2) and (3) change for the Mercury Cell Chlor-Alkali Plants source category?

As discussed above in section IV.B, we changed our decision related to the non-mercury option and are promulgating a prohibition of mercury emissions from the source category. The result of this final amendment prohibiting mercury emissions will be that there will no longer be any operating mercury cell chlor-alkali plants in the U.S. after May 6, 2025.

3. What key comments did we receive on our proposed decision related to CAA sections 112(d)(2) and (3) and (h), and what are our responses?

As discussed above in section IV.B.3, comments were received regarding the proposed determination not to require the non-mercury option as a beyond-the-floor requirement. Comments were also received related to the proposed fugitive chlorine requirements. In addition, comments were received claiming that standards should have been proposed for emissions of HCl. These comments, along with responses from the EPA, are provided below in this section.

Comment: The single operating facility provided several comments regarding the proposed requirements to reduce chlorine emissions. While they corrected the EPA's assumption that the cell room was under negative pressure, they noted that most of the equipment containing chlorine gas is under negative pressure, which would be excluded from the proposed leak detection requirements. They noted that the facility already complies with most of the proposed fugitive chlorine requirements, and they explained how they would comply with the additional requirements. They agreed that the proposed olfactory observations are appropriate versus visual or auditory inspections, due to the low odor threshold of chlorine. They did, however, register concern about the chlorine leak repair requirements, noting that final repairs to leaks from some causes may take more than one day to complete, as required in the proposal. They also provided responses to the EPA's requests for comments regarding the proposed requirements for continuous chlorine sensors and the proposed 2 parts per million by volume (ppmv) action level and averaging time. In response to the EPA's request for comment regarding whether the EPA should specify sensor placement locations, they expressed concern about placing chlorine sensors in the cell room, as they stated that the high magnetic field in the cell room has historically caused unreliable transmitter responses. They indicated that, if the EPA finalized a requirement to place chlorine sensors in the cell room, additional time would be needed to comply with the standard, as the facility would need to evaluate whether the use of a chlorine sensor(s) in the cell room is technically feasible and, if feasible, to procure and install the sensors.

Response: The EPA appreciates the effort provided by the commenter to carefully review the proposed fugitive chlorine requirements, to provide thoughtful comments, and to put forth preliminary ideas on how they would comply. We also appreciate the concerns raised about the repair timing requirement and the placement of chlorine sensors in the cell room. Based on these comments, we have revised the final requirements to add time to make repairs, which would allow time to obtain equipment that is not kept onsite, by increasing the time for final repairs to be made from 24 to 72 hours. Further, based on these comments and the technical feasibility of placing sensors in certain locations, we have not added requirements stipulating sensor locations in the final rule. Finally, we agree that an action level for equipment inspections based on a single sensor reading may not be indicative of a problem that warrants special investigation. Accordingly, we have revised the action level that triggers an inspection of all chlorine-containing equipment to be detection by a sensor of a one-hour average chlorine concentration of 2 ppmv or greater.

Comment: One commenter stated that the EPA must set emissions standards for HCl. The commenter contended that even if the HCl emissions are from direct synthesis HCl production units, these units are part of the mercury cell chlor-alkali plant and must be regulated. The commenter stated that these units would be affected sources because they are ''cell rooms and ancillary operations used in the manufacture of product chlorine, product caustic, and by-product hydrogen at a plant site'' and ''processes and associated operations needed for mercury recovery from wastes at a plant site.''

Response: We disagree with the commenter's rationale of why the direct synthesis HCl production units would be part of an affected source under subpart IIIII. They are not part of the cell room or the ancillary operations used in the manufacture of product chlorine, product caustic, or by-production hydrogen. In fact, the HCl production units are downstream operations from the chlor-alkali process, as they use the product chlorine and by-product hydrogen to create HCl. Additionally, these units are not associated with the processes needed for the recovery of mercury.

While not cited by the commenter, the EPA has previously considered direct synthesis HCl units co-located with chlor-alkali plants to be part of the chlor-alkali plant. In the July 3, 2002, proposal for the chlorine production source category, the EPA stated ''Since chlor-alkali processes produce both chlorine and hydrogen, it is common for a direct synthesis HCl production unit to be incorporated into a chlor-alkali facility. Therefore, we consider these direct synthesis HCl production units to be a part of the chlor-alkali facilities.'' (67 FR 44713). The HCl (and chlorine) emissions from the co-located direct synthesis HCl plants were included in the risk assessment that led to the EPA's decision in 2003 not to develop any NESHAP for non-mercury cell chlor-alkali plants and to delete the non-mercury subcategory. Further, because these units were considered part of the deleted non-mercury cell chlorine production subcategory, they were specifically exempted from the HCl

NESHAP, 40 CFR subpart NNNNN, at 63.8985(d).

At the West Virginia facility, there are three chlor-alkali units: The mercury cell unit and two diaphragm cell units. According to the air permit for the facility, the diaphragm cell units produce approximately four times as much chlorine as the mercury cell unit. Therefore, if the HCl production units were assigned to one of the chlorine production subcategories based on the contribution of the chlorine and hydrogen contributed, they would be considered part of the non-mercury cell subcategory of chlor-alkali plants. In addition, when the EPA finalized the decision to delete the non-mercury subcategory on December 19, 2003, we stated ''we have clarified that chlorine and HCl emissions from the absorber vents of direct synthesis HCl production units at chlor-alkali facilities, as well as the associated storage tanks and transfer operations specified above, are included in the non-mercury cell chlorine production subcategory . . .'' (68 FR 70948)

As shown through this cited history, the EPA has clearly established that HCl direct synthesis units are not part of the mercury cell chlor-alkali source category, and we are not pursuing their regulation under subpart IIIII.

Comment: One commenter stated that the EPA proposed to limit the applicability of the rule with changes to –63.8182, –63.8184(a) and definitions in –62.8266. The commenter asserted that the EPA did not provide any explanation or justification for these proposed changes, which is a violation of the CAA and makes it impossible to determine what the EPA is intending to accomplish. The commenter's interpretation was that the EPA was changing the existing regulation to avoid regulating HCl emissions from the plant. The commenter stated that if that is the case, the EPA is acting unlawfully by attempting to bypass its statutory obligations to regulate all HAP and HAP emission points within a source category.

Response: The commenter is correct that these changes were not explained in the January 2021 proposal. They were changes that were proposed in both the 2008 proposal and the 2011 supplemental proposal, with the purpose of ensuring that a mercury thermal recovery unit affected source at a site where the mercury cell production facility was either converted or closed would continue to be subject to the emission limitations while processing the wastes from the closed mercury cell plant. Since the single remaining mercury cell chlor-alkali plant does not have a thermal mercury recovery unit, these changes are not necessary and should not have been included. They are in no way related to HCl emissions from the plant. In fact, as noted above, these amendments were holdovers from the 2008 proposal and the 2011 supplemental proposal when only mercury emissions were under consideration.

4. What is the rationale for our final approach for the CAA sections 112(d)(2) and (3) and (h)?

The rationale for our final decision regarding the non-mercury option is discussed above in section IV.B.4. For the fugitive chlorine work practices, the facility voluntarily implements work practices that are consistent with the proposed requirements and represents the MACT floor. As these chlorine emissions are fugitive in nature resulting from potential equipment leaks, they cannot be emitted through a conveyance designed and constructed to emit or capture such pollutant or measured. Therefore, we are finalizing the proposed amendments requiring work practices to minimize chlorine emissions. Further, as discussed above, we are not developing standards under section 112(d)(2) and (3) for the HCl emissions from the direct synthesis HCl production units at the West Virginia site.

E. Amendments addressing emissions during periods of startup, shutdown, and malfunction and other topics?

1. What did we propose related to emissions during periods of startup, shutdown, and malfunction and other topics?

We proposed revisions related to emissions during periods of startup, shutdown, and malfunction (SSM); provisions for electronic submission of performance test results, performance evaluation reports, and Notification of Compliance Status (NOCS) reports; and corrections of various errors in compliance provisions in the NESHAP.

2. How did the decision related to emissions during periods of startup, shutdown, and malfunction and other topics change?

No changes have been made regarding our decisions concerning periods of SSM and the corrections of various compliance provisions in the current rule. For submission of performance test results, performance evaluation reports, and Notification of Compliance Status (NOCS) reports, we have determined it is necessary for the facility to switch to electronic reporting, considering the timing of the final non-mercury emission standard and related upcoming closure or conversion of the one remaining mercury cell chlor-alkali unit.

3. What key comments did we receive on proposed decision related to emissions during periods of startup, shutdown, and malfunction and other topics?

Comment: One commenter relayed several concerns regarding the proposed startup, shutdown, and malfunction provisions. According to the commenter, higher mercury emissions may occur during startup due to the hydrogen vent system and its control device, which will cause compliance concerns until alternative work practices can be developed to reduce emissions from this system. The commenter stated, at the time they submitted public comments, that the control device cannot be operated until the exhaust stream composition can be regulated, and the facility would need additional time to evaluate operational methods to improve operation of the control device. The commenter added that additional time would also be needed to determine the modifications necessary to reduce emissions during startup, to develop and implement a recordkeeping system, and perform operator training. The commenter requested a time frame of 12 months rather than 6 months for compliance with all the proposed SSM requirements.

Response: To understand the commenter's concerns better and to determine whether a different standard was needed for startup periods, the EPA had a teleconference meeting with the commenter to discuss the issue. During this discussion, the commenter indicated that the facility had found a way to comply with the emissions standards at all times, including startup. The notes of the meeting are in the docket for this rulemaking (EPA–HQ–OAR–2020–0560). Therefore, with the issue resolved, the EPA is finalizing the proposed requirements that the emissions limits apply at all times and no separate requirements are necessary for periods of startup, and further, no additional time is necessary or provided for compliance.

Comment: One commenter supported electronic reporting in general but stated a preference to submit any such information in PDF format.

Response: Given that the facility could operate for up to 3 more years before it converts to a non-mercury process or shut down, we have decided

to require the facility to switch to electronic reporting.

Comment: One commenter noted that the EPA proposed to add a performance testing requirement at 40 CFR 63.8232(a). The commenter believes that the annual calibration testing at the facility satisfies the requirements of a performance test, and additional performance testing is not needed.

Response: The commenter misinterpreted the proposed changes to 40 CFR 63.8323(a), which did not add a new performance testing requirement. Rather, these proposed changes clarified the conditions under which the performance test must be conducted. These changes establish that performance tests must be conducted during normal operations and remove a reference to 40 CFR 63.7(e)(1), which conflicts with the requirement to comply with the standards at all times, including during periods of SSM. As these requirements are simply clarifying performance test conditions and ensuring the standards are met at all times, we are finalizing the revised provisions as proposed.

4. What is the rationale for our final approach for requirements related to emissions during periods of startup, shutdown, and malfunction and other topics?

The rationale for our final decision regarding the non-mercury option is discussed above in section IV.B.4. As discussed in the responses in the previous section, we are finalizing the proposed electronic reporting amendments for the reasons described above. Furthermore, we have not changed our final approach to the requirements for periods of SSM, and we are finalizing these requirements as proposed based on the considerations described above.

F. Public Notice and Comments

In addition to the comments on the proposal, one commenter objected to the EPA's decision not to publish the proposed rule amendments in the **Federal Register**.

Comment: The commenter observed that the EPA proposed significant changes to the regulatory language, but these changes were not in the EPA's proposed rule. The commenter remarked that the CAA and the Administrative Procedures Act (APA) both make plain that proposed rules must be published in the **Federal Register** (42 U.S.C. 7607(d)(3); 5 U.S.C. 553(b)). Further, the commenter stated that the CAA requires the EPA to include a summary of the major legal interpretations and policy considerations underlying its proposed rules, and the EPA did not provide this explanation nor any explanation for its proposed changes to the regulatory text. The commenter states that if the EPA wishes to make changes to the Code of Federal Regulations, it must withdraw this proposal, publish the proposed changes in the **Federal Register** and provide a new opportunity for public comment.

Response: The proposal met all APA and CAA notice and comment requirements. Nothing in the APA or the CAA, including the language the commenter cites, requires the EPA to publish proposed rule text in the **Federal Register**. The commenter suggests that because the EPA did not publish the proposed rule text, the EPA failed to meet the CAA 307(d)(3) requirement to publish a ''notice of proposed rulemaking.'' However, the requirement to publish a ''notice of proposed rulemaking'' is not a requirement to publish ''proposed rule text.'' Section 307(d)(3) specifies the required elements of a ''notice of proposed rulemaking'' and ''proposed rule text'' is not a required element. The elements the commenter cites that are required to be included in the notice of proposed rulemaking (a ''statement of basis and purpose,'' ''a summary of . . . the major legal interpretations and policy considerations underlying the proposed rule, etc. . .'') were included, and commenter does not suggest otherwise.

The APA does not require publication of proposed rule text in the **Federal Register** either. Section 553(b)(3) of the APA provides that a notice of proposed rulemaking shall include ''*either* the terms or substance of the proposed rule or a description of the subjects and issues involved.'' (emphases added). Thus, the APA clearly provides flexibility to describe the ''subjects and issues involved'' as an alternative to inclusion of the ''terms or substance'' of the proposed rule. See also *Rybachek* v. *U.S. E.P.A.,* 904 F.2d 1276, 1287 (9th Cir. 1990). (The EPA's failure to propose in advance the actual wording of a regulation does not make the regulation invalid where the EPA's discussion of the regulatory provisions ''clearly describe 'the subjects and issues involved.' '').

The commenter claims that the EPA did not publish ''any explanation for its proposed changes''. However, the commenter does not identify any specific regulatory text that was not explained or specify any deficiency in any explanation of regulatory text in the **Federal Register** document. Such a generalized objection is not sufficiently specific. See, *e.g., Appalachian Power Co.* v. *E.P.A.,* 251 F.3d 1026, 1036 (D.C. Cir. 2001) (' 'An objection must be made with sufficient specificity reasonably to alert the agency.' '' (quoting *Tex Tin Corp.* v. *EPA,* 935 F.2d 1321, 1323 (D.C. Cir. 1991)).

The commenter makes a vague assertion that the EPA's approach was prejudicial to the ability of the public to be able to find and comment on the proposed regulatory changes but does not claim any actual difficulty in finding or commenting on the proposed rule language. The EPA approach was not prejudicial to the commenter or any member of the public. The notice of proposed rulemaking clearly explained that the proposed amendatory language and a redline strikeout version of the subpart IIIII showing proposed changes were available in the docket and on EPA's website: *https://www.epa.gov/stationary-sources-air-pollution/mercury-cell-chloralkali-plants-national-emissions-standards.*

The proposed changes to the CFR that would be necessary to incorporate the changes proposed in this action are set out in an attachment to the memorandum titled Proposed Regulation Edits for 40 CFR part 63, subpart IIIII, available in the docket for this action (EPA–HQ–OAR–2020–0560). The document includes the specific proposed amendatory language for revising the CFR and, for the convenience of interested parties, a redline version of the regulation.

Although the EPA's recent practice has generally been to publish proposed amendatory regulatory text, the EPA's practice has varied. See, *e.g.,* Hazardous Air Pollutants: Proposed Regulations Governing Constructed, Reconstructed or Modified Major Sources, 59 FR 15504 (April 1, 1994) (''The proposed regulatory text is not included in the **Federal Register** document, but is available in Docket No. A–91–64 or by request from the EPA contact persons designated earlier in this note. The proposed regulatory language is also available on the technology Transfer Network (TTN), of EPA's electronic bulletin boards.''); Federal Standards for Marine Tank Vessel Loading and Unloading Operations and National Emission Standards for Hazardous Air Pollutants for Marine Tank Vessel Loading and Unloading Operations, 59 FR 25004 (May 13, 1994) (''The proposed regulatory text and other materials related to this rulemaking are available for review in the docket.''). And even when we do include the proposed text in the **Federal Register**, we often include a redline version of proposed regulations in the docket for

rulemakings to assist the public in understanding the proposed regulatory changes. In our experience, stakeholders find the redline version far more useful than the proposed amendatory language in the format required by the Office of the Federal Register. Although appropriate for the task of revising the Code of Federal Regulations, this language can be difficult to assess without the accompanying full regulatory text. Given this and given that we rarely receive comments on the proposed amendatory language or on proposed regulatory language at all, we determined that for rulemakings such as these, it would be more efficient to take the approach here of making both easily accessible but not including the proposed amendatory text in the document.

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

A. What are the affected facilities?

There is one facility affected by this action, which is the one remaining mercury cell chlor-alkali facility operating in the U.S. This facility is located in West Virginia.

B. What are the air quality and other environmental impacts?

The air quality impacts of this final action will be the elimination of approximately 125 pounds of mercury emissions annually. In addition to this air quality impact, this action will result in the elimination of around 900 pounds of mercury that are released annually to other media.

In addition, it is estimated that the conversion of the remaining mercury cell facility to membrane cells will result in an energy savings of around 25 percent which results in an estimated cost savings of around $1.5 million per year.

C. What are the cost impacts?

The capital cost of complying with the promulgation of the non-mercury requirement is estimated to be $69.4 million if the facility chooses to convert its mercury unit to a non-mercury process rather than rely on its two existing non-mercury units. The total estimated annual costs, including the annualized capital costs minus the savings realized from the lower electricity needs and the savings related to the elimination of the burden of the environmental regulations associated with mercury, are $2.7 million per year in 2019 dollars. Table 3 presents the estimated annual cost components for conversion from mercury cell to membrane cell technology.

TABLE 3—TOTAL ANNUAL COST OF CONVERSION OF THE WEST VIRGINIA MERCURY CELLS TO MEMBRANE CELLS

[2019$]

Annual cost component	Annual cost ($/yr)
Capital Recovery	$4,764,982
Mercury Storage	53,364
Compliance Savings	−546,572
Electricity Savings	−1,504,893
Total Annual	2,766,880

D. What are the economic impacts?

The net present value of the estimated cost impacts of the final amendments to the Mercury Cell Chlor-Alkali NESHAP is $43.0 million, discounted at a 7 percent rate to 2020 over a 20-year analytic time frame from 2021 to 2040 in 2019 dollars. Using a 3 percent discount rate, the net present value of the estimated cost impacts is $39.4 million. The equivalent annualized value, which is a measure of the annualized costs of the final rule consistent with the net present value, is $4.0 million and $2.6 million for 7 and 3 percent discount rates respectively.

As stated previously in section B.3., the estimated total annual costs are $2.7 million for the Westlake facility. Based on our analysis, the estimated annualized costs are only about 0.04 percent of the annual revenue of the facility's ultimate parent company in 2020. Since the estimated cost impacts are minimal, no significant economic impacts to the ultimate parent company nor its consumers are anticipated due to the final amendments. For additional details on the economic impact analysis please see the memorandum entitled *Economic Impact Analysis for the Final Mercury Cell Chlor-Alkali National Emission Standard for Hazardous Air Pollutants (NESHAP) Beyond-Floor Determination and Risk and Technology Review (RTR)* available in the docket (EPA–HQ–OAR–2020–0560).

E. What are the benefits?

The EPA anticipates a complete elimination of mercury emissions at the one remaining mercury cell chlor-alkali plant as a result of the final amendments to the Mercury Cell Chlor-Alkali Plants NESHAP. This is estimated to be a reduction of 125 pounds of mercury emitted to the atmosphere annually and approximately 900 pounds of mercury released annually to other media. EPA has not monetized the health benefits of reduced mercury emissions due to this rulemaking due to the lack of site specific data and insufficient economic research to support the valuation of the health impacts often associated with exposure to individual HAP. For the 2022 proposed rule for the Mercury Air Toxics Standard (MATS) EPA did develop bounding estimates for the risk and associated dollar valuation associated with mercury emitted from U.S. Electric Utility Steam Generating Units. These estimates focused on exposure of the general population to methylmercury through commercial fish consumption and included IQ loss for children exposed in-vitro and adult myocardial infarction (MI)-related mortality. These bounding estimates are subject to uncertainty which is discussed in the rule language.[4] While the risk assessment conducted for the RTR indicates that risks from the source category are already low, future risks from this source category will be reduced to zero. Furthermore, as described above, this action will eliminate the releases of mercury to the global pool from this source.

F. What analysis of environmental justice did we conduct?

Consistent with EPA's commitment to integrating environmental justice (EJ) in the agency's actions, and following the directives set forth in multiple Executive Orders, the Agency has carefully considered the impacts of this action on communities with EJ concerns. For this action, we performed a demographic analysis, which is an assessment of risks to individual demographic groups of the populations living within 5 kilometers (km) and within 50 km of the single Mercury Cell Chlor-Alkali facility associated with this rule. While there are three demographic groups (*i.e.,* over age 25 without a high school diploma, those below the poverty level, and those aged 65 and up) around this facility that are higher than the national average, we find that no one is exposed to a cancer risk at or above 1-in-1 million or to a chronic noncancer TOSHI greater than 1. As such, the EPA determined that this action provides an ample margin of safety to protect public health for all populations, including communities already overburdened by pollution. Following is a more detailed description of how the agency considers

[4] National Emission Standards for Hazardous Air Pollutants: Coal- and Oil-Fired Electric Utility Steam Generating Units—Revocation of the 2020 Reconsideration, and Affirmation of the Appropriate and Necessary Supplemental Finding; Notice of Proposed Rulemaking (87 FR 7624, February 9, 2022).

EJ in the context of regulatory development.

Executive Order 12898 directs the EPA to identify the populations of concern who are most likely to experience unequal burdens from environmental harms; specifically, populations of people of color, low-income populations, and indigenous peoples (59 FR 7629, February 16, 1994). Additionally, Executive Order 13985 is intended to advance racial equity and support underserved communities through federal government actions (86 FR 7009, January 20, 2021). Executive Order 14008 further declares a policy ''to secure environmental justice and spur economic opportunity for disadvantaged communities that have been historically marginalized overburdened by pollution and under-investment in housing, transportation, water and wastewater infrastructure, and health care'' (86 FR 7619, February 1, 2021). The EPA defines EJ as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies [5]''. The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies''. In recognizing that people of color and low-income populations often bear an unequal burden of environmental harms and risks, the EPA continues to consider ways of protecting them from adverse public health and environmental effects of air pollution.

To examine the potential for any environmental justice issues that might be associated with the source category, we performed a demographic analysis, which is an assessment of risks to individual demographic groups of the populations living within 5 kilometers (km) and within 50 km of the facilities. In the analysis, we evaluated the distribution of HAP-related cancer and noncancer risks from the Mercury Cell Chlor-Alkali Plants source category across different demographic groups within the populations living near facilities.

As mentioned above, the results of the demographic analysis for the source category indicate that three demographic groups included in the analysis are higher than the national average in percentage terms within 5 km of the facility.[6] These groups include those over 25 without a high school diploma (17 percent versus 14 percent nationally), those below the poverty level (25 percent versus 14 percent nationally) and those aged 65 and up (18 percent versus 14 percent nationally). When examining the risk levels of those exposed to emissions from Mercury Cell Chlor-Alkali plants, we determined that no one is exposed to a cancer risk at or above 1-in-1 million or to a chronic noncancer TOSHI greater than 1. The methodology and the results of the demographic analysis are presented in a technical report, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Mercury Cell Chlor-Alkali Plants Source Category Operations,* which is available in the docket.

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

The EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. The health risk assessments for this action are contained in the document titled *Residual Risk Assessment for the Mercury Cell Chlor-Alkali Plants Source Category in Support of the 2021 Risk and Technology Review Final Rule,* available in the docket (Docket ID No. EPA–HQ–OAR–2020–0560).

VI. 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 Orders 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review because it raises novel legal or policy issues. Any changes made in response to OMB recommendations have been documented in the docket.

B. Paperwork Reduction Act (PRA)

The information collection activities in rule have been submitted for approval to OMB under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2046.11. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The information requirements in this rulemaking are based on the notification, recordkeeping, and reporting requirements in the NESHAP General Provisions (40 CFR part 63, subpart A), which are mandatory for all operators subject to national emission standards. These notifications, reports, and records are essential in determining compliance, and are specifically authorized by CAA section 114 (42 U.S.C. 7414). All information submitted to the EPA pursuant to the recordkeeping and reporting requirements for which a claim of confidentiality is made is safeguarded according to Agency policies set forth in 40 CFR part 2, subpart B.

The EPA is finalizing amendments to eliminate the SSM plan and reporting requirements; add requirements for electronic reporting of notifications and reports and performance test results; and add a reporting requirement for meeting the mercury emissions prohibitions. This information will be collected to assure compliance with the Mercury Cell Chlor-Alkali Plants NESHAP.

Respondents/affected entities: The respondents to the recordkeeping and reporting requirements are owners or operators of flexible polyurethane foam fabrication operations subject to 40 CFR part 63, subpart IIIII.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart IIIII).

Estimated number of respondents: 1 facility.

Frequency of response: Initially, occasionally, and semi-annually.

Total estimated burden: 3,567 total hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $457,200 (per year), includes $29,200 annualized capital or operation & maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the

[5] See *https://www.epa.gov/environmentaljustice.*

[6] When the demographic analysis was completed in mid-2020, there were 2 facilities in the mercury cell chlor-alkali source category and both were subject to 40 CFR part 63, subpart IIIII. However, in late 2020 one of those facilities converted to a non-mercury process. Therefore, currently only one facility remains in the source category.

approved information collection activities contained in this final rule.

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. This action will not impose any requirements on small entities. The ultimate parent company for the single affected facility in the source category is not a small entity given the Small Business Administration small business size definition for this industry (1,000 employees or greater for NAICS 325180).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. While this action creates an enforceable duty on the private sector, the cost does not exceed $100 million or more in any one year.

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. The mercury cell chlor-alkali plant affected by this final action is not owned or operated by tribal governments or located within tribal lands. 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 the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in section IV.A of this preamble and the document, *Residual Risk Assessment for the Mercury Cell Chlor-Alkali Plants Source Category in Support of the 2021 Risk and Technology Review Final Rule,* which is available in the docket for this rulemaking.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. New standards are proposed for 40 CFR part 63, subpart IIIII to limit mercury and Cl emissions from mercury cell chlor-alkali plants. The proposed limits will have lower electricity costs for the one affected facility so it will not have a significant adverse effect on the supply, distribution, or use of energy.

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 does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

The documentation for this decision is contained in the technical report titled, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Mercury Cell Chlor-Alkali Plants Source Category Operations,* available in the docket for this action.

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, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

For the reasons set out in the preamble, 40 CFR part 63 is amended as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

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

■ 2. The heading for subpart IIIII is revised to read as follows:

Subpart IIIII—National Emission Standards for Hazardous Air Pollutants for Mercury Cell Chlor-Alkali Plants

■ 3. Section 63.8180 is revised to read as follows:

§ 63.8180 What is the purpose of this subpart?

This subpart establishes national emission standards for hazardous air pollutants (NESHAP) for affected sources at mercury cell chlor-alkali plants. This subpart also establishes requirements to demonstrate initial and continuous compliance with all applicable emission limitations and work practice standards in this subpart.

■ 4. Section 63.8182 is amended by revising paragraph (c) introductory text to read as follows:

§ 63.8182 Am I subject to this subpart?

* * * * *

(c) Beginning on December 19, 2006, the provisions of subpart E of 40 CFR part 61 that apply to mercury cell chlor-alkali plants, which are listed in paragraphs (c)(1) through (3) of this section, are no longer applicable.

* * * * *

■ 5. Section 63.8184 is amended by revising paragraphs (a)(1) and (2) to read as follows:

§ 63.8184 What parts of my plant does this subpart cover?

(a) * * *

(1) The mercury cell chlor-alkali production facility designates an affected source consisting of all cell rooms and ancillary operations used in the manufacture of product chlorine, product caustic, and by-product hydrogen at a plant site. This subpart covers mercury emissions from by-product hydrogen streams and end box ventilation system vents, mercury fugitive emissions associated with cell rooms, hydrogen systems, caustic systems, and storage areas for mercury-containing wastes; and chlorine fugitive emissions associated with the mercury cell chlor-alkali production facility.

(2) The mercury recovery facility designates an affected source consisting of all processes and associated operations needed for mercury recovery

from wastes at a plant site. This subpart covers mercury emissions from mercury thermal recovery unit vents and fugitive emission sources of mercury associated with storage areas for mercury-containing wastes.

* * * * *

■ 6. Section 63.8186 is amended by revising paragraph (a) to read as follows:

§ 63.8186 When do I have to comply with this subpart?

(a) If you have an existing affected source, you must comply according to the dates specified in paragraphs (a)(1) through (5) of this section, as applicable.

(1) You must comply with each emission limitation, each work practice standard specified in paragraphs § 63.8192(a) through (f) or each work practice standard in paragraphs § 63.8192(e) through (g), and with each recordkeeping and reporting requirement in this subpart that applies to you by December 19, 2006, except as specified in paragraphs (a)(2) through (5) of this section.

(2) You must comply with each work practice standard in § 63.8192(a) through (c) and (e) through (h) and the electronic reporting requirements in § 63.8232(g), § 63.8252(g), and § 63.8254(e) by November 7, 2022.

(3) Until November 7, 2022, you must comply with the requirements in § 63.8226(a) and the requirements specified in the startup, shutdown, and malfunction plan required at § 63.8226(b).

(4) On and after November 7, 2022, you must comply with the applicable requirements in paragraph § 63.8226(c).

(5) On and after May 6, 2025, you must comply with the emission limitations in § 63.8190(a)(2)(ii) and the notification requirement in § 63.8252(h).

* * * * *

■ 7. Section 63.8190 is amended by revising paragraph (a)(2) to read as follows:

§ 63.8190 What emission limitations must I meet?

(a) * * *

(2) Existing mercury cell chlor-alkali production facility. Until the compliance date listed in § 63.8186(a)(5), you must comply with paragraph (a)(2)(i) of this section. On and after the compliance date listed in § 63.8186(a)(5), you must comply with paragraph (a)(2)(ii) of this section.

(i) During any consecutive 52-week period, you must not discharge to the atmosphere total mercury emissions in excess of the applicable limit in paragraph (a)(2)(i)(A) or (B) of this section calculated using the procedures in § 63.8243(a).

(A) 0.076 grams of mercury per megagram of chlorine produced (1.5×10^{-4} pounds of mercury per ton of chlorine produced) from all by-product hydrogen streams and all end box ventilation system vents when both types of emission points are present.

(B) 0.033 grams of mercury per megagram of chlorine produced (6.59×10^{-5} pounds of mercury per ton of chlorine produced) from all by-product hydrogen streams when end box ventilation systems are not present.

(ii) Emissions of mercury are prohibited from an existing mercury cell chlor-alkali production facility.

* * * * *

■ 8. Section 63.8192 is amended by revising the introductory text, paragraph (a), and paragraph (g) introductory text, and adding paragraph (h) to read as follows:

§ 63.8192 What work practice standards must I meet?

In accordance with the compliance dates specified in § 63.8186(a)(1), you must meet the work practice requirements specified in paragraphs (a) through (f) of this section. As an alternative to the requirements specified in paragraphs (a) through (d) of this section, you may choose to comply with paragraph (g) of this section. On and after the compliance date specified in § 63.8186(a)(2) and until the compliance date specified in § 63.8186(a)(5), you must meet the work practice requirements specified in paragraphs (a) through (c) and (e) through (h) of this section.

(a) You must meet the work practice standards in Tables 1 through 4 to this subpart.

* * * * *

(g) You must institute a cell room monitoring program to continuously monitor the mercury vapor concentration in the upper portion of each cell room and to take corrective actions as quickly as possible when elevated mercury vapor levels are detected. As specified in § 63.8252(e)(1)(iv), you must prepare and submit to the Administrator, a cell room monitoring plan containing the elements listed in Table 5 to this subpart and meet the requirements in paragraphs (g)(1) through (4) of this section.

* * * * *

(h) You must comply with the requirements specified in paragraphs (h)(1) through (4) of this section to reduce fugitive chlorine emissions in the mercury cell chlor-alkali production facility affected source.

(1) You must identify each piece of equipment located throughout the mercury cell chlor-alkali production facility affected source that contains chlorine gas at a concentration of at least 5 percent by volume. You may identify equipment by a list or on a process or piping diagram. You may exclude equipment that is under negative pressure.

(2) You must install ambient chlorine sensors at the mercury cell chlor-alkali production facility affected source to measure the ambient chlorine concentration.

(i) Ambient chlorine sensors must have a detection limit of 0.5 ppmv or less.

(ii) The sensors must be operated continuously to obtain a measurement at least once each 15 minutes.

(iii) You must identify the location of the sensors by a list or on a process or piping diagram.

(iv) You must operate, calibrate, and maintain these sensors in accordance with manufacturer instructions.

(v) You must keep the necessary parts for routine repairs of the sensors readily available.

(3) You must perform inspections to identify leaks of chlorine using olfactory observations according to the schedules in paragraphs (h)(3)(i) and (ii) of this section. A leak is detected when there is an olfactory observation of a leak. If a leak is detected, you must comply with the repair provisions in paragraph (h)(4) of this section.

(i) At least once each 12 hours, you must inspect each piece of equipment located throughout the mercury cell chlor-alkali production facility affected source that contains chlorine gas at a concentration of greater than 5 percent by volume for chlorine leaks, excluding equipment that is under negative pressure.

(ii) Within 1 hour of detection of a 1-hour average chlorine concentration of 2 ppmv or greater by a sensor installed and operated in accordance with paragraph (h)(2) of this section, you must inspect each piece of equipment located throughout the mercury cell chlor-alkali production facility affected source that contains chlorine gas at a concentration of greater than 5 percent by volume for chlorine leaks, excluding equipment that is under negative pressure.

(4) You must undertake a first attempt at repair no later than 1 hour after the leak is detected, and the leak must be repaired no later than 72 hours after the leak is detected. A leak is repaired when there is no olfactory observation of a leak.

■ 9. Section 63.8222 is revised to read as follows:

§ 63.8222 What are my operation and maintenance requirements?

At all times you must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require you to make any further efforts to reduce emissions if levels required by the applicable standards have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, reports and inspection of the source.

■ 10. Section 63.8226 is revised to read as follows:

§ 63.8226 What are my general requirements for complying with this subpart?

(a) Until November 7, 2022, you must be in compliance with the applicable emission limitations in § 63.8190 and the applicable work practice standards in § 63.8192 at all times, except during periods of startup, shutdown, and malfunction.

(b) Until November 7, 2022, you must develop and operate as specified by a written startup, shutdown, and malfunction plan (SSMP) according to the provisions in § 63.6(e)(3).

(c) On and after November 7, 2022, the provisions of paragraphs (a) and (b) of this section no longer apply, and you must be in compliance with the applicable emission limitations in § 63.8190 and the applicable work practice standards in § 63.8192 at all times.

■ 11. Section 63.8232 is amended by revising the introductory text and paragraph (a) and adding paragraph (g) to read as follows:

§ 63.8232 What test methods and other procedures must I use to demonstrate initial compliance with the emission limits?

You must conduct a performance test for each by-product hydrogen stream, end box ventilation system vent, and mercury thermal recovery unit vent according to the conditions detailed in paragraphs (a) through (d) of this section.

(a) You must conduct each performance test under conditions representative of normal operations. You may not conduct performance tests during periods of startup, shutdown, or malfunction. You must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, you shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

* * * * *

(g) Within 60 days after the date of completing each performance test specified in this section, you must submit the results of the performance test following the procedures specified in paragraphs (g)(1) through (3) of this section.

(1) *Data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert) at the time of the test.* Submit the results of the performance test to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI), which can be accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*). The data must be submitted in a file format generated using the EPA's ERT. Alternatively, you may submit an electronic file consistent with the extensible markup language (XML) schema listed on the EPA's ERT website.

(2) *Data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test.* The results of the performance test must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(3) *Confidential business information (CBI).* Do not use CEDRI to submit information you claim as CBI. Anything submitted using CEDRI cannot later be claimed CBI. Although we do not expect persons to assert a claim of CBI, if you wish to assert a CBI claim for some of the information submitted under paragraph (g)(1) or (2) of this section, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated using the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraphs (g)(1) and (2) of this section. All CBI claims must be asserted at the time of submission. Furthermore, under CAA section 114(c), emissions data is not entitled to confidential treatment, and the EPA is required to make emissions data available to the public. Thus, emissions data will not be protected as CBI and will be made publicly available.

■ 12. Section 63.8236 is amended by revising paragraph (c) introductory text and adding paragraphs (e) and (f) to read as follows:

§ 63.8236 How do I demonstrate initial compliance with the emission limitations and work practice standards?

* * * * *

(c) Prior to the compliance date specified in § 63.8186(a)(2), for each affected source, you have demonstrated initial compliance with the applicable work practice standards in § 63.8192 if you comply with paragraphs (c)(1) through (7) of this section.

* * * * *

(e) On and after the compliance date specified in § 63.8186(a)(2), for each affected source, you have demonstrated initial compliance with the applicable work practice standards for mercury emissions in § 63.8192(a) through (c) and (e) through (g) if you comply with paragraphs (e)(1) through (4) of this section.

(1) You have submitted a Revised Notification of Compliance Status containing the results of the initial compliance demonstration according to the requirements in § 63.8252(f).

(2) You certify in your Revised Notification of Compliance Status that you are operating according to the work practice standards for mercury emissions in § 63.8192(a) through (c), (e), and (f).

(3) You have submitted your cell room monitoring plan as part of your Revised Work Practice Notification of Compliance Status and you certify in your Revised Notification of Compliance Status that you are operating according to the continuous cell room monitoring program under § 63.8192(g).

(4) You have re-submitted your washdown plan as part of your Revised Notification of Compliance Status and you re-certify in your Revised

Notification of Compliance Status that you are operating according to your washdown plan under § 63.8192(e).

(f) On and after the compliance date specified in § 63.8186(a)(2), for each affected source, you have demonstrated initial compliance with the applicable work practice standards for chlorine emissions in § 63.8192(h) if you meet the requirements of paragraphs (f)(1) through (3) of this section.

(1) You have installed chlorine sensors in accordance with § 63.8192(h)(2).

(2) You have certified in your Revised Notification of Compliance Status that you are operating according to the work practice standards in § 63.8192(h).

(3) You have submitted your Revised Notification of Compliance Status containing the results of the initial compliance demonstration according to the requirements in § 63.8252(f).

■ 13. Section 63.8242 is amended by revising the section heading and paragraphs (a)(2) and (a)(3)(v) to read as follows:

§ 63.8242 What are the installation, operation, and maintenance requirements for my continuous mercury monitoring systems?

(a) * * *

(2) Each mercury continuous emissions monitor analyzer must have a detector with the capability to detect a mercury concentration of either 0.1 μg/m^3 or 0.5 times the mercury concentration level measured during the performance test conducted according to § 63.8232.

(3) * * *

(v) Ongoing data quality assurance procedures according to the requirements of § 63.8(d)(1) and (2). You shall keep these written procedures on record for the life of the affected source or until the affected source is no longer subject to the provisions of this part, to be made available for inspection, upon request, by the Administrator. If the performance evaluation plan is revised, you shall keep previous (*i.e.,* superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Administrator, for a period of 5 years after each revision to the plan. The program of corrective action shall be included in the plan required under § 63.8(d)(2).

* * * * *

■ 14. Section 63.8246 is amended by revising paragraphs (b)(1) introductory text and (c) and adding paragraph (d) to read as follows:

§ 63.8246 How do I demonstrate continuous compliance with the emission limitations and work practice standards?

* * * * *

(b) * * *

(1) For each mercury thermal recovery unit vent, you must demonstrate continuous compliance with the applicable emission limit specified in § 63.8190(a)(3) by maintaining the outlet mercury daily-average concentration no higher than the applicable limit. To determine the outlet mercury concentration, you must monitor according to paragraph (b)(1)(i) or (ii) of this section.

* * * * *

(c) You must demonstrate continuous compliance with the applicable work practice standards for mercury emissions in § 63.8192 by maintaining records in accordance with § 63.8256(c) and (e).

(d) You must demonstrate continuous compliance with the applicable work practice standards for chlorine emissions in § 63.8192(h) by continuously operating the chlorine sensors required by § 63.8192(h)(2), inspecting equipment in accordance with § 63.8192(h)(3), repairing equipment in accordance with § 63.8192(h)(4) and maintaining records in accordance with § 63.8256(f).

■ 15. Section 63.8248 is amended by revising paragraphs (a) introductory text, (a)(1) and (2), and (2), and adding paragraph (b) introductory text to read as follows:

§ 63.8248 What other requirements must I meet?

(a) *Deviations.* The instances specified in paragraphs (a)(1) through (4) of this section are deviations and must be reported according to the requirements in § 63.8254 and recorded according to the requirements in § 63.8256(a)(2).

(1) You must report each instance in which you did not meet each emission limitation in § 63.8190 that applies to you.

(2) You must report each instance in which you did not meet each work practice standard in § 63.8192 that applies to you.

* * * * *

(b) * * * The provisions of paragraphs (b)(1) through (3) of this section apply until November 7, 2022. On and after November 7, 2022, the provisions of paragraphs (b)(1) through (3) of this section no longer apply.

* * * * *

■ 16. Section 63.8252 is amended by revising paragraphs (d) and (e)(1)(i) and adding paragraphs (f) through (h) to read as follows:

§ 63.8252 What notifications must I submit and when?

* * * * *

(d) For each performance test that you are required to conduct for by-product hydrogen streams and end box ventilation system vents and for mercury thermal recovery unit vents, you must submit a notification of intent to conduct a performance test at least 60 calendar days before the performance test is scheduled to begin as required in § 63.7(b)(1).

(e) * * *

(1) * * *

(i) If you choose not to implement a cell room monitoring program according to § 63.8192(g), a certification that you are operating according to the applicable work practice standards for mercury emissions in § 63.8192(a) through (d) and your floor-level mercury vapor measurement plan required by § 63.8192(d).

* * * * *

(f) You must submit a Revised Notification of Compliance Status before the close of business on the date 30 days after the compliance date in § 63.8186(a)(2) containing the items in paragraphs (f)(1) through (5) of this section:

(1) A certification that you are operating according to the work practice standards for mercury emissions in § 63.8192(a) through (c) and (e) through (g).

(2) Your cell room monitoring plan, including your initial action level determined in accordance with § 63.8192(g)(2), and a certification that you are operating according to the continuous cell room monitoring program under § 63.8192(g).

(3) Your washdown plan, and a certification that you are operating according to your washdown plan under § 63.8192(e).

(4) Records of the mass of virgin mercury added to cells for every year since 2001.

(5) A certification that you have installed chlorine sensors in accordance with § 63.8192(h)(2) and that you are operating according to the work practice standards for chlorine emissions in § 63.8192(h).

(g) You must submit all subsequent Notification of Compliance Status reports and Revised Notification of Compliance Status reports in PDF format to the EPA via CEDRI, which can be accessed through EPA's CDX (*https://cdx.epa.gov/*).

(h) You must submit a notification of compliance with the prohibition of mercury emissions as specified in paragraphs (e)(1) and (2) of this section.

(1) The notification must include the information specified in paragraph (e)(1)(i) and (ii) of this section.

(i) A certification that the requirement of § 63.8190(a)(2)(ii) has been met.

(ii) A brief explanation of how the requirement of § 63.8190(a)(2)(ii) has been met.

(2) You must submit this notification before the close of business on the 30th calendar day following the date when compliance with § 63.8190(a)(2)(ii) is attained.

■ 17. Section 63.8254 is amended by:
■ a. Revising paragraph (b) introductory text;
■ b. Removing and reserving paragraph (b)(4);
■ c. Revising paragraphs (b)(7) through (9);
■ d. Adding paragraphs (b)(13) and (14);
■ e. Removing and reserving paragraph (c); and
■ f. Adding paragraph (e).

The revisions and additions read as follows:

§ 63.8254 What reports must I submit and when?

* * * * *

(b) *Compliance report contents.* Each compliance report must contain the information in paragraphs (b)(1) through (3) of this section, and as applicable, paragraphs (b)(5) through (13) of this section.

* * * * *

(7) For each deviation from the requirements for work practice standards in § 63.8192, the information in paragraphs (b)(7)(i) and (ii) of this section.

(i) For each deviation from the mercury work practice standards in Tables 1 through 4 to this subpart that occurs at an affected source (including deviations where the response intervals were not adhered to as described in § 63.8192(b)), each deviation from the cell room monitoring program monitoring and data recording requirements in § 63.8192(g)(3), and each deviation from the response intervals required by § 63.8192(g)(4) when an action level is exceeded, the compliance report must contain the information in paragraphs (b)(1) through (3) of this section and the information in paragraphs (b)(7)(i)(A) through (C) of this section.

(A) The total operating time of each affected source during the reporting period.

(B) Information on the number, date, time, duration, and cause of deviations (including unknown cause, if applicable), as applicable, and the corrective action taken.

(C) A list of the affected sources or equipment.

(ii) For each deviation from the fugitive chlorine requirements in § 63.8192(h), including periods when the chlorine sensors required by § 63.8192(h)(2) were not operating; instances where the chlorine sensors required by § 63.8192(h)(2) were not calibrated and maintained in accordance with manufacturer instructions or spare parts were not maintained; instances where inspections were not performed in accordance with § 63.8192(h)(3)(i) and (ii); and instances where leak repair intervals in § 63.8192(h)(4) were not met; the compliance report must contain the information in paragraphs (b)(1) through (3) of this section and the information in paragraphs (b)(7)(ii)(A) through (C) of this section.

(A) The total operating time of each affected source during the reporting period.

(B) Information on the number, date, time, duration, and cause of deviations (including unknown cause, if applicable), as applicable, and the corrective action taken.

(C) A list of the affected sources or equipment.

(8) For each deviation from an emission limitation occurring at an affected source where you are using a mercury continuous emission monitor, according to the site-specific monitoring plan required in § 63.8242(a)(3), to comply with the emission limitation in this subpart, you must include the information in paragraphs (b)(1) through (3) of this section and the information in paragraphs (b)(8)(i) through (xv) of this section.

(i) A list of the affected sources and equipment.

(ii) The date and time that each deviation started and stopped.

(iii) For each deviation, the cause of the deviation (including unknown cause, if applicable), as applicable, and corrective action taken.

(iv) For each deviation, an estimate of the quantity of each regulated pollutant emitted over any emission limit.

(v) A description of the method used to estimate the emissions.

(vi) The date and time of each instance in which a continuous monitoring system was inoperative, except for zero (low-level) and high-level checks.

(vii) The date, time, and duration of each instance in which a continuous monitoring system was out-of-control, including the information in § 63.8(c)(8).

(viii) A summary of the total duration of the deviation during the reporting period and the total duration as a percent of the total source operating time during that reporting period.

(ix) A breakdown of the total duration of the deviations during the reporting period including those that are due to control equipment problems, process problems, other known causes, and other unknown causes.

(x) A summary of the total duration of continuous monitoring system downtime during the reporting period and the total duration of monitoring system downtime as a percent of the total source operating time during the reporting period.

(xi) An identification of each hazardous air pollutant that was monitored at the affected source.

(xii) A brief description of the process units.

(xiii) A brief description of the continuous monitoring system.

(xiv) The date of the latest continuous monitoring system certification or audit.

(xv) A description of any changes in monitoring system, processes, or controls since the last reporting period.

(9) For each deviation from an operation and maintenance standard occurring at an affected source where you are using the periodic monitoring option specified in § 63.8240(b) and your final control device is not a nonregenerable carbon adsorber, the compliance report must include the information in paragraphs (b)(1) through (3) of this section and the information in paragraphs (b)(9)(i) through (xiii) of this section.

(i) A list of the affected sources or equipment.

(ii) The total operating time of each affected source during the reporting period.

(iii) Information on the number, duration, and cause of deviations (including unknown cause, if applicable), as applicable, and the corrective action taken.

(iv) For each deviation, an estimate of the quantity of each regulated pollutant emitted over any emission limit.

(v) A description of the method used to estimate the emissions.

(vi) The date and time of each instance in which a CPMS was inoperative, except for zero (low-level) and high-level checks.

(vii) The date, time, and duration of each instance in which a CPMS was out-of-control, including the information specified in § 63.8(c)(8).

(viii) A summary of the total duration of the deviation during the reporting period and the total duration as a percent of the total source operating time during that reporting period.

(ix) A breakdown of the total duration of the deviations during the reporting

period including those that are due to control equipment problems, process problems, other known causes, and other unknown causes.

(x) A summary of the total duration of continuous monitoring system downtime during the reporting period and the total duration of monitoring system downtime as a percent of the total source operating time during the reporting period.

(xi) A brief description of the CPMS.

(xii) The date of the latest CPMS certification or audit.

(xiii) A description of any changes in monitoring system, processes, or controls since the last reporting period.

* * * * *

(13) The compliance report must contain the information specified in paragraphs (b)(13)(i) through (iii) for each instance where the 1-hour average concentration of chlorine detected by a chlorine sensor required by § 63.8192(h)(2) was 2 ppmv or greater.

(i) The date and times a chlorine sensor detected chlorine concentrations of 2 ppmv or greater.

(ii) The location of the sensor.

(iii) The date and time that the sensor returned to a 1-hour average concentration of less than 2 ppmv.

(14) The compliance report must contain the information specified in paragraphs (b)(14)(i) and (ii) for all inspections conducted under either § 63.8192(h)(3)(i) or (ii). You must also record the information in paragraphs (b)(14)(iii) through (vii) of this section for each leak identified.

(i) The date of each inspection.

(ii) The reason for each inspection (*i.e.,* a routine inspection conducted each 12 hours or an inspection conducted in response to a 2 ppmv or greater 1-hour average concentration of chlorine, as detected by a sensor).

(iii) Location of the leak.

(iv) Date and time the leak was identified.

(v) Date and time of initial repair attempt.

(vi) Date and time the leak is repaired.

(vii) A description of the repair made to stop the leak.

* * * * *

(e) The owner or operator must submit semiannual compliance reports in PDF formatto the EPA viaCEDRI, which can be accessedthrough EPA's CDX (*https://cdx.epa.gov/*).

■ 18. Section 63.8256 is amended by revising paragraphs (a)(2) and (c) introductory text and adding paragraphs (e) and (f) to read as follows:

§ 63.8256 What records must I keep?

(a) * * *

(2) The records specified in paragraphs (a)(2)(i) and (ii) of this section related to deviations.

(i) Record actions taken to minimize emissions in accordance with § 63.8222 and any corrective actions taken to return the affected unit to its normal or usual manner of operation.

(ii) Records of the information reported as required in § 63.8254(b)(7) through (9) and (11) through (13).

* * * * *

(c) Records associated with the work practice standards for mercury emissions that must be kept prior to the compliance date in § 63.8186(a)(2).

* * * * *

(e) Records associated with the work practice standards for mercury emissions that must be kept after the compliance date in § 63.8186(a)(2).

(1) The records specified in Table 9 to this subpart related to the work practice standards in Tables 1 through 4 of this subpart.

(2) You must maintain a copy of your current washdown plan and records of when each washdown occurs.

(3) You must maintain records of the mass of virgin mercury added to cells for each reporting period.

(4) You must keep your current cell room monitoring plan and the records specified in paragraphs (e)(4)(i) through (v) of this section.

(i) Records of the monitoring conducted in accordance with § 63.8192(g)(2)(i) to establish your action level, and records demonstrating the development of this action level.

(ii) Records of the cell room mercury concentration monitoring data collected.

(iii) Instances when the action level is exceeded.

(iv) Records specified in § 63.8192(g)(4)(i) for maintenance activities that cause the mercury vapor concentration to exceed the action level.

(v) Records of all inspections and corrective actions taken in response to a non-maintenance related situation in which the mercury vapor concentration exceeds the action level.

(f) You must keep the records specified in paragraphs (f)(1) through (4) of this section associated with the work practice standards for fugitive chlorine emissions specified in § 63.8192(h) after the compliance date in § 63.8186(a)(2).

(1) Identification of all equipment in the mercury cell chlor-alkali production facility affected source containing chlorine gas at a concentration of greater than 5 percent by volume. You may exclude equipment that is under negative pressure.

(2) Records of the information reported as required in § 63.8254(b)(13) and (14).

(3) You must record the information specified in paragraphs (f)(3)(i) through (iv) of this section for the chlorine sensors required by § 63.8192(h)(2).

(i) The location, manufacturer, and model number of each sensor.

(ii) The manufacturer's instructions for operation, maintenance, and calibration of the chlorine sensors.

(iii) Records of all maintenance and calibration of the chlorine sensors.

(iv) You must record all periods when the chlorine sensors are not operating.

(4) You must maintain records of all chlorine concentration measurements.

■ 19. Section 63.8262 is revised to read as follows:

§ 63.8262 What parts of the General Provisions apply to me?

Table 10 to this subpart shows which parts of the General Provisions in §§ 63.1 through 63.13 apply to you.

■ 20. Section 63.8264 is amended by revising paragraph (c) introductory text and adding paragraph (c)(5) to read as follows:

§ 63.8264 Who implements and enforces this subpart?

* * * * *

(c) The authorities in paragraphs (c)(1) through (5) of this section will not be delegated to State, local, or tribal agencies.

* * * * *

(5) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

■ 21. Section 63.8266 is amended by revising the definition of ''Deviation'' to read as follows:

§ 63.8266 What definitions apply to this subpart?

* * * * *

Deviation means any instance in which an affected source subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart including, but not limited to, any emission limitation (including any operating limit) or work practice standard (including any monitoring plan);

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the title V operating permit for any affected source required to obtain such a permit; or

(3) Fails to take corrective actions within 48 hours that result in parameter monitoring values being within range.

* * * * *

■ 22. Table 5 to subpart IIIII of part 63 is amended by revising the introductory text to read as follows:

Table 5 to Subpart IIIII of Part 63—Required Elements of Floor-Level Mercury Vapor Measurement and Cell Room Monitoring Plans

Your Floor-Level Mercury Vapor Measurement Plan required by § 63.8192(d) prior to the applicable compliance date specified in § 63.8186(a)(2) and Cell Room Monitoring Plan required by § 63.8192(g) must contain the elements listed in the following table:

* * * * *

■ 23. Table 10 to subpart IIIII of part 63 is revised to read as follows:

Table 10 to Subpart IIIII of Part 63—Applicability of General Provisions to Subpart IIIII

As stated in § 63.8262, you must comply with the applicable General Provisions requirements according to the following table:

Citation	Subject	Applies to subpart IIIII	Explanation
§ 63.1	Applicability	Yes.	
§ 63.2	Definitions	Yes.	
§ 63.3	Units and Abbreviations	Yes.	
§ 63.4	Prohibited Activities	Yes.	
§ 63.5	Construction/Reconstruction	Yes.	
§ 63.6(a)–(g), (i), (j), except for (e)(1)(i) and (ii), (e)(3), and (f)(1).	Compliance with Standards and Maintenance Requirements.	Yes.	
§ 63.6(e)(1)(i) and (ii), (e)(3), and (f)(1)	SSM Requirements	Yes	Only applies until the date specified in § 63.8186(a)(3).
§ 63.6(h)	Compliance with Opacity and Visible Emission Standards.	No	Subpart IIIII does not have opacity and visible emission standards.
§ 63.7(a)–(h), except for (a)(2) and (e)(1)	Performance Testing Requirements	Yes	Subpart IIIII specifies additional requirements related to site-specific test plans and the conduct of performance tests.
§ 63.7(a)(2)	Applicability and Performance Test Dates	No	Subpart IIIII requires the performance test to be performed on the compliance date.
§ 63.7(e)(1)	Performance Test Conditions	No	See § 63.8232(a).
§ 63.8(a)(1), (a)(3); (b); (c)(1)(ii), (2)–(4), (6)–(8); (d)(1)–(2); (e); and (f)(1)–(5).	Monitoring Requirements	Yes	Only applies for CEMS, except Subpart IIIII specifies how and when the performance evaluation results are reported.
§ 63.8(a)(2)	Continuous Monitoring System (CMS) Requirements.	No	Subpart IIIII requires a site-specific monitoring plan in lieu of a promulgated performance specification for a mercury concentration CMS.
§ 63.8(a)(4)	Additional Monitoring Requirements for Control Devices in § 63.11.	No	Subpart IIIII does not require flares.
§ 63.8(c)(1)(i) and (iii)	CMS Operation and SSM Plan	Yes	Only applies until the date specified in § 63.8186(a)(3).
§ 63.8(c)(5)	COMS Minimum Procedures	No	Subpart IIIII does not have opacity and visible emission standards.
§ 63.8(d)(3)	Written Procedures for CMS	No	See § 63.8242(a)(3)(v).
§ 63.8(f)(6)	Alternative to Relative Accuracy Test	No	Subpart IIIII does not require CEMS.
§ 63.8(g)	Data Reduction	No	Subpart IIIII specifies mercury concentration CMS data reduction requirements.
§ 63.9(a)–(e), (g)–(j)	Notification Requirements	Yes.	
§ 63.9(f)	Notification of VE/Opacity Test	No	Subpart IIIII does not have opacity and visible emission standards.
§ 63.9(k)	Electronic reporting procedures	Yes	Only as specified in § 63.9(j).
§ 63.10(a); (b)(1); (b)(2)(vi)–(xii), (xiv); (b)(3); (c)(1)–(14); (d)(1), (4); (e); (f).	Recordkeeping/Reporting	Yes.	
§ 63.10(b)(2)(i)–(v)	Recordkeeping/Reporting Associated with Startup, Shutdown, and Malfunctions.	Yes	Only applies until the date specified in § 63.8186(a)(3).
§ 63.10(b)(2)(xiii)	CMS Records for RATA Alternative	No	Subpart IIIII does not require CEMS.
§ 63.10(c)(15)	Use of SSM Plan	Yes	Only applies until the date specified in § 63.8186(a)(3).
§ 63.10(d)(2)	Performance Test Results	No	This subpart at 63.8232(g) specifies how and when the performance test results are reported electronically.
§ 63.10(d)(3)	Reporting Opacity or VE Observations	No	Subpart IIIII does not have opacity and visible emission standards.
§ 63.10(d)(5)	Startup, Shutdown, and Malfunction Reports.	No.	
§ 63.10(e)(2)(i)	CEM Reporting	Yes	Except this subpart specifies how and when the performance evaluation results are reported.
§ 63.11	Flares	No	Subpart IIIII does not require flares.
§ 63.12	Delegation	Yes.	
§ 63.13	Addresses	Yes.	
§ 63.14	Incorporation by Reference	Yes.	
§ 63.15	Availability of Information	Yes.	

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Proposed Rules

Federal Register
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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.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20, 26, 50, 51, 52, 72, 73, and 140

[NRC–2015–0070]

RIN 3150–AJ59

Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning: Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule; correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is correcting a proposed rule that was published in the **Federal Register** on March 3, 2022. The proposed rule would amend the NRC's regulations that relate to the decommissioning of production and utilization facilities to maintain a safe, effective, and efficient decommissioning process; reduce the need for license amendment requests and exemptions from existing regulations; address other decommissioning issues deemed relevant by the NRC; and support the NRC's Principles of Good Regulation. This action is necessary to correct a reference.

DATES: The correction takes effect on May 6, 2022.

ADDRESSES: Please refer to Docket ID NRC–2015–0070 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2015–0070. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.*
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *pdr.resource@nrc.gov.*
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Dawn Forder, Office of Nuclear Material Safety and Safeguards; U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3407, email: *Dawn.Forder@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** (FR) on March 3, 2022, in proposed rule FR Doc. 2022–03131, the following corrections are made:

1. On page 12301, under ''O. Removal of License Conditions and Withdrawal of Orders,'' in the center column, beginning with the first full sentence through the end of the paragraph, the text is corrected to read, ''The Mitigation of Beyond-Design-Basis Events rule subsequently moved § 50.54(hh)(2) to § 50.155(b)(2). As a result, neither Order EA–06–137 nor the license condition is necessary. Accordingly, the NRC proposes finding that good cause is shown to rescind Order EA–06–137 for each licensee that received the order. In addition, because § 50.155(b)(2) provides the same requirements as the license condition associated with Order EA–06–0137, the NRC proposes deeming the license condition removed from each applicable nuclear power reactor license.''

2. On page 12301, under ''O. Removal of License Conditions and Withdrawal of Orders,'' in the center column, beginning with the last sentence through the third column, end of the first paragraph, the text is corrected to read, ''Because licensees comply with both the regulations and Mitigation Strategy License Condition via the same guidance, such that the former § 50.54(hh)(2) requirements encompass the license condition requirements, the NRC proposes concluding that § 50.155(b)(2) fully replaces the requirements that exist in the Mitigation Strategy License Condition and deeming that the Mitigation Strategy License Conditions imposed in 2007 are removed from the licenses for those licensees that received that license condition.''

Dated: May 3, 2022.

Cindy K. Bladey,

Chief, Regulatory Analysis and Rulemaking Support Branch, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2022–09832 Filed 5–5–22; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF ENERGY

10 CFR Part 431

[EERE–2022–BT–TP–0019]

RIN 1904–AF08

Energy Conservation Program: Test Procedure for Compressors

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Request for information (''RFI'').

SUMMARY: The U.S. Department of Energy (''DOE'') is initiating a review through this RFI to consider whether to amend DOE's test procedure for compressors. To inform interested parties and to facilitate this process, DOE has identified certain issues associated with the currently applicable test procedure on which DOE is interested in receiving comment. The issues outlined in this document mainly concern the scope of coverage, updated industry test procedures and the accuracy, representativeness and cost of existing test requirements. DOE welcomes written comments from the public on any subject within the scope of this document (including topics not raised in this RFI), as well as the submission of data and other relevant information.

DATES: Written comments and information are requested and will be accepted on or before June 6, 2022.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov,* under docket number EERE–2022–BT–TP–0019. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments by email to *Compressors2022TP0019@ee.doe.gov.* Include docket number EERE–2022–BT–TP–0019 in the subject line of the message. No telefacsimiles (''faxes'') will be accepted. For detailed instructions on submitting comments and additional information on this process, see section IV of this document.

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including postal mail and hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing coronavirus 2019 (''COVID–19'') pandemic. DOE is currently suspending receipt of public comments via postal mail and hand delivery/courier. If a commenter finds that this change poses an undue hardship, please contact Appliance Standards Program staff at (202) 586–1445 to discuss the need for alternative arrangements. Once the COVID–19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at: *www.regulations.gov/docket/EERE-2022-BT-TP-0019.* The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section III of this document for information on how to submit comments through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Mr. Jeremy Dommu, 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. Telephone: (202) 586–9870. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Ms. Celia Sher, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–6122. Email: *celia.sher@hq.doe.gov.*

For further information on how to submit a comment or review other public comments and the docket, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

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I. Introduction

Compressors are among the consumer and industrial equipment for which DOE is authorized to establish and amend test procedures and energy conservation standards. (42 U.S.C. 6311(2)) DOE's test procedures for compressors are prescribed at title 10 of the Code of Federal Regulations (''CFR'') 431.344 and appendix A to subpart T of part 431. The following sections discuss DOE's authority to establish and amend test procedures for compressors, as well as relevant background information regarding DOE's consideration of test procedures for this equipment.

A. Authority and Background

The Energy Policy and Conservation Act, as amended (''EPCA''),[1] authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part C[2] of EPCA, added by Public Law 95–619, Title IV, § 441(a) (42 U.S.C. 6311–6317 as codified), established the Energy Conservation Program for Certain Industrial Equipment, which sets forth a variety of provisions designed to improve energy efficiency. Under EPCA, DOE may include a type of industrial equipment, including compressors, as covered equipment if it determines that to do so is necessary to carry out the purposes of Part A–1. (42 U.S.C. 6311(1)(L), 42 U.S.C. 6311(2)(B)(i), and 42 U.S.C. 6312(b)). The purpose of Part A–1 is to improve the efficiency of electric motors and pumps and certain other industrial equipment in order to conserve the energy resources of the Nation. (42 U.S.C. 6312(a)) On November 15, 2016, DOE published a final rule, which determined that coverage for compressors is necessary to carry out the purposes of Part A–1 of Title III of EPCA. 81 FR 79991. (42 U.S.C. 6311(1)(L); 42 U.S.C. 6311 (2)(A); 42 U.S.C. 6311 (2)(B)(i))

The energy conservation program under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA include definitions (42 U.S.C. 6311), test procedures (42 U.S.C. 6314), labeling provisions (42 U.S.C. 6315), energy conservation standards (42 U.S.C. 6313), and the authority to require information and reports from manufacturers (42 U.S.C. 6316; 42 U.S.C. 6296).

Federal energy efficiency requirements for covered equipment established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6316(a) and 42 U.S.C. 6316(b); 42 U.S.C. 6297).) DOE may, however, grant waivers of Federal preemption in limited instances for particular State laws or regulations, in accordance with the procedures and other provisions set forth under 42 U.S.C. 6316(b)(2)(D).

The Federal testing requirements consist of test procedures that manufacturers of covered equipment must use as the basis for: (1) Certifying to DOE that their equipment complies with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6316(a); 42 U.S.C. 6295(s)), and (2) making other representations about the efficiency of that equipment (42 U.S.C. 6314(d)). Similarly, DOE must use these test procedures to determine whether the equipment complies with relevant standards promulgated under EPCA. (42 U.S.C. 6316(a); 42 U.S.C. 6295(s))

EPCA also requires that, at least once every 7 years, DOE evaluate test procedures for each type of covered equipment, including compressors, to determine whether amended test procedures would more accurately or fully comply with the requirements for the test procedures to not be unduly burdensome to conduct and be reasonably designed to produce test results that reflect energy efficiency,

[1] All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020), which reflect the last statutory amendments that impact Parts A and A–1 of EPCA.

[2] For editorial reasons, upon codification in the U.S. Code, Part C was redesignated Part A–1.

energy use, and estimated operating costs during a representative average use cycle. (42 U.S.C. 6314(a)(1)) In addition, if the Secretary determines that a test procedure amendment is warranted, the Secretary must publish proposed test procedures in the **Federal Register**, and afford interested persons an opportunity (of not less than 45 days' duration) to present oral and written data, views, and arguments on the proposed test procedures. (42 U.S.C. 6314(b)) If DOE determines that test procedure revisions are not appropriate, DOE must publish its determination not to amend the test procedures. DOE is publishing this RFI to collect data and information to inform its decision in satisfaction of the 7-year review requirement specified in EPCA. (42 U.S.C. 6314(a)(1)).

B. Rulemaking History

As stated, DOE published a final rule on November 15, 2016, in which DOE determined that coverage of compressors is necessary to carry out the purposes of Part A–1 of Title III of EPCA. 81 FR 79991. DOE's test procedure for determining compressor energy efficiency of certain varieties of compressors was established in a final rule published on January 4, 2017. 82 FR 1052. The test procedure is codified in 10 CFR 431.344 and appendix A to subpart T of part 431.

The compressor test procedure currently adopts through reference certain sections of the ISO Standard 1217:2009(E) ''Displacement compressors—Acceptance tests'' and accompanying ISO standard 1217:2009/Amd.1:2016(E) ''Displacement compressors—Acceptance tests (Fourth edition); Amendment 1: Calculation of isentropic efficiency and relationship with specific energy,'' (''ISO 1217:2009(E)'') in conjunction with the additional clarifications and test methods and calculations established in the final rule. 82 FR 1052, 1054.

II. Request for Information

In the following sections, DOE has identified a variety of issues on which it seeks input to aid in its analysis of whether an amended test procedure for compressors would more accurately or fully comply with the requirement in EPCA that the test procedure produces results that measure energy use during a representative average use cycle for the product, and not be unduly burdensome to conduct. (42 U.S.C. 6314(a)(2)) Additionally, DOE welcomes comments on any aspect of the existing test procedures for compressors and on other relevant issues that may not specifically be identified in this document.

A. Scope and Definitions

A compressor is a machine or apparatus that converts different types of energy into the potential energy of gas pressure for displacement and compression of gaseous media to any higher pressure values above atmospheric pressure and has a pressure ratio at full-load operating pressure greater than 1.3. 10 CFR 431.342.

DOE's test procedure applies to compressors that meet the following criteria:

(1) Is an air compressor;

(2) Is a rotary compressor;

(3) Is not a liquid ring compressor;

(4) Is driven by a brushless electric motor;

(5) Is a lubricated compressor;

(6) Has a full-load operating pressure greater than or equal to 75 pounds per square inch gauge (psig) and less than or equal to 200 psig;

(7) Is not designed and tested to the requirements of the American Petroleum Institute Standard 619, ''Rotary-Type Positive-Displacement Compressors for Petroleum, Petrochemical, and Natural Gas Industries;''

(8) Has full-load actual volume flow rate greater than or equal to 35 cubic feet per minute (cfm), or is distributed in commerce with a compressor motor nominal horsepower greater than or equal to 10 horsepower (hp); and

(9) Has a full-load actual volume flow rate less than or equal to 1,250 cfm, or is distributed in commerce with a compressor motor nominal horsepower less than or equal to 200 hp. 10 CFR 431.344(a).

To support the scope of the compressor test method at appendix A to subpart T of part 431, DOE established the following definitions related to compressors:

Actual volume flow rate means the volume flow rate of air, compressed and delivered at the standard discharge point, referred to conditions of total temperature, total pressure and composition prevailing at the standard inlet point, and as determined in accordance with the test procedures prescribed in § 431.344.

Air compressor means a compressor designed to compress air that has an inlet open to the atmosphere or other source of air, and is made up of a compression element (bare compressor), driver(s), mechanical equipment to drive the compressor element, and any ancillary equipment.

Brushless electric motor means a machine that converts electrical power into rotational mechanical power without use of sliding electrical contacts.

Compressor motor nominal horsepower means the motor horsepower of the electric motor, as determined in accordance with the applicable procedures in subparts B and X of this part, with which the rated air compressor is distributed in commerce.

Full-load actual volume flow rate means the actual volume flow rate of the compressor at the full-load operating pressure.

Lubricated compressor means a compressor that introduces an auxiliary substance into the compression chamber during compression.

Positive displacement compressor means a compressor in which the admission and diminution of successive volumes of the gaseous medium are performed periodically by forced expansion and diminution of a closed space(s) in a working chamber(s) by means of displacement of a moving member(s) or by displacement and forced discharge of the gaseous medium into the high-pressure area.

Pressure ratio at full-load operating pressure means the ratio of discharge pressure to inlet pressure, determined at full-load operating pressure in accordance with the test procedures prescribed in § 431.344.

Rotary compressor means a positive displacement compressor in which gas admission and diminution of its successive volumes or its forced discharge are performed cyclically by rotation of one or several rotors in a compressor casing. 10 CFR 431.342.

Issue 1: DOE requests comment on the scope of the compressors test procedure, and on any developments in the industry that may warrant reexamination of the respective scope criteria.

Issue 2: DOE requests comment on the definitions related to the scope of the compressors test procedures, and whether any of the terms should be amended, and if so the reason for any such change and how the terms should be amended. In particular, DOE requests comment on whether the terms are sufficient to identify which equipment is subject to the test procedure and whether any test procedure amendments are required to ensure that all such equipment can be appropriately tested in accordance with the test procedure.

B. Test Procedure

DOE specifies package isentropic efficiency as the test metric for compressors. 10 CFR 431.464(b). Package isentropic efficiency is

determined at ''full-load'' and ''part-load,'' which respectively apply to fixed- and variable-speed compressors. 10 CFR 431.344(b).

1. Energy Use Measurements

As stated, the current DOE test procedure for compressors is codified in 10 CFR part 431, subpart T, appendix A. The test procedure provides for measuring the energy required by a compressor to compress a certain volume of air under specific conditions and divides that value by the energy that would be required by a thermodynamically idealized compressor performing an identical compression process with no increase in entropy.[3]

Issue 3: DOE seeks comment on whether existing test procedure requirements (*e.g.,* instrumentation, testing configurations/specifications, calculation methodologies) accurately measure energy use. DOE requests comment on the costs associated with the test procedure and whether amendments would reduce test cost while maintaining the representativeness of the results.

2. Representative Average Use Cycle

Compressors supply pressurized gas at pressure levels greater than ambient at flow rates matched to application demand. Accordingly, energy use varies as a function of the quantity of pressurized gas called for. The current DOE test procedure for compressors measures energy use during a representative average use cycle.

Issue 4: DOE seeks comment on what constitutes a representative average use cycle/period of use for compressors with distinction made, as appropriate, between fixed- and variable-speed compressors.

3. Updates to Industry Test Procedures

DOE's established practice is to adopt industry standards as DOE test procedures unless such methodology would be unduly burdensome to conduct or would not produce test results that reflect the energy efficiency, energy use, water use (as specified in EPCA) or estimated operating costs of that product during a representative average use cycle. 10 CFR 431.4; 10 CFR part 430 subpart C appendix A section 8(c). In cases where the industry testing standard does not meet the EPCA statutory criteria for test procedures, DOE will make any necessary modifications to these testing standards through the rulemaking process when adopting them for inclusion into DOE's regulations.

DOE's compressor test procedures incorporate certain sections of industry standard ISO 1217:2009(E), in conjunction with the additional detail and test methods and calculations established in the DOE test procedure. 10 CFR 431.343(b). ISO 1217:2009(E) was reviewed and reaffirmed by ISO in 2021 and remains current.[4]

Issue 5: DOE requests comment on ISO 1217:2009(E) and its associated amendment, ISO 1217:2009/Amd.1:2016(E), in the context of suitability for continued use as the basis of compressors test procedures and on any anticipated forthcoming updates.

III. Submission of Comments

DOE invites all interested parties to submit in writing by the date specified under the **DATES** heading, comments and information on matters addressed in this RFI and on other matters relevant to DOE's consideration of amended test procedures for compressors. These comments and information will aid in the development of a test procedure NOPR for compressors if DOE determines that amended test procedures may be appropriate for this equipment.

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 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. Following this instruction, 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 on 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. Faxes will not 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, written in English and 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.

[3] An idealized compressor would perform compression with no increase in entropy, which is commonly understood as disorder in a thermodynamic system and represents an irreversible loss of energy. In practice, all real compressors will cause a finite entropy increase.

[4] ISO 1217:2009. ''Displacement compressors — Acceptance tests''. Available at: *www.iso.org/standard/44769.html.* Accessed 2022–04–18.

Confidential Business Information. According 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).

DOE considers public participation to be a very important part of the process for developing test procedures and energy conservation standards. DOE actively encourages the participation and interaction of the public during the comment period in each stage of this process. Interactions with and between members of the public provide a balanced discussion of the issues and assist DOE in the process. Anyone who wishes to be added to the DOE mailing list to receive future notices and information about this process should contact Appliance and Equipment Standards Program staff at (202) 287–1445 or via email at *ApplianceStandardsQuestions@ee.doe.gov.*

Signing Authority

This document of the Department of Energy was signed on May 2, 2022, by Kelly J. Speakes-Backman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, 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 May 3, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–09810 Filed 5–5–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0505; Project Identifier MCAI–2021–01289–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus SAS Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes). This proposed AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by June 21, 2022.

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

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

For material that will be incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* internet: *www.easa.europa.eu.* You may find this material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0505.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0505; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3225; email: *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0505; Project Identifier MCAI–2021–01289–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3225; email: *dan.rodina@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0258, dated November 17, 2021 (EASA AD 2021–0258) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS Model A300–600 series airplanes.

This proposed AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is proposing this AD to prevent reduced structural integrity of the airplane.

EASA previously issued EASA AD 2019–0090, dated April 26, 2019 (EASA AD 2019–0090), requiring the actions described in the Airbus A300–600 Airworthiness Limitations Section (ALS), Part 2, ''Damage Tolerant Airworthiness Limitation Items (DT–ALI),'' Revision 03, dated December 14, 2018, which also includes the limit of validity (LOV) for the Model A300–600 airplanes. EASA AD 2019–0090 corresponds to FAA AD 2019–21–01, Amendment 39–19767 (84 FR 56935, October 24, 2019) (AD 2019–21–01). Since that EASA AD was issued, Airbus published the Variation, as defined in EASA AD 2021–0258, which reduces the LOV for Model A300–600 airplanes, reflecting the engineering data that supports the structural maintenance program and that corresponds to the period of time during which it is demonstrated that Widespread Fatigue Damage will not occur. EASA AD 2021–0258 does not supersede EASA AD 2019–0090, but does specify that it invalidates the LOV as specified in the Airbus A300–600 ALS, Part 2. Therefore, this proposed AD would replace the LOVs specified in Airbus A300–600 Airworthiness Limitations Section (ALS), Part 2, ''Damage Tolerant Airworthiness Limitation Items (DT–ALI),'' Revision 03, dated December 14, 2018, as required by FAA AD 2019–21–01.

For the reason described above, this AD requires compliance with the reduced LOV as specified in the variation. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0258 describes new or more restrictive airworthiness limitations for airplane LOVs. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, which are specified in EASA AD 2021–0258 described previously, as incorporated by reference. Any differences with EASA AD 2021–0258 are identified as exceptions in the regulatory text of this AD.

This proposed AD would require revisions to certain operator maintenance documents to include new actions. Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (j)(1) of this proposed AD.

As described in FAA Advisory Circular 120–104 (*https://www.faa.gov/documentLibrary/media/Advisory_Circular/120-104.pdf*), several programs have been developed to support initiatives that will ensure the continued airworthiness of aging airplane structure. The last element of those initiatives is the requirement to establish a LOV of the engineering data that support the structural maintenance program under 14 CFR 26.21. This proposed AD is the result of an assessment of the previously established programs by the design approval holder (DAH) during the process of establishing the LOV for the affected airplanes. The actions specified in this proposed AD are necessary to complete certain programs to ensure the continued airworthiness of aging airplane structure and to support an airplane reaching its LOV.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2021–0258 by reference in the FAA final rule. Service information required by EASA AD 2021–0258 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0505 after the FAA final rule is published.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes

airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in the AMOCs paragraph under ''Additional FAA Provisions.'' This new format includes a ''New Provisions for Alternative Actions and Intervals'' paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action or interval.

Costs of Compliance

The FAA estimates that this proposed AD would affect 110 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, the agency estimates the average total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus SAS: Docket No. FAA–2022–0505; Project Identifier MCAI–2021–01289–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by June 21, 2022.

(b) Affected ADs

This AD affects AD 2019–21–01, Amendment 39–19767 (84 FR 56935, October 24, 2019) (AD 2019–21–01).

(c) Applicability

This AD applies to all Airbus SAS Model A300 B4–601, B4–603, B4–620, B4–622 B4–605R, B4–622R, C4–605R Variant F, F4–605R, and F4–622R airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to prevent reduced structural integrity of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2021–0258, dated November 17, 2021 (EASA AD 2021–0258).

(h) Exceptions to EASA AD 2021–0258

(1) Where EASA AD 2021–0258 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph (1) of EASA AD 2021–0258 specifies ''This AD invalidates the LOV [limit of validity] as specified in Airbus A300–600 ALS Part 2 Revision 03 [EASA AD 2019–0090],'' this AD replaces the LOVs specified in paragraph 3.1 of Airbus A300–600 Airworthiness Limitations Section (ALS), Part 2, ''Damage Tolerant Airworthiness Limitation Items (DT–ALI),'' Revision 03, dated December 14, 2018, as required by FAA AD 2019–21–01.

(3) Paragraph (2) of EASA AD 2021–0258 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(4) The ''Remarks'' section of EASA AD 2021–0258 does not apply to this AD.

(i) Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2021–0258.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (k)(2) of this AD.

Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Related Information

(1) For EASA AD 2021–0258, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* internet: *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0505.

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

Issued on April 22, 2022.

Gaetano A. Sciortino,

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

[FR Doc. 2022–09419 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0503; Project Identifier MCAI–2021–01244–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2018–03–12, which applies to certain Airbus SAS Model A318 series airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2018–03–12 requires repetitive rototest inspections for cracking of the fastener holes in certain door stop fittings, and repair if necessary. Since the FAA issued AD 2018–03–12, new analysis by the manufacturer resulted in optimized compliance times for the inspections. This proposed AD would require repetitive rototest inspections for cracking of the fastener holes in certain door stop fittings at revised compliance times, and corrective actions if necessary, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by June 21, 2022.

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

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

For material that will be incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0503.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0503; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3229; email *vladimir.ulyanov@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0503; Project Identifier MCAI–2021–01244–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this

NPRM. Submissions containing CBI should be sent to Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3229; email *vladimir.ulyanov@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The FAA issued AD 2018–03–12, Amendment 39–19185 (83 FR 5906, February 12, 2018) (AD 2018–03–12), which applies to certain Airbus SAS Model A318 series airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2018–03–12 requires repetitive rototest inspections for cracking of the fastener holes in certain door stop fittings, and repair if necessary. The FAA issued AD 2018–03–12 to address cracking at the door stop fitting holes of fuselage frame (FR) 66 and FR68. Such cracking could result in reduced structural integrity of the airplane due to the failure of structural components.

Actions Since AD 2018–03–12 Was Issued

Since the FAA issued AD 2018–03–12, Airbus has revised the compliance times to accomplish the rototest inspections based on reports from operators and new analysis.

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0242, dated November 8, 2021 (EASA AD 2021–0242) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for certain Airbus SAS Model A318 series airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –215, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. EASA AD 2021–0242 supersedes EASA AD 2016–0238 (which corresponds to FAA AD 2018–03–12). Model A320–215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those airplanes in the applicability.

This proposed AD was prompted by reports of fatigue damage in the structure for the door stop fittings on certain fuselage frames. The FAA is proposing this AD to address cracking at the door stop fitting holes of fuselage FR66 and FR68 which could result in reduced structural integrity of the airplane. See the MCAI for additional background information.

Model A320–216 Airplanes

The Airbus SAS Model A320–216 was U.S. type certificated on December 19, 2016. Before that date, any EASA ADs that affected Model A320–216 airplanes were included in the U.S. type certificate as part of the Required Airworthiness Actions List (RAAL). One or more Model A320–216 airplanes have subsequently been placed on the U.S. Register, and will now be included in FAA AD actions. For Model A320–216 airplanes, the requirements that correspond to AD 2018–03–12 were mandated by the MCAI via the RAAL. Although that RAAL requirement is still in effect, for continuity and clarity the FAA has identified Model A320–216 airplanes in paragraph (c) of this proposed AD; the MCAI that is specified in paragraph (g) in this proposed AD includes retained requirements, which would therefore apply to those airplanes.

Explanation of Retained Requirements

Although this proposed AD does not explicitly restate the requirements of AD 2018–03–12, this proposed AD would retain all of the requirements of AD 2018–03–12. Those requirements are referenced in EASA AD 2021–0242, which, in turn, is referenced in paragraph (g) of this proposed AD.

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0242 describes procedures for rototest inspections for cracking of the fastener holes in the airframe structure for the door stop fittings installation in FR66 and FR68, and corrective actions. Corrective actions include repair or modification of fastener holes at door stop locations.

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

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is proposing this AD because the FAA evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in EASA AD 2021–0242 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2021–0242 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2021–0242 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2021–0242 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2021–0242. Service information required by EASA AD 2021–0242 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0503 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD affects 1,084 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections	Up to 25 work-hours × $85 per hour = $2,125	$0	Up to $2,125	Up to $2,303,500.

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
Up to 27 work-hours × $85 per hour = $2,295	$610	$2,905

The FAA has received no definitive data on which to base the cost estimates for the on-condition repairs specified in this proposed AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2018–03–12, Amendment 39–19185 (83 FR 5906, February 12, 2018); and

■ b. Adding the following new AD:

Airbus SAS: Docket No. FAA–2022–0503; Project Identifier MCAI–2021–01244–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by June 21, 2022

(b) Affected ADs

This AD replaces AD 2018–03–12, Amendment 39–19185 (83 FR 5906, February 12, 2018) (AD 2018–03–12).

(c) Applicability

This AD applies to Airbus SAS Model airplanes specified in paragraphs (c)(1) through (4) of this AD, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2021–0242, dated November 8, 2021 (EASA AD 2021–0242).

(1) Model A318–111, –112, –121, and –122 airplanes.

(2) Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(3) Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes.

(4) Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(d) Subject

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

(e) Reason

This AD was prompted by reports of fatigue damage in the structure for the door stop fittings on certain fuselage frames, and new analysis by the manufacturer, which resulted in optimized compliance times for the inspections. The FAA is issuing this AD to address cracking at the door stop fitting holes of fuselage frame (FR) 66 and FR68, which could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2021–0242.

(h) Exceptions to EASA AD 2021–0242

(1) Where EASA AD 2021–0242 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2021–0242 does not apply to this AD.

(3) Where paragraph (3) of EASA AD 2021–0242 specifies if any crack is found during any inspection to ''contact Airbus for approved instructions for corrective actions and accomplish those instructions accordingly,'' this AD requires if any cracking is found, the cracking must be repaired before further flight using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(4) Where paragraphs (2), (3), (5), and (5.1) of EASA AD 2021–0242 specify limits or actions in ''the applicable SRM'' or ''the

SRM,'' for purposes of this AD, replace those phrases with the following phrase: ''the applicable SRM as specified in the instructions of the inspection SB.''

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2021–0242 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

(i) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(ii) AMOCs approved previously for AD 2018–03–12 are approved as AMOCs for the corresponding provisions of EASA AD 2021–0242 that are required by paragraph (g) of this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* For any service information referenced in EASA AD 2021–0242 that contains RC procedures and tests: Except as required by paragraph (j)(2) of this AD, RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Related Information

(1) For information about EASA AD 2021–0242 contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0503.

(2) For more information about this AD, contact Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3229; email *vladimir.ulyanov@faa.gov.*

Issued on April 21, 2022.

Gaetano A. Sciortino,

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

[FR Doc. 2022–08909 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0507; Project Identifier MCAI–2021–01372–T]

RIN 2120–AA64

Airworthiness Directives; Saab AB, Support and Services (Formerly Known as Saab AB, Saab Aeronautics) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Saab AB, Support and Services Model 340A (SAAB/SF340A) and SAAB 340B airplanes. This proposed AD was prompted by a report that there is no evidence that post-machining stress relief or de-embrittlement post-cadmium plating treatments were performed on certain torque arm center pins. This proposed AD would require replacing each affected torque arm center pin on the main landing gear (MLG), as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. This proposed AD would also prohibit the installation of affected parts. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by June 21, 2022.

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

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

For material that will be incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0507.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0507; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Shahram Daneshmandi, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3220; email *shahram.daneshmandi@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0507; Project Identifier MCAI–2021–01372–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing

date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Shahram Daneshmandi, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3220; email *shahram.daneshmandi@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0273, dated December 8, 2021 (EASA AD 2021–0273) (also referred to as the MCAI), to correct an unsafe condition for certain Saab AB, Support and Services Model 340A (SAAB/SF340A) and SAAB 340B airplanes.

This proposed AD was prompted by a report that there is no evidence that post-machining stress relief or de-embrittlement post-cadmium plating was performed on affected torque arm center pins. Affected torque arm center pins are pins with part number (P/N) AIR134762 and batch number 17138, 21098, or 22863. Absence of the treatments could degrade the mechanical characteristics of the pins. The FAA is proposing this AD to address untreated torque arm center pins installed on any MLG, which, if not corrected, could lead to failure of the torque arm center pin and free swinging of the MLG, possibly resulting in loss of control of the airplane on ground, or loss of the MLG hydraulic braking function. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0273 specifies procedures for replacing each affected torque arm center pin on the MLG. EASA AD 2021–0273 also prohibits the installation of affected parts. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2021–0273 described previously. This proposed AD would also prohibit the installation of affected parts.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2021–0273 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2021–0273 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2021–0273 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2021–0273. Service information required by EASA AD 2021–0273 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0507 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD would affect 43 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators *
8 work-hours × $85 per hour = $680	$2,839	$3,519	$151,317

* According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all known costs in the cost estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Saab AB, Support and Services (Formerly Known as Saab AB, Saab Aeronautics): Docket No. FAA–2022–0507; Project Identifier MCAI–2021–01372–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by June 21, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Saab AB, Support and Services Model 340A (SAAB/SF340A) and SAAB 340B airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2021–0273, dated December 8, 2021 (EASA AD 2021–0273).

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

(e) Unsafe Condition

This AD was prompted by a report that there is no evidence that post-machining stress relief or de-embrittlement post-cadmium plating treatments were performed on certain torque arm center pins. The FAA is issuing this AD to address untreated torque arm center pins installed on any main landing gear (MLG), which, if not corrected, could lead to failure of the torque arm center pin and free swinging of the MLG, possibly resulting in loss of control of the airplane on ground, or loss of the MLG hydraulic braking function.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2021–0273.

(h) Exceptions to EASA AD 2021–0273

(1) Where EASA AD 2021–0273 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2021–0273 does not apply to this AD.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Saab AB, Support and Services' EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Related Information

(1) For EASA AD 2021–0273, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0507.

(2) For more information about this AD, contact Shahram Daneshmandi, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3220; email *shahram.daneshmandi@faa.gov.*

Issued on April 22, 2022.

Gaetano A. Sciortino,

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

[FR Doc. 2022–09420 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0508; Project Identifier MCAI–2021–01120–T]

RIN 2120–AA64

Airworthiness Directives; BAE Systems (Operations) Limited Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2015–07–05, which applies to all BAE Systems (Operations) Limited Model BAe 146 series airplanes and Model Avro 146–RJ series airplanes. AD 2015–07–05 requires repetitive external eddy current inspections on the aft skin lap joints of the rear fuselage for cracking, corrosion, and other defects, and repair if necessary. Since the FAA issued AD 2015–07–05, an inspection has been added and certain compliance times must be revised to address the unsafe condition. This proposed AD would continue to require the actions in AD

2015–07–05, at certain revised compliance times, and also require repetitive low frequency eddy current (LFEC) inspections for any cracking, corrosion, and other defects in the aft skin lap joints of the rear fuselage and in the fuselage skin panels, and repair if necessary. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by June 21, 2022.

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

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

For service information identified in this NPRM, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email *RApublications@baesystems.com;* internet *https://www.baesystems.com/Businesses/RegionalAircraft/index.htm.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0508; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3228; email *Todd.Thompson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0508; Project Identifier MCAI–2021–01120–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Todd Thompson, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3228; email *Todd.Thompson@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The FAA issued AD 2015–07–05, Amendment 39–18133 (80 FR 19871, April 14, 2015) (AD 2015–07–05), for all BAE Systems (Operations) Limited Model BAe 146 series airplanes and Model Avro 146–RJ series airplanes. AD 2015–07–05 requires repetitive external eddy current inspections on the aft skin lap joints of the rear fuselage for cracking, corrosion, and other defects, and repair if necessary. AD 2015–07–05 resulted from a report of a pressurization problem on an airplane during climb-out; a subsequent investigation showed a crack in the fuselage skin. The FAA issued AD 2015–07–05 to address cracking, corrosion, and other defects, which could affect the structural integrity of the airplane.

Actions Since AD 2015–07–05 Was Issued

Since the FAA issued AD 2015–07–05, it has been determined that adding repetitive LFEC inspections for any cracking, corrosion, and other defects in the aft skin lap joints of the rear fuselage and in the fuselage skin panels are necessary. The compliance times for inspection of certain stringers must also be revised.

The Civil Aviation Authority (CAA), which is the aviation authority for the United Kingdom, has issued CAA AD G–2021–0008, dated September 8, 2021 (also referred to after this as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for all BAE Systems (Operations) Limited Model BAe 146 series airplanes and Model Avro 146–RJ series airplanes. You may examine the MCAI in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0508.

This proposed AD was prompted by a report of a pressurization problem on an airplane during climb-out; a subsequent investigation showed a crack in the fuselage skin; and that repetitive LFEC inspections in the rear fuselage aft skin lap joints and in the fuselage skin panels are necessary. Certain compliance times also must be revised. The FAA is proposing this AD to address cracking, corrosion, and other defects on the rear fuselage aft skin joints and frames and in the fuselage panels, which could affect the structural integrity of the airplane. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

BAE Systems (Operations) Limited has issued Inspection Service Bulletin 53–239, including Appendix 2, Revision 5, and including Appendix 3, Revision 1, dated March 2, 2017. This service information describes procedures for repetitive external eddy current and LFEC inspections on the aft skin lap

joints of the rear fuselage and in the fuselage skin panels, for any cracking, corrosion, and other defects (*e.g.,* surface damage and spot displacement); and repair if necessary.

This proposed AD would also require BAE Systems (Operations) Limited Inspection Service Bulletin 53–239, including Appendix 2, Revision 3, dated May 7, 2014, which the Director of the Federal Register approved for incorporation by reference as of May 19, 2015 (80 FR 19871, April 14, 2015).

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

FAA's Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI and service information referenced above. The FAA is proposing this AD because the FAA evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed Requirements of This NPRM

This proposed AD would retain all of the requirements of AD 2015–07–05, with certain revised compliance times. This proposed AD would also require accomplishing the actions specified in the service information described previously.

Costs of Compliance

The FAA estimates that this proposed AD affects 20 airplanes of U.S. registry.

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

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2015-07-05.	8 work-hours × $85 per hour = $680 per inspection cycle.	$0	$680 per inspection cycle	$13,600 per inspection cycle.
New proposed actions	5 work-hours × $85 per hour = $425.	0	$425	$8,500 per inspection cycle.

The FAA has received no definitive data on which to base the cost estimates for the repairs specified in this proposed AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2015–07–05, Amendment 39–18133 (80 FR 19871, April 14, 2015); and

■ b. Adding the following new AD:

BAE Systems (Operations) Limited: Docket No. FAA–2022–0508; Project Identifier MCAI–2021–01120–T.

(a) Comments Due Date

The FAA must receive comments by June 21, 2022.

(b) Affected Airworthiness Directives (ADs)

This AD replaces AD 2015–07–05, Amendment 39–18133 (80 FR 19871, April 14, 2015) (AD 2015–07–05).

(c) Applicability

This AD applies to all BAE Systems (Operations) Limited Model BAe 146–100A, –200A, and –300A airplanes; and Model Avro 146–RJ70A, 146–RJ85A, and 146–RJ100A airplanes; certificated in any category.

(d) Subject

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

(e) Reason

This AD was prompted by a report of a pressurization problem on an airplane during climb-out; a subsequent investigation showed a crack in the fuselage skin; and that repetitive low frequency eddy current (LFEC) inspections in the rear fuselage aft skin lap joints and in the fuselage skin panels are necessary. Certain compliance times must also be revised. The FAA is issuing this AD to address cracking, corrosion, and other defects on the rear fuselage aft skin joints and frames and in the fuselage panels, which could affect the structural integrity of the airplane.

(f) Compliance

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

(g) Retained Repetitive Inspections, With New Service Information

This paragraph restates the requirements of paragraph (g) of AD 2015–07–05, with new service information.

(1) Within the compliance times specified in paragraphs (g)(1)(i) and (ii) of this AD, as applicable: Do an external eddy current inspection on the aft skin lap joints of the rear fuselage for cracking, corrosion, and other defects (*i.e.,* surface damage and spot displacement); in accordance with paragraph 2.C. of the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin 53–239, including Appendix 2, Revision 3, dated May 7, 2014; or paragraph 2. of the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin 53–239, including Appendix 2, Revision 5, and including Appendix 3, Revision 1, dated March 2, 2017. As of the effective date of this AD, use BAE Systems (Operations) Limited Inspection Service Bulletin 53–239, including Appendix 2, Revision 5, and including Appendix 3, Revision 1, dated March 2, 2017, only.

(i) For any airplane which has accumulated 9,000 flight cycles or more since the airplane's first flight as of May 19, 2015 (the effective date of AD 2015–07–05): Do the inspection within 1,000 flight cycles or 6 months after May 19, 2015, whichever occurs first.

(ii) For any airplane which has accumulated less than 9,000 flight cycles since the airplane's first flight as of May 19, 2015 (the effective date of AD 2015–07–05): Do the inspection before accumulating 10,000 flight cycles since the airplane's first flight.

(2) Repeat the inspection required by paragraph (g)(1) of this AD thereafter at intervals not to exceed the times specified in paragraphs (g)(2)(i) and (ii) of this AD, as applicable to the airplane's modification status.

(i) For Model BAe 146 series airplanes and Model Avro 146–RJ series airplanes post modification HCM50070E, or post modification HCM50070F, or post modification HCM50259A, repeat the inspection at intervals not to exceed 4,000 flight cycles.

(ii) For Model BAe 146 series airplanes and Model Avro 146–RJ series airplanes premodification HCM50070E, and premodification HCM50070F, and premodification HCM50259A, repeat the inspection at intervals not to exceed 7,500 flight cycles.

(h) Retained Corrective Action With Revised Repair Approval

This paragraph restates the requirements of paragraph (h) of AD 2015–07–05, with revised repair approval. If any cracking, corrosion, or other defect is found during any inspection required by AD 2015–07–05: Before further flight as of May 19, 2015 (the effective date of AD 2015–07–05), repair using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or the European Aviation Safety Agency (EASA); or BAE Systems (Operations) Limited's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature. Accomplishment of the repair does not constitute a terminating action for the inspections required by paragraph (g) of this AD. As of the effective date of this AD, repair approvals must be obtained through the Manager, Large Aircraft Section, International Validation Branch, FAA; or the Civil Aviation Authority of the United Kingdom (UK CAA); or BAE Systems (Operations) Limited's UK CAA Design Organization Approval (DOA).

(i) New Requirement of This AD: Repetitive LFEC Inspections

After the effective date of this AD, at the applicable times specified in paragraph 1.D. ''Compliance'' of BAE Systems (Operations) Limited Inspection Service Bulletin 53–239, including Appendix 2, Revision 5, and including Appendix 3, Revision 1, dated March 2, 2017: Do a LFEC inspection for any cracking, corrosion, and other defects in the aft skin lap joints of the rear fuselage and in the fuselage skin panels, in accordance with paragraph ''1. Procedure'' of Appendix 2 and Appendix 3 of BAE Systems (Operations) Limited Inspection Service Bulletin 53–239, including Appendix 2, Revision 5, and including Appendix 3, Revision 1, dated March 2, 2017. Repeat the LFEC inspection thereafter at intervals not to exceed the times specified in paragraph 1.D. ''Compliance'' of BAE Systems (Operations) Limited Inspection Service Bulletin 53–239, including Appendix 2, Revision 5, and including Appendix 3, Revision 1, dated March 2, 2017.

(j) New Requirement of This AD: Corrective Action

If any cracking, corrosion, or other defect is found during any inspection required by this AD: Before further flight, repair using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or the UK CAA; or BAE Systems (Operations) Limited's UK CAA DOA. If approved by the DOA, the approval must include the DOA-authorized signature. Accomplishment of the repair does not constitute a terminating action for the inspections required by paragraphs (i) of this AD.

(k) Credit for Previous Actions

This paragraph provides credit for the following actions required by this AD.

(1) This paragraph provides credit for the initial inspection and corrective action on stringer 30, left hand (LH) and right hand (RH), as required by paragraph (g) of this AD, if those actions were performed before May 19, 2015 (the effective date of AD 2015–07–05), using BAE Systems (Operations) Limited Inspection Service Bulletin 53–239, dated June 13, 2012, which is not incorporated by reference in this AD.

(2) This paragraph provides credit for the initial inspection and corrective action, as required by paragraph (g) of this AD, if those actions were performed before May 19, 2015 (the effective date of AD 2015–07–05), using BAE Systems (Operations) Limited Inspection Service Bulletin 53–239, Revision 1, dated June 18, 2013, which is not incorporated by reference in this AD.

(3) This paragraph provides credit for the initial inspection and corrective action, as required by paragraph (g) of this AD, if those actions were performed before May 19, 2015 (the effective date of AD 2015–07–05), using BAE Systems (Operations) Limited Inspection Service Bulletin 53–239, Revision 2, dated July 15, 2013, which is not incorporated by reference in this AD.

(4) This paragraph provides credit for the initial inspection and corrective action, as required by paragraph (g) of this AD, if those actions were performed before May 19, 2015 (the effective date of AD 2015–07–05), using BAE Systems (Operations) Limited Inspection Service Bulletin 53–239, including Appendix 2, Revision 3, dated May 7, 2014, which was incorporated by reference in AD 2015–07–05, Amendment 39–18133 (80 FR 19871, April 14, 2015).

(5) This paragraph provides credit for the actions required by paragraph (i) of this AD, if those actions were performed before the effective date of this AD using BAE Systems (Operations) Limited Inspection Service Bulletin 53–239, Revision 4, including Appendix 2, Revision 4, and Appendix 3, Initial issue, dated March 31, 2016.

(l) No Reporting Requirement

Although BAE Systems (Operations) Limited Inspection Service Bulletin 53–239, including Appendix 2, Revision 5, and including Appendix 3, Revision 1, dated March 2, 2017, specifies to report inspection findings, this AD does not require any report.

(m) Other FAA AD Provisions

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (n)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov*.

(i) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(ii) AMOCs for the repetitive external eddy current inspections approved previously for AD 2015–07–05 are approved as AMOCs for the corresponding actions in paragraph (g) of this AD.

(2) *Contacting the Manufacturer:* As of the effective date of this AD, for any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or the UK CAA; or BAE Systems (Operations) Limited's UK CAA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(n) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) CAA AD G–2021–0008, dated September 8, 2021, for related information. This MCAI may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0508.

(2) For more information about this AD, contact Todd Thompson, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3228; email *Todd.Thompson@faa.gov.*

(3) For service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email *RApublications@baesystems.com;* internet *https://www.baesystems.com/Businesses/RegionalAircraft/index.htm.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on April 22, 2022.

Gaetano A. Sciortino,

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

[FR Doc. 2022–09418 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 641

[Docket No. ETA–2022–0002]

RIN 1205–AC04

Senior Community Service Employment Program Conforming Changes to the Supporting Older Americans Act of 2020—Updated Guidance on Priority of Service, Durational Limits, and State Plan Submissions

AGENCY: Employment and Training Administration, Labor.

ACTION: Proposed rule; withdrawal.

SUMMARY: On February 14, 2022, the Department of Labor (Department) concurrently published both a direct final rule (DFR) and proposed rule putting forth guidance on priority service, durational limits, and State Plan submissions regarding a State's Senior Community Service Employment Program, or SCSEP. Because the Department did not receive any significant adverse comments that were within the scope of the rulemaking, the Department is withdrawing the proposed rule and is implementing the DFR.

DATES: As of May 6, 2022, the proposed rule published at 87 FR 8218 on February 14, 2022, is withdrawn.

FOR FURTHER INFORMATION CONTACT: Steven Rietzke, Chief, Division of National Programs, Tools and Technical Assistance, Office of Workforce Investment, at 202–693–3980 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: In the proposed rule, the Department stated that, if no significant adverse comments were received by March 16, 2022 (the end of the public comment period), the Department would publish a timely withdrawal in the **Federal Register** informing the public that the proposed rule was being withdrawn and the DFR would become effective. As the Department received no significant adverse comments within the scope of the rulemaking prior to the close of the comment period, the Department is withdrawing the proposed rule and implementing the DFR, which took effect April 15, 2022, a notice of which has been published in the **Federal Register** concurrent with this withdrawal.

The Department received seven comments on this rulemaking. Several of these comments were supportive of the provisions this rulemaking proposed to implement. While other comments could be characterized as negative or adverse, none of those comments were significant or within the scope of this rulemaking. One commenter was opposed to the time limit; however, that time limit is set forth in the Supporting Older Americans Act of 2020, and is, therefore, a statutory requirement beyond the purview of the rulemaking. The remaining comments were outside the scope of the rulemaking. The comments are publicly available as part of the rulemaking docket at *https://www.regulations.gov/docket/ETA-2022-0002/comments.*

The Department has determined that none of the negative or adverse comments are significant and within the scope of the rulemaking. Therefore, the proposed rule published at 87 FR 8186 on February 14, 2022, is withdrawn.

Angela Hanks,

Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2022–09492 Filed 5–5–22; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2022–0340]

RIN 1625–AA08

Special Local Regulation; Ohio River, Louisville, KY

AGENCY: Coast Guard, Homeland Security (DHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a special local regulation for certain waters of the Ohio River. This action is necessary to provide for the safety of life on these navigable waters near Louisville, KY, during a triathalon on July 24, 2022. This proposed rulemaking would prohibit persons and vessels from being in the special local regulation unless authorized by the Captain of the Port (COTP) Ohio Valley or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before June 6, 2022.

ADDRESSES: You may submit comments identified by docket number USCG–2022–0340 using the Federal Decision Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email MST3 Bryan Crane, U.S. Coast Guard; telephone 502–779–5336, email *bryan.m.crane@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background, Purpose, and Legal Basis

On April 21, 2022, Team Magic Inc. notified the Coast Guard that it will be conducting a triathlon from 6 a.m. though 10 a.m. on July 24, 2022. The swim will be held between Mile Markers 602 and 603 on the Ohio River

near Louisville, KY. The swim will consist of roughly 700 participants.

The purpose of this rulemaking would be to ensure the safety of vessels and the navigable waters during, the scheduled event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231).

III. Discussion of Proposed Rule

The COTP is proposing to establish a special local regulation from 6 a.m. to 10 a.m. on July 24, 2022. The special local regulation would cover all navigable waters of the Ohio River from mile markers 602 to 603. The duration of the special local regulation is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled triathalon. No vessel or person would be permitted to enter the special local regulation without obtaining permission from the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, and duration of the special local regulation. This special local regulation would restrict transit on a one-mile stretch of the Ohio River for 4 hours on one day. Moreover, the Coast Guard would issue Broadcast Notice to Mariners (BNMs), Local Notices to Mariners (LNMs), and Marine Safety Information Bulletins (MSIBs) about this special local regulation so that waterway users may plan according for this restriction on transit, and the rule would allow vessels to request permission to enter the zone.

B. Impact on Small Entities

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

While some owners or operators of vessels intending to transit the special local regulation may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a special local regulation lasting 4 hours that would prohibit entry between mile marker 602 to 603 on the Ohio River. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Memorandum for the Record supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters.

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

V. Public Participation and Request for Comments

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

Submitting comments. We encourage you to submit comments through the Federal Decision Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2022–0340 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov.* Frequently Asked Questions web page. We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.T08–0340 to read as follows:

§ 100.T08–0340 Tri Louisville, Ohio River, Louisville, KY.

(a) *Regulated area.* The regulations in this section apply to the following area: All waters of Ohio River, from mile marker 602 to 603 extending the entire width of the river.

(b) *Definitions.* As used in this section—

Designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sector Ohio Valley (COTP) in the enforcement of the regulations in this section.

Participant means all persons and vessels registered with the event sponsor as a participants in the race.

(c) *Regulations.* (1) All non-participants are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area described in paragraph (a) of this section unless authorized by the Captain of the Port Ohio Valley or their designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by Sector Ohio Valley command center at 502–779–5422. Those in the regulated area must comply with all lawful orders or directions given to them by the COTP or the designated representative.

(3) The COTP will provide notice of the regulated area through advanced notice via broadcast notice to mariners and by on-scene designated representatives.

(d) *Enforcement period.* This section will be enforced from 6 a.m. through 10 a.m. on July 24, 2022.

Dated: April 29, 2022.

A.M. Beach,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2022–09698 Filed 5–5–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO–P–2021–0061]

RIN 0651–AD59

Establishing Permanent Electronic Filing for Patent Term Extension Applications

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) proposes to amend the Rules of Practice in Patent Cases to require that patent term extension (PTE) applications, interim PTE applications, and any related submissions to the USPTO be submitted electronically via the USPTO patent electronic filing system (EFS-Web or Patent Center). The proposed rule changes would reduce the administrative burden on PTE applicants. They also would further advance the USPTO's information technology (IT) strategy to achieve complete beginning-to-end electronic processing of patent-related submissions, thereby improving administrative efficiency by facilitating electronic file management, optimizing workflow processes, and reducing processing errors.

DATES: Comments must be received by July 5, 2022 to ensure consideration.

ADDRESSES: 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–P–2021–0061 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 document 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 in the comments.

Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic submission of, or access to, comments is

not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Ali Salimi, Senior Legal Advisor, Office of Patent Legal Administration, at 571–272–0909; or Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, at 571–272–7728. You can also send inquiries to *patentpractice@uspto.gov.*

SUPPLEMENTARY INFORMATION: PTE under 35 U.S.C. 156 enables the owners of patents that claim certain human drug products, medical device products, animal drug products, veterinary biological products, and food or color additive products to restore to the terms of those patents some of the time lost while awaiting premarket Government approval for the products from a regulatory agency. *See, e.g.,* section 2750 of the Manual of Patent Examining Procedure (MPEP, Ninth Edition, R–10.2019). The USPTO administers 35 U.S.C. 156 in partnership with the relevant regulatory agencies (*i.e.,* the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA)). As part of its administration, the USPTO sends to the relevant agency a copy of any initial submission for PTE that the USPTO receives (*i.e.,* a copy of any PTE application under 35 U.S.C. 156(d)(1) and 37 CFR 1.740 or any interim PTE application under 35 U.S.C. 156(d)(5) and 37 CFR 1.790).

Prior to the COVID–19 pandemic, the USPTO prohibited the electronic filing of initial submissions for PTE. *See* section B2 of the Legal Framework for Patent Electronic System, available at *www.uspto.gov/patents/apply/filing-online/legal-framework-efs-web,* and section 502.05(I)(B)(2) of the MPEP. Requiring initial PTE submissions, which often comprise hundreds of pages, to be physically filed in triplicate under 37 CFR 1.740(b) was viewed as the most effective way to minimize processing errors.

Due to the workplace changes caused by the COVID–19 pandemic, the USPTO waived its prohibition on the electronic filing of initial submissions for PTE and the triplicate copy requirements in 37 CFR 1.740(b) and 1.790(b). *See* Relief Available to Patentees in View of the COVID–19 Outbreak for Submission of Initial Patent Term Extension Applications Filed Pursuant to 35 U.S.C. 156, 1475 Off. Gaz. Pat. Office 234 (June 23, 2020). The waiver did not impact related follow-on submissions to the USPTO, which were already permitted to be filed electronically prior to the pandemic.

Through informal feedback received during the processing of PTE applications, stakeholders have thus far communicated unanimous support for electronic filing of initial PTE submissions. Additionally, the USPTO and its partner agencies have successfully implemented a system by which the USPTO electronically transmits a copy of any initial submission for PTE to the relevant agency. The new system has not caused any processing errors.

Accordingly, the USPTO is proposing to change its rules of practice to require that PTE applications, interim PTE applications, and any related submissions to the USPTO be submitted electronically via the USPTO patent electronic filing system. The proposed rule changes are designed to streamline the filing of PTE applications and related documents and minimize paper handling. As has been the case since the June 2020 implementation of the electronic filing waiver, the proposed rule changes will result in PTE applications being viewable in USPTO patent electronic viewing systems (the Patent Application Information Retrieval (PAIR) system or Patent Center) immediately upon filing. Additionally, the changes would permit the USPTO to more efficiently allocate the personnel and physical space it currently deploys for the handling of physical copies of PTE submissions.

If the proposed rule changes are adopted, PTE applicants must use the correct document description to ensure that USPTO personnel are timely apprised of electronic submissions. ''Patent Term Extension Application Under 35 U.S.C. 156'' (Doc Code TERM.REQ) is the correct document description for a PTE application under 35 U.S.C. 156(d)(1) and 37 CFR 1.740, and ''Interim Patent Term Extension Application Under 35 U.S.C. 156(d)(5)'' (Doc Code TERM.REQ.ITM) is the correct document description for an interim PTE application under 35 U.S.C. 156(d)(5) and 37 CFR 1.790. The USPTO has also created the new document descriptions ''Interim Patent Term Extension Request Under 35 U.S.C. 156(e)(2)'' (Doc Code TERM.REQ.E2) for requests for interim extension of the patent term under 35 U.S.C. 156(e)(2) and 37 CFR 1.760, and ''Disclosure Under 37 CFR 1.765 in a Patent Term Extension Application'' (Doc Code TERM.DISCL) for disclosures to the USPTO under 37 CFR 1.765. PTE applicants are reminded that, when multiple PTE applications are filed for different patents based on the same regulatory review period, it is incumbent upon the PTE applicants to inform the USPTO of the various PTE applications, pursuant to 37 CFR 1.740(a)(13) and 37 CFR 1.765. *See also* section 2761 of the MPEP.

In addition, the USPTO has created the new document description ''Limited POA and/or Change of Address for a Patent Term Extension Application'' (Doc Code PTE.POA) for limited powers of attorney and/or changes of correspondence address that are filed specifically for PTE applications. Although a power of attorney or limited power of attorney is not required for a practitioner to prosecute a PTE application (practitioners may prosecute PTE applications by acting in a representative capacity pursuant to 37 CFR 1.34), the USPTO routinely receives limited powers of attorney specifying that the power is limited to prosecution of the PTE application. A limited power of attorney filed using the document description ''Limited POA and/or Change of Address for a Patent Term Extension Application'' (Doc Code PTE.POA) will not be processed by the Office of Patent Application Processing (OPAP) and will not serve to change an existing power for the underlying patent or establish power for the underlying patent.

As for a change of the correspondence address that is filed specifically for a PTE application, the USPTO uses the 37 CFR 1.740(a)(15) address provided in an initial PTE or interim PTE application strictly for communications regarding the PTE application. If a PTE applicant subsequently wishes to change the 37 CFR 1.740(a)(15) address, the document description ''Limited POA and/or Change of Address for a Patent Term Extension Application'' (Doc Code PTE.POA) should be used for the submission. A change of address filed using the document description ''Limited POA and/or Change of Address for a Patent Term Extension Application'' (Doc Code PTE.POA) will not be processed by the OPAP and will not serve to change the correspondence address for the underlying patent. PTE applicants are reminded to separately file a change of address with any other relevant regulatory agency to timely receive copies of correspondence from that agency.

PTE applicants are strongly encouraged to confirm that they have used the correct document description for any PTE submission, especially time-sensitive PTE submissions, such as interim PTE applications under 35 U.S.C. 156(d)(5) and 37 CFR 1.790. Use of the correct document description may be verified by reviewing the EFS

Acknowledgement Receipt (Doc Code N417) issued for the submission. In addition, both the document description and code for a submission may be verified in the electronic application file. If a mistake is identified, PTE applicants should contact the Patent Electronic Business Center at 866–217–9197 or *EBC@uspto.gov.*

When electronically filing a PTE or interim PTE application, the PTE or interim PTE application, including all exhibits, attachments, or appendices, should be submitted as a single file. If the single file comprising the application and its exhibits, attachments, or appendices exceeds the upload limit of the USPTO patent electronic filing system, the file may be split into smaller files to permit uploading, but the number of separate files to be uploaded should be minimized. Additionally, when splitting a file into smaller files, the order of the exhibits, attachments, or appendices as mentioned in the application should be maintained, and a single exhibit, attachment, or appendix should not be split, if possible. The USPTO has created a new document description, ''Continuation of Patent Term Extension Application'' (Doc Code PTE.APPENDIX), to be used for any exhibit, attachment, or appendix to a PTE or interim PTE application that is filed separately from the application.

Discussion of Specific Rules

The following is a discussion of the proposed amendments to 37 CFR part 1.

Section 1.740: Section 1.740(a)(15) is proposed to be amended to require the provision of an email address of the person to whom inquiries and correspondence related to the PTE application are to be directed. The USPTO has found that the availability of an email address facilitates contact with the PTE applicant's representative.

Section 1.740(b) is proposed to be amended to require that PTE applications under § 1.740, and any related submissions to the USPTO, be submitted using the USPTO patent electronic filing system in accordance with the USPTO patent electronic filing system requirements. Submissions to the USPTO related to PTE applications under § 1.740 include any related follow-on documents that must be submitted to the USPTO, such as corrections of informalities under § 1.740(c), petitions requesting review of incomplete filings or review of an accorded filing date under § 1.741(b), requests for reconsideration of notices of final determination and responses to requirements for information under § 1.750, requests for 35 U.S.C. 156(e)(2) interim extensions under § 1.760, disclosures to the USPTO under § 1.765, express withdrawals under § 1.770, and replies to requests to identify the holder of an approval under § 1.785(d). PTE-related submissions to the FDA or the USDA, such as disclosures to the Secretary of Health and Human Services or the Secretary of Agriculture under § 1.765, should continue to be filed directly with the relevant agency. The proposed amendment of § 1.740(b) would remove the requirement in the current § 1.740(b) to file each PTE application in triplicate.

Section 1.741: Section 1.741(a) is proposed to be amended to provide that the filing date of a PTE application is the date on which a complete PTE application is either received in the USPTO via the USPTO patent electronic filing system or filed pursuant to the procedure set forth in § 1.8(a)(1)(i)(C) and (a)(1)(ii). The provision in the current § 1.741(a), which provides that the filing date of a PTE application may be the date on which a complete application is filed pursuant to the physical mailing or facsimile transmission procedures set forth in §§ 1.8(a)(1)(i)(A) or (B) or 1.10, is proposed to be removed in view of the proposed requirement to file PTE applications via the USPTO patent electronic filing system.

Section 1.770: Section 1.770 is proposed to be amended to remove the requirement to file duplicates of express declarations of withdrawal of PTE applications. The requirement would no longer be needed in view of the proposed requirement to file submissions related to PTE applications via the USPTO patent electronic filing system.

Section 1.790: Section 1.790(a) is proposed to be amended to clarify that the referenced paragraphs are paragraphs of 35 U.S.C. 156(g). Additionally, the time periods in the current § 1.790(a) for filing initial and subsequent applications for interim extension are proposed to be moved to newly proposed paragraphs (c)(1) and (d)(1), respectively, of this section.

Section 1.790(b) is proposed to be amended to require any application for interim extension under this section (*i.e.,* both initial and subsequent interim extension applications) to be filed using the USPTO patent electronic filing system in accordance with the USPTO patent electronic filing system requirements. The provisions in the current § 1.790(b) regarding a complete application for interim extension are proposed to be moved to newly proposed paragraph (c)(2) of this section.

Section 1.790(c) is proposed to be amended to provide the requirements for complete initial applications for interim extension. Newly proposed § 1.790(c)(1) contains the time period in the current § 1.790(a) for filing an initial interim extension application. Newly proposed § 1.790(c)(2) contains the provisions in the current § 1.790(b) regarding a complete interim extension application. Note that the reference in the current § 1.790(b) to § 1.740(a)(16) and (17) is proposed to not be included in newly proposed § 1.790(c)(2) to correct an oversight. Paragraphs (a)(16) and (17) were removed from § 1.740 on September 8, 2000. Newly proposed § 1.790(c)(3) requires a statement that the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), has begun for the product. It also requires an identification of the application, petition, or notice that caused the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), to begin. For a human drug, antibiotic, or human biological product, it would be the number associated with the new drug application or Product License Application submitted for the product. For a new animal drug, it would be the number associated with the new animal drug application submitted for the drug. For a veterinary biological product, it would be the number associated with the application for license submitted under the Virus-Serum-Toxin Act for the product. For a food or color additive, it would be the number associated with the petition for product approval submitted under the Federal Food, Drug, and Cosmetic Act for the additive. For a medical device, it would be the number associated with the premarket approval application or notice of completion of a product development protocol submitted for the device. The USPTO has occasionally received applications for interim extension under 35 U.S.C. 156(d)(5) and § 1.790 that fail to meet the statutory requirement regarding the applicable regulatory review period.

Newly proposed § 1.790(d) contains the requirements for subsequent interim extension applications. Newly proposed § 1.790(d)(1) contains the time period in the current § 1.790(a) for filing each subsequent interim extension application. Newly proposed § 1.790(d)(2) contains provisions in the current § 1.790(c) regarding the content of each subsequent interim extension application. Newly proposed § 1.790(d)(3) contains the requirement

in the current § 1.790(c) that an application contain a statement that the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), has not been completed.

Rulemaking Requirements

A. Administrative Procedure Act: The changes proposed in this rulemaking involve rules of agency practice and procedure, and/or interpretive rules. *See Perez* v. *Mortg. Bankers Ass'n,* 135 S. Ct. 1199, 1204 (2015) (Interpretive rules ''advise the public of the agency's construction of the statutes and rules which it administers.'' (citation and internal quotation marks omitted)); *Nat'l Org. of Veterans' Advocates* v. *Sec'y of Veterans Affairs,* 260 F.3d 1365, 1375 (Fed. Cir. 2001) (rule that clarifies the interpretation of a statute is interpretive); *Bachow Commc'ns Inc.* v. *FCC,* 237 F.3d 683, 690 (D.C. Cir. 2001) (Rules governing an application process are procedural under the Administrative Procedure Act.); *Inova Alexandria Hosp.* v. *Shalala,* 244 F.3d 342, 350 (4th Cir. 2001) (Rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims.).

Accordingly, prior notice and opportunity for public comment for the changes proposed in this rulemaking are not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. *See Perez,* 135 S. Ct. at 1206 (Notice-and-comment procedures are required neither when an agency ''issue[s] an initial interpretive rule'' nor ''when it amends or repeals that interpretive rule.''); *Cooper Techs. Co.* v. *Dudas,* 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice-and-comment rulemaking for ''interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice'' (quoting 5 U.S.C. 553(b)(A))). However, the USPTO has chosen to seek public comment before implementing this rule to benefit from the public's input.

B. Regulatory Flexibility Act: Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), whenever an agency is required by 5 U.S.C. 553 (or any other law) to publish a notice of proposed rulemaking, the agency must prepare and make available for public comment an Initial Regulatory Flexibility Analysis, unless the agency certifies under 5 U.S.C. 605(b) that the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 603, 605. For the reasons set forth in this document, the Senior Counsel for Regulatory and Legislative Affairs, Office of General Law, of the USPTO has certified to the Chief Counsel for Advocacy of the Small Business Administration that the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b).

As a threshold matter, PTE under 35 U.S.C. 156 is only available for patents that claim drug products, medical devices, food or color additives, or methods of using or manufacturing such products, devices, or additives. Approximately 100 PTE applications are filed annually, and they are typically filed by non-small entity pharmaceutical and medical device companies because of the expense required to develop and obtain marketing approval for such inventions.

The changes proposed in this rule are procedural in nature and are not expected to result in significant costs to applicants. The current rules of practice permit follow-on documents related to PTE applications to be filed electronically. The USPTO estimates that approximately 99% of follow-on documents related to PTE applications are filed electronically. Accordingly, the proposed rule change requiring follow-on documents related to PTE applications to be filed electronically should not cause a substantial change in practice or result in additional costs to applicants. As for the proposed rule change requiring PTE applications to be filed electronically, although this would be a change in practice, stakeholders have unanimously communicated support for the USPTO's current waiver of the prohibition against electronic filing of PTE applications as a result of the COVID–19 outbreak, and the proposed rule change would not result in any additional cost to applicants. Thus, this proposed rule change requiring PTE applications to be filed electronically is not expected to negatively impact stakeholders' PTE practice.

Finally, the USPTO patent electronic filing system will allow PTE applicants to file PTE documents through their standard web browser without downloading special software, changing their documentation preparation tools, or altering their workflow processes. PTE applicants may create their documents using the tools and processes that they already use and then convert those documents into standard PDF files for submission through the USPTO patent electronic filing system.

For these reasons, the proposed changes will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review): This proposed rule has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The USPTO has complied with Executive Order 13563 (Jan. 18, 2011). Specifically, the USPTO has, to the extent feasible and applicable: (1) Made a reasoned determination that the benefits justify the costs of the proposed rule; (2) tailored the proposed rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across Government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

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

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

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

H. Executive Order 12988 (Civil Justice Reform): This proposed rule meets applicable standards to minimize

litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

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

J. Executive Order 12630 (Taking of Private Property): This proposed rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

K. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801–808), prior to issuing any final rule, the USPTO will submit a report containing any final rule resulting from this proposed rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this proposed rule are not expected to result in an annual effect on the economy of $100 million or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this proposed rule is not a ''major rule'' as defined in 5 U.S.C. 804(2).

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

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

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

O. Paperwork Reduction Act of 1995: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) requires that the USPTO consider the impact of paperwork and other information collection burdens imposed on the public. In accordance with section 3507(d) of the Paperwork Reduction Act of 1995, the paperwork and other information collection burdens involved with this proposed rule have already been approved under the Office of Management and Budget (OMB) Control Number 0651–0020 (Patent Term Extension). However, 0651–0020 will be updated to reflect a reduction in burden (time) due to the removal of the requirement to file PTE applications in paper in triplicate. The USPTO estimates that this information collection's annual burden will decrease by a total of approximately 51 burden hours. This estimate is based on the current OMB-approved burdens (response volumes) associated with this information collection, which may fluctuate over time and may be different from any forecasts mentioned in other parts of this proposed rule.

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

P. E-Government Act Compliance: The USPTO is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Biologics, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons set forth in the preamble, the USPTO proposes to amend 37 CFR part 1 as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

■ 1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

■ 2. Amend § 1.740 by revising paragraphs (a)(15) and (b) to read as follows:

§ 1.740 Formal requirements for application for extension of patent term; correction of informalities.

(a) * * *

(15) The name, address, telephone number, and email address of the person to whom inquiries and correspondence related to the application for patent term extension are to be directed.

(b) The application under this section, and any related submissions to the Office, must be submitted using the USPTO patent electronic filing system in accordance with the USPTO patent electronic filing system requirements.

* * * * *

■ 3. Amend § 1.741 by revising paragraph (a) introductory text to read as follows:

§ 1.741 Complete application given a filing date; petition procedure.

(a) The filing date of an application for extension of a patent term is the date on which a complete application is either received in the Office via the USPTO patent electronic filing system or filed pursuant to the procedure set forth in § 1.8(a)(1)(i)(C) and (a)(1)(ii). A complete application must include:

* * * * *

■ 4. Amend § 1.770 by revising the first sentence to read as follows:

§ 1.770 Express withdrawal of application for extension of patent term.

An application for extension of patent term may be expressly withdrawn before a determination is made pursuant to § 1.750 by filing in the Office a written declaration of withdrawal signed by the owner of record of the patent or its agent. * * *

■ 5. Revise § 1.790 to read as follows:

§ 1.790 Interim extension of patent term under 35 U.S.C. 156(d)(5).

(a) An owner of record of a patent or its agent who reasonably expects that the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect may submit one or more applications for interim extensions for periods of up to one year each. In no event will the interim extensions granted under this section be longer than the maximum period of extension to which the applicant would be entitled under 35 U.S.C. 156(c).

(b) Any application for interim extension under this section must be filed using the USPTO patent electronic filing system in accordance with the USPTO patent electronic filing system requirements.

(c) Complete initial applications for interim extension under this section must:

(1) Be filed during the period beginning 6 months and ending 15 days before the patent term is due to expire, and include a statement that the initial application is being submitted within the period and an identification of the date of the last day on which the initial application could be submitted;

(2) Include all of the information required for a formal application under § 1.740 and a complete application under § 1.741, except as follows:

(i) Paragraphs (a)(1), (2), (4), and (6) through (15) of §§ 1.740 and 1.741 shall be read in the context of a product currently undergoing regulatory review; and

(ii) Paragraphs (a)(3) and (5) of § 1.740 are not applicable to an application for interim extension under this section; and

(3) Include a statement that the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), has begun for the product that is the subject of the patent, and identify the application, petition, or notice that caused the applicable regulatory review period to begin.

(d) Each subsequent application for interim extension:

(1) Must be filed during the period beginning 60 days before and ending 30 days before the expiration of the preceding interim extension and include a statement that it is being submitted within the period and an identification of the date of the last day on which it could be submitted;

(2) May be limited in content to a request for a subsequent interim extension along with any materials or information required under §§ 1.740 and 1.741 that are not present in the preceding interim extension application; and

(3) Must include a statement that the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), has not been completed.

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2022–09535 Filed 5–5–22; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2022–0382; FRL–9767–01–R7]

Air Plan Approval; Missouri; Removal of Control of Emissions From Bakery Ovens

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing approval of a State Implementation Plan (SIP) revision submitted by the State of Missouri on January 15, 2019 and supplemented by letter on July 11, 2019. Missouri requests that the EPA remove from its SIP a rule related to control of emissions from bakery ovens in St. Louis City and Jefferson, St. Charles, Franklin, and St. Louis Counties. The EPA's proposed approval of this rule revision is in accordance with the requirements of the Clean Air Act (CAA).

DATES: Comments must be received on or before June 6, 2022.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–R07–OAR–2022–0382 to *https://www.regulations.gov.* Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received will be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Written Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: William Stone, Environmental Protection Agency, Region 7 Office, Air Quality Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551–7714; email address: *stone.william@epa.gov.*

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

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I. Written Comments

Submit your comments, identified by Docket ID No. EPA–R07–OAR–2022–0382, at *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. What is being addressed in this document?

The EPA is proposing to approve the removal of 10 Code of State Regulation (CSR) 10–5.440, *Control of Emissions From Bakery Ovens,* from the Missouri SIP.

Section 110(l) of the CAA prohibits the EPA from approving a SIP revision that interferes with any applicable requirement concerning attainment and reasonable further progress (RFP), or any other applicable requirement of the CAA. The State supplemented its SIP revision with a July 11, 2019 letter in order to address the requirements of section 110(l) of the CAA.

III. What is the EPA's analysis of Missouri's SIP revision request?

According to the January 15, 2019, letter from the Missouri Department of Natural Resources (MoDNR), available in the docket for this proposed action, Missouri rescinded 10 CSR 10–5.440, *Control of Emissions from Bakery Ovens* because the only source subject to the rule ceased operations in 2012. The state asserts in their submission to the Agency that this rule is no longer necessary for controlling emissions of volatile organic compounds (VOC's) because there are no existing sources subject to the rule and new sources would be controlled by other rules.

In its supplemental submission dated July 11, 2019, MoDNR notes that the purpose of 10 CSR 10–5.440, Control of Emissions From Bakery Ovens, was to reduce VOC emissions from bakery ovens located in the St. Louis nonattainment area, which at the time of promulgation (state effective Date: December 30, 1996), included the City of St. Louis and the counties of Franklin, Jefferson, St. Charles, and St. Louis (hereinafter referred to in this document as the ''St. Louis Area'').[1] The rule applied to new or existing commercial bakeries with potential VOC emissions greater than 100 tons per year (tpy).

MoDNR stated that following rescission of this rule, any new source is required to meet New Source Review (NSR) in attainment or attainment/unclassifiable areas, and for nonattainment areas, Nonattainment New Source Review (NANSR) in the St. Louis Area.

EPA agrees that in the St. Louis nonattainment area for the 2015 ozone standard, which includes St. Louis City and the counties of Franklin (partial; Boles Township), Jefferson, St. Charles, and St. Louis, any new sources or major modifications of existing sources are subject to NANSR permitting.[2] Under NANSR, a new major source or major modification of an existing source with a PTE of 100 tpy or more of any NAAQS pollutant is required to obtain a NANSR permit when the area is in nonattainment, which requires an analysis of Lowest Achievable Emission Rate (LAER) in addition to an air quality analysis, an additional impacts analysis and emission offsets. LAER is defined in § 51.165(a)(1)(xiii), in pertinent part, ''. . . for any source, the more stringent rate of emissions based on the following: (A) The most stringent emissions limitation which is contained in the implementation plan of any State for such class or category of stationary source, unless the owner or operator of the proposed stationary source demonstrates that such limitations are not achievable; or (B) The most stringent emissions limitation which is achieved in practice by such class or category of stationary sources. This limitation, when applied to a modification, means the lowest achievable emissions rate for the new or modified emissions units within or stationary source. In no event shall the application of the term permit a proposed new or modified stationary source to emit any pollutant in excess of the amount allowable under an applicable new source standard of performance.'' [3]

Therefore, any new bakery oven that would have been subject to 10 CSR 10–5.440, in the St. Louis ozone Nonattainment Area, will be subject to NANSR permitting which would result in a LAER limit at least as stringent as the limit in this rule in addition to the requirement to offset the emissions.

In the rest of Franklin County (the portions that do not include Boles Township), any new sources or major modifications of existing sources are subject to NSR permitting. Under NSR, for attainment or attainment/unclassifiable areas, a new major source or major modification of an existing source with a potential to emit (PTE) of 250 tpy or more of any NAAQS pollutant is required to obtain a Prevention of Significant Deterioration (PSD) permit. Sources with a PTE greater than 100 tpy of VOC's, but less than 250 tpy, are required to obtain a minor permit in accordance with Missouri's NSR permitting program, which is approved into the SIP.[4] In the Final Area Designations for the 2015 Ozone National Ambient Air Quality Standards (NAAQS) Technical Support Document (TSD) EPA observes that emissions from sources outside Boles Township are relatively low, with levels less than the more densely populated City of St. Louis and five other counties in the area of analysis.[5] As noted in the TSD, there are no other large sources of VOC or NOx in Franklin County, outside of Boles Township, which remains a nonattainment area and therefore subject to NANSR permitting. Therefore, EPA believes that any newly permitted NSR or minor NSR bakery ovens in Franklin County would have little to no impact on the St. Louis Area ozone levels.

Therefore, EPA agrees with the State that approving this SIP revision will not have an adverse impact on air quality because the only source subject to the rule has permanently shutdown and new sources would be subject to NANSR, NSR and minor NSR in the St. Louis Area. As stated above, new bakery ovens with a PTE of 100 tpy or more of VOC's would be very well controlled in all areas where 10 CSR 10–5.440 previously applied.

Further, the rescission of this rule from the SIP will have no impact on any approved maintenance plan. On September 20, 2018, the EPA redesignated the St. Louis, Missouri area to attainment of the 2008 ozone NAAQS. In the state's maintenance plan submittal for this standard, this rule was not relied upon. The EPA agrees with this analysis.

For these reasons, EPA proposes to determine that the SIP revision submission meets the substantive requirements of the CAA, including section 110 and implementing regulations.

EPA is proposing to approve this SIP revision.

IV. Have the requirements for approval of a SIP revision been met?

The State submission has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. The State provided public notice on this SIP revision from May 15, 2018 to August 2, 2018 and received 11 comments from the EPA. Missouri received 11 comments from the EPA that related to Missouri's lack of an adequate demonstration that the rule could be removed from the SIP in accordance with section 110(l) of the CAA. Missouri's July 11, 2019 letter addressed the EPA's comments. In addition, as explained above, the revision meets the substantive SIP requirements of the CAA, including section 110 and implementing regulations.

V. What action is the EPA taking?

The EPA is proposing to approve Missouri's request to rescind 10 CSR 10–5.440 from the SIP because the rule applied to a single source that has permanently ceased operations and it therefore no longer serves to reduce emissions in the St. Louis Area. Furthermore, any new sources or major modifications of existing sources in the St. Louis Area are subject to NSR permitting.[6] We are processing this as a proposed action because we are soliciting comments on this proposed action. Final rulemaking will occur after consideration of any comments.

VI. Incorporation by Reference

In this document, the EPA is proposing to amend regulatory text that

[1] These counties were previously designated for nonattainment for ozone for the 1979, 1997 and 2008 standards. They are currently designated attainment for each of those standards.

[2] *https://www.federalregister.gov/documents/2021/06/14/2021-11454/revised-air-quality-designations-for-the-2015-ozone-national-ambient-air-quality-standards.*

[3] *https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-51/subpart-I.*

[4] EPA's latest approval of Missouri's NSR permitting program rule was published in the **Federal Register** on October 11, 2016. 81 FR 70025.

[5] *https://www.epa.gov/sites/default/files/2021-05/documents/st._louis_mo-il_tsd_remand_final.pdf.*

[6] ''NSR Permitting'' includes PSD permitting in areas designated attainment and unclassifiable, NANSR in areas designated nonattainment and minor source permitting.

includes incorporation by reference. As described in Sections II, III, and V of this preamble and set forth below in the proposed amendments to 40 CFR part 52, the EPA is proposing to remove provisions of the EPA-Approved Missouri Regulations from the Missouri State Implementation Plan, which is incorporated by reference in accordance with the requirements of 1 CFR part 51.

VII. Statutory and Executive Order Reviews

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

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

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

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Ozone, Volatile organic compounds.

Dated: April 27, 2022.

Meghan A. McCollister,

Regional Administrator, Region 7.

For the reasons stated in the preamble, the EPA proposes to amend 40 CFR part 52 as set forth below:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart AA—Missouri

§ 52.1320 [Amended]

■ 2. In § 52.1320, the table in paragraph (c) is amended by removing the entry ''10–5.440'' under the heading ''Chapter 5—Air Quality Standards and Air Pollution Control Regulations for the St. Louis Metropolitan Area''.

[FR Doc. 2022–09468 Filed 5–5–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2019–0140; EPA–HQ–OAR–2021–0663; FRL–9782–01–R8]

Air Plan Approval; Colorado; Addressing Remanded Portions of the Previously Approved Infrastructure Requirements for the 2015 Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On January 5, 2021, the United States Court of Appeals for the Tenth Circuit granted the Environmental Protection Agency's (EPA) motion for a voluntary remand without vacatur of two parts of EPA's 2020 final rule approving Colorado's infrastructure state implementation plan (SIP) submission for the 2015 8-hour ozone national ambient air quality standards (NAAQS) (2020 final rule). In this document, EPA proposes to address those two remanded parts of the 2020 final rule: EPA's conclusion that Colorado's infrastructure SIP submission met the State's good neighbor obligation under Clean Air Act (CAA) section 110(a)(2)(D)(i)(I); and EPA's conclusion that Colorado's infrastructure SIP submission provided ''necessary assurances'' of the State's authority to regulate agricultural sources under CAA section 110(a)(2)(E)(i). EPA is proposing to approve Colorado's infrastructure SIP submission pursuant to CAA section 110.

DATES: Written comments must be received on or before June 6, 2022.

ADDRESSES: You may send comments, identified as Docket No. EPA–R08–OAR–2019–0140, using the Federal eRulemaking Portal at *https://www.regulations.gov,* following the online instructions for submitting comments. Include Docket ID No. EPA–R08–OAR–2019–0140 in the subject line of the message.

Instructions: All submissions received must include Docket ID No. EPA–R08–OAR–2019–0140. Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, EPA Docket Center and Reading Room are open to the public by appointment only to reduce the risk of transmitting COVID–19. Our Docket Center staff also continues to provide remote customer service via email, phone, and webform. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.* Please email or call a person listed in the **FOR FURTHER INFORMATION CONTACT** section if you need to make alternative arrangements for access to the docket.

FOR FURTHER INFORMATION CONTACT: Amrita Singh, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD–IO, 1595 Wynkoop Street, Denver, Colorado, 80202–1129, telephone number: (303) 312–6103, email address: *singh.amrita@epa.gov;* or

Ellen Schmitt, telephone number: (303) 312–6728, email address: *schmitt.ellen@epa.gov.*

SUPPLEMENTARY INFORMATION: *Public participation:* Submit your comments, identified by Docket No. EPA–R08–OAR–2019–0140, at *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system).

There are two dockets supporting this proposed action, EPA–R08–OAR–2019–0140 and EPA–HQ–OAR–2021–0663. Docket No. EPA–R08–OAR–2019–0140 contains information specific to Colorado, including the notice of proposed rulemaking. Docket No. EPA–HQ–OAR–2021–0663 contains additional modeling files, emissions inventory files, technical support documents, and other relevant supporting documentation regarding interstate transport of emissions for the 2015 8-hour ozone NAAQS which are being used to support this proposed action. All comments regarding information in either of these dockets must be made in Docket No. EPA–R08–OAR–2019–0140. For additional submission methods, please email or call a person listed in the **FOR FURTHER INFORMATION CONTACT**. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

The index to Docket No. EPA–HQ–OAR–2021–0663 is available electronically at *https://www.regulations.gov.* While all documents in that docket are listed in the index, some information may not be publicly available due to docket file size restrictions or content (*e.g.,* CBI).

Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

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I. Background

A. Statutory and Regulatory Background

On October 1, 2015, EPA promulgated a revision to the ozone NAAQS (2015 8-hour ozone NAAQS), lowering the level of both the primary and secondary standards to 0.070 parts per million (ppm).[1] Section 110(a)(1) of the CAA requires states to submit, within three years after promulgation of a new or revised standard, SIP submissions meeting the applicable requirements of CAA section 110(a)(2).[2]

1. Ozone Transport

One of the applicable requirements of section 110(a)(2) is found in CAA section 110(a)(2)(D)(i)(I), otherwise known as the ''interstate transport'' or ''good neighbor'' provision, which generally requires SIPs to contain adequate provisions to prohibit in-state emissions activities from having certain adverse air quality effects on other states due to interstate transport of pollution. There are two so-called ''prongs'' within CAA section 110(a)(2)(D)(i)(I). A SIP submission for a new or revised NAAQS must contain adequate provisions prohibiting any source or other type of emissions activity within the state from emitting air pollutants in amounts that will significantly contribute to nonattainment of the NAAQS in another state (prong 1) or interfere with maintenance of the NAAQS in another state (prong 2). EPA and states must give independent significance to prong 1 and prong 2 when evaluating downwind air quality problems under CAA section 110(a)(2)(D)(i)(I).[3]

EPA is using the 4-step interstate transport framework (or 4-step framework) to evaluate state SIP submissions addressing the interstate transport provision for the 2015 8-hour ozone NAAQS. EPA has addressed the interstate transport requirements of CAA section 110(a)(2)(D)(i)(I) with respect to prior ozone NAAQS in several regional regulatory actions, including the Cross-State Air Pollution Rule (CSAPR), which addressed interstate transport with respect to the 1997 ozone NAAQS as well as the 1997 and 2006 fine particulate matter standards,[4] and the CSAPR Update,[5] and the Revised CSAPR Update, both of which addressed the 2008 ozone NAAQS.[6]

Through the development and implementation of the CSAPR rulemakings and prior regional rulemakings pursuant to the interstate transport provision,[7] EPA, working in partnership with states, developed the following 4-step interstate transport framework to evaluate a state's obligations to eliminate interstate transport emissions under the interstate

[1] National Ambient Air Quality Standards for Ozone, Final Rule, 80 FR 65292 (October 26, 2015). Although the level of the standard is specified in the units of ppm, ozone concentrations are also described in parts per billion (ppb). For example, 0.070 ppm is equivalent to 70 ppb.

[2] SIP submissions that are intended to meet the applicable requirements of section 110(a)(1) and (2) of the CAA are often referred to as infrastructure SIPs and the applicable elements under section 110(a)(2) are referred to as infrastructure requirements.

[3] See *North Carolina* v. *EPA,* 531 F.3d 896, 909–11 (D.C. Cir. 2008).

[4] See Federal Implementation Plans: Interstate Transport of Fine Particulate Matter and Ozone and Correction of SIP Approvals, 76 FR 48208 (August 8, 2011).

[5] Cross-State Air Pollution Rule Update for the 2008 Ozone NAAQS, 81 FR 74504 (October 26, 2016).

[6] In 2019, the United States Court of Appeals for the D.C. Circuit remanded the CSAPR Update to the extent it failed to require upwind states to eliminate their significant contribution by the next applicable attainment date by which downwind states must come into compliance with the NAAQS, as established under CAA section 181(a). *Wisconsin* v. *EPA,* 938 F.3d 303, 313 (D.C. Cir. 2019). The Revised CSAPR Update for the 2008 Ozone NAAQS, 86 FR 23054 (April 30, 2021), responded to the remand of the CSAPR Update in *Wisconsin* and the vacatur of a separate rule, the ''CSAPR Close-Out,'' 83 FR 65878 (December 21, 2018), in *New York* v. *EPA,* 781 F. App'x. 4 (D.C. Cir. 2019).

[7] In addition to the CSAPR rulemakings, other regional rulemakings addressing ozone transport include the ''NO_X SIP Call,'' 63 FR 57356 (October 27, 1998), and the ''Clean Air Interstate Rule'' (CAIR), 70 FR 25162 (May 12, 2005).

transport provision for the ozone NAAQS: (1) Identify monitoring sites that are projected to have problems attaining and/or maintaining the NAAQS (*i.e.,* nonattainment and/or maintenance receptors); (2) identify states that impact those air quality problems in other (*i.e.,* downwind) states sufficiently such that the states are considered ''linked'' and therefore warrant further review and analysis; (3) identify the emissions reductions necessary (if any), applying a multifactor analysis, to eliminate each linked upwind state's significant contribution to nonattainment or interference with maintenance of the NAAQS at the locations identified in step 1; and (4) adopt permanent and enforceable measures needed to achieve those emissions reductions.

a. Background on EPA's Ozone Transport Modeling Information

In general, EPA has performed nationwide air quality modeling to project ozone design values which are used in combination with measured data to identify nonattainment and maintenance receptors. To quantify the contribution of emissions from specific upwind states on 2023 ozone design values for the identified downwind nonattainment and maintenance receptors, EPA performed nationwide, state-level ozone source apportionment modeling for 2023. The source apportionment modeling provided contributions to ozone at receptors from precursor emissions of anthropogenic nitrogen oxides (NO_X) and volatile organic compounds (VOC) in individual upwind states.

EPA has released several documents containing projected ozone design values, contributions, and information relevant to evaluating interstate transport with respect to the 2015 8-hour ozone NAAQS. First, on January 6, 2017, EPA published a notice of data availability (NODA) in which we requested comment on preliminary interstate ozone transport data including projected ozone design values and interstate contributions for 2023 using a 2011 base year platform.[8] In the NODA, EPA used the year 2023 as the analytic year for this preliminary modeling because that year aligns with the expected attainment year for moderate ozone nonattainment areas for the 2015 8-hour ozone NAAQS.[9] On October 27, 2017, we released a memorandum (October 2017 memorandum) containing updated modeling data for 2023, which incorporated changes made in response to comments on the NODA, and noted that the modeling may be useful for states developing SIPs to address interstate transport obligations for the 2008 ozone NAAQS.[10] On March 27, 2018, we issued a memorandum (March 2018 memorandum) noting that the same 2023 modeling data released in the October 2017 memorandum could also be useful for identifying potential downwind air quality problems with respect to the 2015 8-hour ozone NAAQS at Step 1 of the 4-step interstate transport framework.[11] The March 2018 memorandum also included the then newly available contribution modeling data to assist states in evaluating their impact on potential downwind air quality problems for the 2015 8-hour ozone NAAQS under Step 2 of the 4-step interstate transport framework.[12] EPA subsequently issued two more memoranda in August and October 2018, providing additional information to states developing interstate transport SIP submissions for the 2015 ozone NAAQS concerning, respectively, potential contribution thresholds that may be appropriate to apply in Step 2 of the 4-step framework, and considerations for identifying downwind areas that may have problems maintaining the standard at Step 1 of the 4-step framework.[13]

Since the release of the modeling data shared in the March 2018 memorandum, EPA performed updated modeling using a 2016-based emissions modeling platform (*i.e.,* 2016v1). This emissions platform was developed under the EPA/Multi-Jurisdictional Organization (MJO)/state collaborative project.[14] This collaborative project was a multi-year joint effort by EPA, the MJOs, and states to develop a new, more recent emissions platform for use by EPA and states in regulatory modeling as an improvement over the dated 2011-based platform that EPA had used to project ozone design values and contribution data provided in the 2017 and 2018 memoranda. EPA used the 2016v1 emissions to project ozone design values and contributions for 2023. On October 30, 2020, in the Notice of Proposed Rulemaking for the Revised CSAPR Update, EPA released and accepted public comment on 2023 modeling that used the 2016v1 emissions platform.[15] Although the Revised CSAPR Update addressed transport for the 2008 ozone NAAQS, the projected design values and contributions from the 2016v1 platform are also useful for identifying downwind ozone problems and linkages with respect to the 2015 ozone NAAQS.[16]

Following the final Revised CSAPR Update, EPA made further updates to the 2016 emissions platform to include mobile emissions from EPA's Motor Vehicle Emission Simulator MOVES3 model[17] and updated emissions projections for electric generating units (EGUs) that reflect the emissions reductions from the Revised CSAPR Update, recent information on plant closures, and other sector trends. The construct of the updated emissions platform, 2016v2, is described in an emissions modeling technical support document (TSD).[18] EPA performed air

[8] See Notice of Availability of the Environmental Protection Agency's Preliminary Interstate Ozone Transport Modeling Data for the 2015 8-hour Ozone National Ambient Air Quality Standard (NAAQS), 82 FR 1733 (January 6, 2017).

[9] 82 FR 1735.

[10] See Information on the Interstate Transport State Implementation Plan Submissions for the 2008 Ozone National Ambient Air Quality Standards under Clean Air Act Section 110(a)(2)(D)(i)(I), October 27, 2017, available in Docket No. EPA–HQ–OAR–2021–0663 or at *https://www.epa.gov/node/194139/.*

[11] See Information on the Interstate Transport State Implementation Plan Submissions for the 2015 Ozone National Ambient Air Quality Standards under Clean Air Act Section 110(a)(2)(D)(i)(I), March 27, 2018 (''March 2018 memorandum''), available in Docket No. EPA–HQ–OAR–2021–0663 or at *https://www.epa.gov/airmarkets/memo-and-supplemental-information-regarding-interstate-transport-sips-2015-ozone-naaqs.*

[12] The March 2018 memorandum, however, provided, ''While the information in this memorandum and the associated air quality analysis data could be used to inform the development of these SIPs, the information is not a final determination regarding states' obligations under the good neighbor provision. Any such determination would be made through notice-and-comment rulemaking.'' March 2018 memorandum at 2.

[13] See Analysis of Contribution Thresholds for Use in Clean Air Act Section 110(a)(2)(D)(i)(I) Interstate Transport State Implementation Plan Submissions for the 2015 Ozone National Ambient Air Quality Standards, August 31, 2018 (''August 2018 memorandum''), and Considerations for Identifying Maintenance Receptors for Use in Clean Air Act Section 110(a)(2)(D)(i)(I) Interstate Transport State Implementation Plan Submissions for the 2015 Ozone National Ambient Air Quality Standards, October 19, 2018, available in Docket No. EPA–HQ–OAR–2021–0663 or at *https://www.epa.gov/airmarkets/memo-and-supplemental-information-regarding-interstate-transport-sips-2015-ozone-naaqs.*

[14] The results of this modeling, as well as the underlying modeling files, are included in Docket No. EPA–HQ–OAR–2021–0663.

[15] See Revised CSAPR Update for the 2008 Ozone NAAQS, 85 FR 68964, 68981 (October 30, 2020).

[16] See the Air Quality Modeling Technical Support Document for the Final Revised Cross-State Air Pollution Rule Update, included in the Headquarters Docket No. EPA–HQ–OAR–2021–0663.

[17] Additional details and documentation related to the MOVES3 model can be found at *https://www.epa.gov/moves/latest-version-motor-vehicle-emission-simulator-moves.*

[18] See Technical Support Document (TSD) Preparation of Emissions Inventories for the 2016v2 North American Emissions Modeling Platform. Dated: February 2022. (2016v2 TSD). Included under Docket No. EPA–HQ–OAR–2021–0663.

quality modeling of the 2016v2 emissions using the most recent public release version of the Comprehensive Air-quality Model with extensions (CAMx) photochemical modeling, version 7.10.[19]

EPA now proposes to primarily rely on modeling based on the updated and newly available 2016v2 emissions platform in evaluating these submissions with respect to Steps 1 and 2 of the 4-step framework and generally references it within this action as 2016v2 modeling for 2023. By using the updated modeling results, EPA is using the most current and technically appropriate information for this proposed rulemaking. Section III of this document and the Air Quality Modeling TSD for 2015 Ozone NAAQS Transport SIP Proposed Actions, included in Docket No. EPA–HQ–OAR–2021–0663 for this proposal, contain additional detail on EPA's 2016v2 modeling. EPA is accepting public comment on this updated 2023 modeling, which uses a 2016v2 emissions platform as the modeling pertains to this proposed action. Comments on EPA's air quality modeling as used in this proposed action should be submitted in the Regional docket for this action, Docket No. EPA–R08–OAR–2019–0140. EPA is not accepting comments in Docket No. EPA–HQ–OAR–2021–0663.

2. Necessary Assurances of State Authority

CAA section 110(a)(2)(E)(i) requires that a state provide ''necessary assurances'' that it will have, among other things, adequate authority under state law to carry out its SIP to meet CAA requirements with respect to the relevant NAAQS.[20] Specifically, a state's infrastructure SIP submission should show that the state has the legal authority to carry out the provisions identified in the state's infrastructure SIP submission and is not prohibited by federal or state law from carrying out the SIP submission.

B. EPA's 2020 Action and the 2021 Voluntary Remand

On September 17, 2018, the State of Colorado submitted to EPA its infrastructure SIP submission for the 2015 ozone NAAQS. On July 29, 2019, EPA proposed to approve Colorado's submission with respect to all relevant CAA elements.[21] EPA proposed approval of the portion of Colorado's infrastructure SIP related to prongs 1 and 2 of CAA section 110(a)(2)(D)(i)(I), primarily relying on the 2023 modeling (2011 base year platform) presented in the March 2018 memorandum.[22] EPA's analysis of the 2023 modeling indicated that Colorado's largest impacts at any identified downwind receptor would be less than 1 percent (0.70 ppb) of the 2015 ozone NAAQS.[23] Thus, EPA proposed to find that Colorado's emissions would not significantly contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other state.[24]

On September 13, 2019, the United States Court of Appeals for the D.C. Circuit issued a decision in *Wisconsin* v. *EPA,* remanding the CSAPR Update to the extent that it failed to require upwind states to eliminate their significant contribution by the next applicable attainment date by which downwind states must come into compliance with the NAAQS, as established under CAA section 181(a).[25] In our 2020 final rule (published on April 10, 2020), EPA defended the use of the 2023 analytical year on the basis of what was then, in the Agency's view, a position consistent with *Wisconsin*—specifically that the *Wisconsin* holding did not apply with respect to the attainment date for marginal areas.[26] However, EPA also offered an alternative rationale. EPA used linear interpolation to estimate Colorado's maximum contribution to a potential receptor in 2021 and concluded that even if it were appropriate to use the 2021 marginal area date rather than the 2023 moderate area date, Colorado's impacts would be similar to those projected for 2023 and thus it would not significantly contribute to nonattainment or interfere with maintenance in other states.[27]

On May 19, 2020, the D.C. Circuit issued a ruling in *Maryland* v. *EPA* that cited the *Wisconsin* decision in holding that EPA must assess the impact of interstate transport on air quality at the next downwind attainment date, including marginal area attainment dates, in evaluating the basis for EPA's denial of a petition under CAA section 126(b).[28] The court noted that ''section 126(b) incorporates the Good Neighbor Provision,'' and, therefore, ''EPA must find a violation [of section 126] if an upwind source will significantly contribute to downwind nonattainment at the next downwind attainment deadline. Therefore, the Agency must evaluate downwind air quality at that deadline, not at some later date.'' *Id.* at 1204 (emphasis added).

On June 9, 2020, the Center for Biological Diversity (Center) filed a petition for review of the 2020 final rule in the United States Court of Appeals for the Tenth Circuit (Tenth Circuit).[29] The Center challenged two sub-elements of the SIP approval: (1) EPA's conclusion that Colorado's infrastructure SIP submission satisfies the good neighbor provision, CAA section 110(a)(2)(D)(i)(I); and (2) EPA's conclusion that the State's infrastructure SIP submission satisfies Colorado's obligation to provide necessary assurances that the State has authority to regulate all agricultural sources of air pollution as may be required by the CAA section 110(a)(2)(E)(i).[30]

In challenging EPA's approval of the portion of Colorado's infrastructure SIP submission addressing CAA section 110(a)(2)(D)(i)(I), the Center argued that EPA's analysis focused on the wrong analytical year, failed to adequately analyze all of the relevant potential out-of-state receptor locations, and should have accounted for air quality impacts from various proposed and final federal rules.[31]

With respect to the state authority issue, the Center argued that a provision of state law, Colo. Rev. Stat. § 25–7–109(8)(a), bars Colorado from regulating agricultural sources other than those that are major sources. The Center argued that this means that Colorado's infrastructure SIP submission failed to provide ''necessary assurances'' of the State's authority to regulate all agricultural sources, as may be needed to comply with CAA requirements for SIPs, pursuant to CAA section 110(a)(2)(E)(i).[32]

On December 31, 2020, EPA filed a motion for a voluntary remand without vacatur of the two challenged parts of the 2020 final rule. EPA stated that it

[19] Ramboll Environment and Health, January 2021, *www.camx.com.*

[20] 42 U.S.C. 7410(a)(2)(E)(i).

[21] Promulgation of State Implementation Plan Revisions; Infrastructure Requirements for the 2015 Ozone National Ambient Air Quality Standards; Colorado and North Dakota, 84 FR 36516 (July 29, 2019). In the same rulemaking EPA also proposed to act on North Dakota's infrastructure SIP submission for the 2015 ozone NAAQS. EPA's final action with respect to North Dakota's SIP submission was neither challenged nor remanded and thus is not addressed in this action.

[22] 84 FR 36516, 36524–25.

[23] Id. n.24.

[24] 84 FR 36524–25.

[25] 938 F.3d at 313.

[26] Approval and Promulgation of State Implementation Plan Revisions; Infrastructure Requirements for the 2015 Ozone National Ambient Air Quality Standards; Colorado and North Dakota, 85 FR 20169, 20169–71 (April 10, 2020).

[27] Id. at 20169.

[28] 958 F.3d 1185, 1203–04 (D.C. Cir. 2020).

[29] *Center for Biological Diversity* v. *EPA,* No. 20–9560 (Tenth Cir.).

[30] *Center for Biological Diversity* v. *EPA,* No. 20–9560 (Tenth Cir.), Petitioner's Opening Brief at 10–11.

[31] Id.

[32] Id.

intended to consider additional information, including the *Maryland* decision and new information developed after EPA issued the 2020 final rule that was not available in the administrative record for the 2020 final rule.[33] The Tenth Circuit granted EPA's motion on January 5, 2021.[34]

In this document, EPA proposes to address the two remanded portions of EPA's 2020 final rule by proposing to approve Colorado's infrastructure SIP submission for the 2015 ozone standards with respect to CAA section 110(a)(2)(D)(i)(I) and (E)(i). EPA seeks comment on its conclusions under CAA section 110(a)(2)(D)(i)(I) and (E)(i) in this proposed approval. We are not otherwise addressing or reopening for comment any of the other portions of our 2020 final rule. We will deem any comments on such portions beyond the scope of this action.

II. EPA's Evaluation and Proposed Approval of Colorado's Infrastructure SIP Submission Under CAA Section 110(a)(2)(D)(i)(I) and (E)(i)

A. Good Neighbor Provision

1. EPA's Approach to Evaluating Interstate Transport SIP Submissions for the 2015 8-Hour Ozone NAAQS

EPA proposes to apply a consistent set of policy judgments across all states for purposes of evaluating interstate transport obligations and the approvability of interstate transport SIP submissions for the 2015 8-hour ozone NAAQS. These policy judgments reflect consistency with relevant case law and past agency practice as reflected in the CSAPR and related rulemakings. Nationwide consistency in approach is particularly important in the context of interstate ozone transport, which is a regional-scale pollution problem involving many smaller contributors. Effective policy solutions to the problem of interstate ozone transport going back to the NO_X SIP Call have necessitated the application of a uniform framework of policy judgments in order to ensure an ''efficient and equitable'' approach.[35]

The remainder of this section describes EPA's proposed framework with respect to analytic year, definition of nonattainment and maintenance receptors, selection of contribution threshold, and multifactor control strategy assessment.

2. Selection of Analytic Year

In general, the states and EPA must implement the interstate transport provision in a manner ''consistent with the provisions of [title I of the CAA].'' [36] This requires, among other things, that these obligations are addressed consistently with the timeframes for downwind areas to meet their CAA obligations. With respect to ozone NAAQS, under CAA section 181(a), this means obligations must be addressed ''as expeditiously as practicable'' and no later than the schedule of attainment dates provided in CAA section 181(a)(1).[37] As discussed in Section I of this proposed rulemaking, recent case law makes clear that the states and the Agency are obligated, under the good neighbor provision, to assess downwind air quality as expeditiously as practicable and no later than the next applicable attainment date. This is now the moderate area attainment date under CAA section 181 for ozone nonattainment. The moderate area attainment date for the 2015 8-hour ozone NAAQS is August 3, 2024.[38] EPA believes that 2023 is now the appropriate year for analysis of interstate transport obligations for the 2015 8-hour ozone NAAQS, because the 2023 ozone season is the last relevant ozone season during which achieved emissions reductions in linked upwind states could assist downwind states with meeting the August 3, 2024, moderate area attainment date for the 2015 8-hour ozone NAAQS.

EPA recognizes that the attainment date for nonattainment areas classified as marginal for the 2015 8-hour ozone NAAQS was August 3, 2021. Under the *Maryland* holding, any necessary emissions reductions to satisfy interstate transport obligations should have been implemented by no later than this date. At the time of the statutory deadline to submit interstate transport SIPs (October 1, 2018), many states, including Colorado, relied upon EPA modeling of the year 2023, and no state provided an alternative analysis using a 2021 analytic year (or the prior 2020 ozone season). EPA appreciates that among the arguments raised by the Center in challenging the 2020 final rule was the failure to analyze a year earlier than 2023. However, EPA must act on SIP submissions—even in this action on remand—using the information available at the time it takes such action. In this circumstance, EPA does not believe it would be appropriate to evaluate Colorado's obligations under CAA section 110(a)(2)(D)(i)(I) as of an attainment date that is wholly in the past, because the Agency interprets the interstate transport provision as forward looking.[39] It would not make sense to analyze air quality, contribution levels, or emissions control strategies for the 2021 attainment date, for purposes of interstate transport obligations, when no emissions reductions, if shown to be needed, could be implemented by that date anyway.[40] Consequently, in this proposal EPA will use the analytical year of 2023 to evaluate Colorado's CAA section 110(a)(2)(D)(i)(I) SIP submission with respect to the 2015 8-hour ozone NAAQS.

3. Step 1 of the 4-Step Interstate Transport Framework

In Step 1, EPA identifies monitoring sites that are projected to have problems attaining and/or maintaining the NAAQS in the 2023 analytic year. Where EPA's analysis shows that a site does not fall under the definition of a nonattainment or maintenance receptor, that site is excluded from further analysis under EPA's 4-step interstate transport framework. For sites that are identified as a nonattainment or maintenance receptor in 2023, we proceed to the next step of our 4-step interstate transport framework by identifying the upwind state's contribution to those receptors.

EPA's approach to identifying ozone nonattainment and maintenance receptors in this action is consistent with the approach used in previous transport rulemakings. EPA's approach gives independent consideration to both the ''contribute significantly to nonattainment'' and the ''interfere with maintenance'' prongs of CAA section 110(a)(2)(D)(i)(I), consistent with the

[33] *Center for Biological Diversity* v. *EPA,* No. 20–9560 (Tenth Cir.), EPA's Motion for Voluntary Remand, Ex. 1, Declaration in Support of Motion for Voluntary Remand, at ¶ 8–10.

[34] *Center for Biological Diversity* v. *EPA,* No. 20–9560 (Tenth Cir.), January 5, 2021 Order.

[35] See *EME Homer City Generation, LP* v. *EPA,* 572 U.S. 489, 519 (2014). As discussed later in this section, EPA recognizes that the nature of high ozone levels due to wintertime inversion conditions in the Uinta Basin in Utah raises unique analytical challenges in assessing whether there is transport from Colorado during those wintertime episodes. EPA has separately analyzed that unique situation and proposes to conclude that emissions from Colorado do not contribute to high ozone levels in Utah. That analysis, however, is separate from the generally applicable 4-step analytical framework for ozone transport described here.

[36] 42 U.S.C. 7410(a)(2)(D)(i).

[37] For attainment dates for the 2015 8-hour ozone NAAQS, refer to 42 U.S.C. 7511(a), 40 CFR 51.1303, and Additional Air Quality Designations for the 2015 Ozone National Ambient Air Quality Standards, 83 FR 25776 (June 4, 2018, effective August 3, 2018).

[38] See 42 U.S.C. 7511(a); 40 CFR 51.1303; 83 FR 25776.

[39] See 86 FR 23074; see also *Wisconsin,* 938 F.3d at 322.

[40] Nor does EPA view 2022 as a reasonable analytic year for a similar reason: it would be impossible to finalize this action and implement any emissions reductions measures that could be shown to be needed by the 2022 ozone season. Thus, 2023 is the appropriate analytic year and also aligns with the next attainment date.

D.C. Circuit's direction in *North Carolina* v. *EPA*.[41]

For this proposal, EPA identifies nonattainment receptors as those monitoring sites that are projected to have average design values that exceed the NAAQS and that are also measuring nonattainment based on the most recent monitored design values. This approach is consistent with prior transport rulemakings, such as the CSAPR Update, where EPA defined nonattainment receptors as those areas that both currently measure nonattainment and that EPA projects will be in nonattainment in the future analytic year (*i.e.,* 2023).[42]

In addition, in this proposal, EPA identifies a receptor to be a ''maintenance'' receptor for purposes of defining interference with maintenance, consistent with the method used in the CSAPR and upheld by the D.C. Circuit in *EME Homer City Generation, L.P.* v. *EPA*.[43] Specifically, EPA identified maintenance receptors as those receptors that would have difficulty maintaining the relevant NAAQS in a scenario that takes into account historical variability in air quality at that receptor. The variability in air quality was determined by evaluating the ''maximum'' future design value at each receptor based on a projection of the maximum measured design value over the relevant period. EPA interprets the projected maximum future design value to be a potential future air quality outcome consistent with the meteorology that yielded maximum measured concentrations in the ambient data set analyzed for that receptor (*i.e.,* ozone conducive meteorology). EPA also recognizes that previously experienced meteorological conditions (*e.g.,* dominant wind direction, temperatures, air mass patterns) promoting ozone formation that led to maximum concentrations in the measured data may reoccur in the future. The maximum design value gives a reasonable projection of future air quality at the receptor under a scenario in which such conditions do, in fact, reoccur. The projected maximum design value is used to identify upwind emissions that, under those circumstances, could interfere with the downwind area's ability to maintain the NAAQS.

Recognizing that nonattainment receptors are also, by definition, maintenance receptors, EPA often uses the term ''maintenance-only'' to refer to those receptors that are not nonattainment receptors. Consistent with the concepts for maintenance receptors, as described above, EPA identifies ''maintenance-only'' receptors as those monitoring sites that have projected average design values above the level of the applicable NAAQS, but that are not currently measuring nonattainment based on the most recent official design values. In addition, those monitoring sites with projected average design values below the NAAQS, but with projected maximum design values above the NAAQS are also identified as ''maintenance-only'' receptors, even if they are currently measuring nonattainment based on the most recent official design values.

4. Step 2 of the 4-Step Interstate Transport Framework

In Step 2, EPA quantifies the contribution of each upwind state to each receptor in the 2023 analytic year. The contribution metric used in Step 2 is defined as the average impact from each state to each receptor on the days with the highest ozone concentrations at the receptor based on the 2023 modeling. If a state's contribution value does not equal or exceed the threshold of 1 percent of the NAAQS (*i.e.,* 0.70 ppb for the 2015 8-hour ozone NAAQS), the upwind state is not ''linked'' to a downwind air quality problem, and EPA, therefore, concludes that the state does not significantly contribute to nonattainment or interfere with maintenance of the NAAQS in the downwind states. However, if a state's contribution equals or exceeds the 1 percent threshold, the state's emissions are further evaluated in Step 3, considering both air quality and cost as part of a multi-factor analysis, to determine what, if any, emissions might be deemed ''significant'' and, thus, must be eliminated under CAA section 110(a)(2)(D)(i)(I). EPA is proposing to rely in the first instance on the 1 percent threshold for the purpose of evaluating a state's contribution to nonattainment or maintenance of the 2015 8-hour ozone NAAQS (*i.e.,* 0.70 ppb) at downwind receptors. This is consistent with the Step 2 approach that EPA applied in CSAPR for the 1997 ozone NAAQS, which has subsequently been applied in the CSAPR Update when evaluating interstate transport obligations for the 2008 ozone NAAQS. EPA continues to find 1 percent to be an appropriate threshold.

For ozone, as EPA found in the Clean Air Interstate Rule (CAIR), CSAPR, and CSAPR Update, a portion of the nonattainment problems from anthropogenic sources in the United States results from the combined impact of relatively small contributions from many upwind states, along with contributions from in-state sources and, in some cases, substantially larger contributions from a subset of particular upwind states. EPA's analysis shows that much of the ozone transport problem being analyzed in this proposed rule is still the result of the collective impacts of contributions from many upwind states. Therefore, application of a consistent contribution threshold is necessary to identify those upwind states that should have responsibility for addressing their contribution to the downwind nonattainment and maintenance problems to which they collectively contribute. Continuing to use 1 percent of the NAAQS as the screening metric to evaluate collective contribution from many upwind states also allows EPA (and states) to apply a consistent framework to evaluate interstate emissions transport under the interstate transport provision from one NAAQS to the next.[44]

5. Step 3 of the 4-Step Interstate Transport Framework

Consistent with EPA's longstanding approach to eliminating significant contribution or interference with maintenance, at Step 3, states linked at Steps 1 and 2 are generally expected to prepare a multifactor assessment of potential emissions controls. EPA's analysis at Step 3 in prior federal actions addressing interstate transport requirements has focused primarily on an evaluation of cost-effectiveness of potential emissions controls (on a marginal cost-per-ton basis), the total emissions reductions that may be achieved by requiring such controls (if applied across all linked upwind states), and an evaluation of the air quality impacts such emissions reductions would have on the downwind receptors to which a state is linked; other factors may potentially be relevant if adequately supported. In general, where EPA's or alternative air quality and contribution modeling establishes that a state is linked at Steps 1 and 2, it will

[41] See 531 F.3d at 910–11 (holding that EPA must give ''independent significance'' to each prong of CAA section 110(a)(2)(D)(i)(I)).

[42] See 81 FR 74504. This same concept, relying on both current monitoring data and modeling to define nonattainment receptor, was also applied in CAIR. *See* 70 FR at 25241, 25249 (January 14, 2005); see also *North Carolina,* 531 F.3d at 913–14 (affirming as reasonable EPA's approach to defining nonattainment in CAIR).

[43] 795 F.3d 118, 136 (D.C. Cir. 2015); see 76 FR 48208 (August 8, 2011). CSAPR Update and Revised CSAPR Update also used this approach. *See* 81 FR 74504 and 86 FR 23054.

[44] See 81 FR 74518. See also 86 FR 23085 (reviewing and explaining rationale from CSAPR, 76 FR 48237–38, for selection of 1 percent threshold).

be insufficient at Step 3 for a state merely to point to its existing rules requiring control measures as a basis for approval. In general, the emissions-reducing effects of all existing emissions control requirements are already reflected in the air quality results of the modeling for Steps 1 and 2. If the state is shown to still be linked to one or more downwind receptor(s), states must provide a well-documented evaluation determining whether their emissions constitute significant contribution or interference with maintenance by evaluating additional available control opportunities by preparing a multifactor assessment. While EPA has not prescribed a particular method for this assessment, EPA expects states at a minimum to present a sufficient technical evaluation. This would typically include information on emissions sources, applicable control technologies, emissions reductions, costs, cost effectiveness, and downwind air quality impacts of the estimated reductions, before concluding that no additional emissions controls should be required.[45]

6. Step 4 of the 4-Step Interstate Transport Framework

At Step 4, states (or EPA) develop permanent and federally enforceable control strategies to achieve the emissions reductions determined to be necessary at Step 3 to eliminate significant contribution to nonattainment or interference with maintenance of the NAAQS. For a state linked at Steps 1 and 2 to rely on an emissions control measure at Step 3 to address its interstate transport obligations, that measure must be included in the state's SIP so that it is permanent and federally enforceable.[46]

7. EPA's Evaluation of Colorado's CAA Section 110(a)(2)(D)(i)(I) Submission

As mentioned above, the State of Colorado submitted a SIP submission to EPA on September 17, 2018, to meet the good neighbor requirements for the 2015 ozone NAAQS. In its prong 1 and prong 2 analysis, Colorado's SIP submission relies on analysis of the year 2023 (using a 2011 base year platform), among other things, to conclude that the State does not significantly contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other state.[47] As explained in Section I of this proposed rulemaking, EPA has conducted an updated analysis for the 2023 analytical year (using a 2016 base year platform) and proposes to rely primarily on this updated modeling to evaluate Colorado's transport SIP submission.

As described in Section I, EPA performed air quality modeling to project design values and contributions for 2023 using the 2016v2 emissions platform. EPA examined these data to determine if emissions in Colorado contribute at or above the threshold of 1 percent of the 2015 8-hour ozone NAAQS (0.70 ppb) to any downwind nonattainment or maintenance receptor in this most recent round of modeling. The data[48] indicate that the highest contribution in 2023 from Colorado to a downwind nonattainment or maintenance receptor is 0.06 ppb and 0.20 ppb, respectively.[49] Specifically, EPA's analysis indicates that Colorado will have a 0.06 ppb impact at the projected nonattainment receptor in Kenosha County, Wisconsin (Site ID 550590019), which has a 2023 projected average design value of 72.8 ppb and a 2023 projected maximum design value of 73.7 ppb. EPA's analysis further indicates that Colorado will have a 0.20 ppb impact at a projected maintenance receptor in Denton County, Texas (Site ID 481210034), which has a projected 2023 average design value of 70.4 ppb and a 2023 projected maximum design value of 72.2 ppb. The data also indicate that the only contribution in 2023 from Colorado to any downwind monitor above the 1 percent threshold is to a monitor in San Juan, New Mexico (0.99 ppb). This monitor's 2023 average and maximum design values are projected to be below the 2015 ozone NAAQS and the monitor is therefore not projected to be a nonattainment and/or maintenance receptor for the 2015 ozone NAAQS. Accordingly, EPA proposes to conclude that the most recent data support EPA's conclusion that Colorado does not contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other state.

In its comments on the 2020 rule and in its brief in the Tenth Circuit litigation, the Center identified several downwind areas that it argued may have been in nonattainment in 2020 but that EPA had screened out by using the incorrect analytic year of 2023. These included: Tarrant and Denton County, Texas; the Northern and Southern Wasatch Fronts in Utah; and monitors in New Mexico.[50] In response to this argument, EPA is providing in Table 1 the projected 2023 design values (DV) and associated contributions from Colorado for all monitors located in these areas for which EPA's modeling provides valid contribution data.[51]

[45] As examples of general approaches for how such an analysis could be conducted for their sources, states could look to the CSAPR Update, 81 FR 74504, 74539–51; CSAPR, 76 FR 48208, 48246–63; CAIR, 70 FR 25162, 25195–229; or the NO_X SIP Call, 63 FR 57356, 57399–405. See also Revised CSAPR Update, 86 FR 23054, 23086–23116. Consistently across these rulemakings, EPA has developed emissions inventories, analyzed different levels of control stringency at different cost thresholds, and assessed resulting downwind air quality improvements.

[46] See 42 U.S.C. 7410(a)(2)(D) (''Each such [SIP] shall . . . contain adequate provisions . . . .''); see also 42 U.S.C. 7410(a)(2)(A); *Committee for a Better Arvin* v. *EPA,* 786 F.3d 1169, 1175–76 (9th Cir. 2015) (holding that measures relied on by state to meet CAA requirements must be included in the SIP).

[47] Letter from Dr. Larry Wolk, Executive Director, Colorado Department of Health & Environment, to Douglas Benevento, Regional Administrator, EPA Region 8, Attachment 9, Adopted SIP at 4–5 (August 16, 2018) (Colorado SIP Submission).

[48] Design values and contributions at individual monitoring sites nationwide are provided in the file ''2016v2_DVs_state_contributions.xlsx,'' which is included in Docket No. EPA–HQ–OAR–2021–0663.

[49] Both 0.06 ppb and 0.20 ppb are below the 1 percent threshold of the 2015 ozone NAAQS (.70 ppb).

[50] *Center for Biological Diversity* v. *EPA,* No. 20–9560 (Tenth Cir.), Petitioner's Opening Brief at 29–31.

[51] As described in the Air Quality Modeling Technical Support Document 2015 Ozone NAAQS Transport SIP Proposed Actions, EPA's method for calculating an average contribution metric for use in Step 2 of the 4-step transport framework is based on the average of daily contributions on the top 10 ozone concentrations days as modeled in 2023. However, in order to avoid including contributions on days with low ozone concentrations, EPA requires at least 5 days with model-predicted maximum daily average 8-hour ozone concentrations greater than or equal to 60 ppb. In EPA's method, contribution metric values are not calculated for monitors with fewer than 5 days that meet the 60 ppb threshold. As a result of applying this criterion, there were three monitoring sites in the areas identified by the Center, excluding the Uinta Basin, that are projected to have problems attaining and/or maintaining the NAAQS in 2023 for which EPA did not calculate contribution metric values. These monitors include two sites in Dona Ana County, New Mexico, and one site in Toole County, Utah. Although EPA does not have contribution data for these specific monitors, the data at near-by monitors indicate that the contributions from Colorado to Dona Ana and Toole Counties are expected to be well below the 1 percent threshold. Specifically, the contribution from Colorado to a monitoring site in El Paso, Texas, which is in the Dona Ana-El Paso interstate nonattainment area, is 0.04 ppb and, as indicated in Table 1, the contributions from Colorado to monitoring sites in Salt Lake County, which is closer to Colorado than Toole County, are 0.03 ppb.

TABLE 1—COLORADO CONTRIBUTIONS AND SELECT MONITORS

Monitor (AQS site ID)	State	County	Projected 2023 average DV	Projected 2023 maximum DV	Colorado contribution (ppb)
350010029	New Mexico	Bernalillo	62.0	62.7	0.27
350450018	New Mexico	San Juan	64.7	66.6	1.00
350610008	New Mexico	Valencia	62.2	63.9	0.30
481210034	Texas	Denton	70.4	72.2	0.20
481211032	Texas	Denton	67.2	69.0	0.22
484393009	Texas	Tarrant	68.0	68.7	0.17
481410029	Texas	El Paso	62.3	64.6	0.04
490030003	Utah	Box Elder	65.2	66.5	0.02
490110004	Utah	Davis	72.9	75.1	0.03
490353006	Utah	Salt Lake	73.6	75.3	0.03
490353013	Utah	Salt Lake	74.4	74.9	0.03
490570002	Utah	Weber	70.6	72.5	0.02
490571003	Utah	Weber	70.5	71.5	0.02

Table 1 shows that there are six monitors predicted to be violating the 2015 ozone NAAQS in 2023, one in Texas and five in Utah.[52] However, Colorado's projected contribution to each of these monitors is below the 1 percent threshold. Thus, no further analysis is required to address Colorado's good neighbor obligations for the areas relevant to the listed monitors at Step 3.

The Center also claimed that it could not find any documents in the record which address Colorado's contribution to nonattainment in the Uinta Basin.[53] EPA projected the design values for several of the monitoring sites in Duchesne County and Uintah County, Utah, but the Agency's modeling represents summertime ozone conditions and is not designed to capture the conditions that result in the high wintertime ozone concentrations in the Uinta Basin nonattainment area.

In order to characterize potential transport from Colorado to the Uinta Basin nonattainment area in the absence of reliable modeling to inform wintertime ozone levels and contributions, EPA conducted a separate analysis for the Uinta Basin, which is provided in a Uinta Basin TSD accompanying this action and included in Docket EPA–R08–OAR–2019–0140.[54] To summarize EPA's TSD findings, the ozone levels in the Uinta Basin nonattainment area are caused by a combination of meteorological inversion conditions, the unique topography of the Uinta Basin, and significant emissions of ozone precursors from sources within Utah. Generally, EPA concludes that ozone-precursor emissions do not transport into the Uinta Basin from outside the area during wintertime inversion episodes that produce high ozone conditions. Further, with respect to the portion of Colorado located within the regional Uinta Basin, available data shows that, because of low wind speed during wintertime inversion conditions and the unique topographical features within the regional Uinta Basin, emissions from the relevant area of Colorado are unlikely to transport to the Utah portion of the Uinta Basin.[55]

EPA reaches these conclusions recognizing the unique challenges associated with characterizing wintertime ozone concentrations and contributions in the Uinta Basin. As such, for this portion of the analysis, EPA is supplementing the consistently applied 4-step interstate transport framework used to characterize ozone transport at a broader, regional scale and during the summertime ozone season. Based on the information and analysis presented in the Uinta Basin TSD, EPA proposes to find that it is reasonable to conclude that Colorado does not significantly contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in the Utah portion of the Uinta Basin.[56]

In summary, based on the analyses provided in this document and in the Uinta Basin TSD, EPA proposes to conclude that emissions from sources in Colorado will not contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other state. Accordingly, EPA proposes to approve Colorado's infrastructure SIP submission for the 2015 ozone NAAQS under CAA section 110(a)(2)(D)(i)(I).

8. Emissions Assumptions Used in Modeling

The Center argued that in the context of evaluating Colorado's good neighbor SIP submission, EPA should have accounted for air quality impacts from various proposed and final federal rules.[57] EPA's normal practice is to include in its modeling only changes in emissions from final regulatory actions because, until such rules are finalized, any potential changes in NO_X or VOC emissions are speculative. EPA's updated 2023 modeling using the 2016v2 platform reflects an updated assessment of the emissions inventory nationwide based on changes in federal and state rules and other relevant changes in the emissions inventory known at the time this latest modeling was conducted. All assumptions that formed the basis of the updated 2023 modeling (2016v2) are available in the emissions modeling TSD.[58] EPA encourages commenters to review this information, which supports the updated basis for this proposed action. This information supersedes the older modeling of 2023 that had been used in the 2020 final rule (2011 base year platform).

B. Colorado's Authority To Regulate Agricultural Emissions

1. EPA's Prior Approval

CAA section 110(a)(2)(E)(i) requires that a state must provide ''necessary assurances'' that it has, among other things, adequate authority under state law to carry out the provisions of its SIP with respect to the relevant NAAQS. In the context of an infrastructure SIP submission, EPA expects states to

[52] See monitors 481210034, 490110004, 490353006, 490353013, 490570002, and 490571003.

[53] *Center for Biological Diversity* v. *EPA,* No. 20–9560 (Tenth Cir.), Petitioner's Opening Brief at 30.

[54] EPA, Technical Support Document, Ozone Transport Analysis: Colorado and the Uinta Basin Nonattainment Area, April 2022 (Uinta Basin TSD).

[55] Id.

[56] Id.

[57] *Center for Biological Diversity* v. *EPA,* No. 20–9560 (Tenth Cir.), Petitioner's Opening Brief at 33–37.

[58] *See generally* 2016v2 TSD; *see also, e.g.,* 2016v2 TSD Section 4, 157–213.

provide such necessary assurances for the new or revised NAAQS at issue.

In its September 17, 2018 infrastructure SIP submission, Colorado stated that ''[t]here are no state or federal provisions prohibiting the implementation of any provision of the Colorado SIP.'' Specifically, Colorado cited to its ''general authority to adopt the rules and regulations necessary to implement the SIP'' as ''set out in the Colorado Air Pollution Prevention and Control Act Section 25–7–105 of the Colorado Revised Statutes (C.R.S);'' general authority to administer and enforce the program in C.R.S. 25–7–111; additional authority to regulate air pollution and implement provisions in the SIP in the Colorado Air Pollution Prevention and Control Act, Article 7 of title 25; and authority delegated under C.R.S. 42–4–301 through 42–4–414 (concerning motor vehicle emissions) and 42–4–414, C.R.S. (concerning emissions from diesel-powered vehicles).[59]

The Center commented on EPA's proposed approval of the State's infrastructure SIP submission, stating that C.R.S. 25–7–109(8)(a) prohibits Colorado from regulating agricultural sources of air pollution unless they are major sources. EPA evaluated the Center's concern with respect to Colorado's authority. In response, EPA explained that the provision cited by the Center does not bar the State from carrying out its existing SIP, and that in fact, the provision *requires* regulation of agricultural sources if they are major stationary sources, *or* if regulation is required by Part C, Part D, or title V of the CAA. In other words, EPA interpreted the provision to mean that if it is necessary to regulate agricultural sources beyond those that are major sources in order to attain and maintain the NAAQS, then the State has authority to do so. EPA noted that whether Colorado will need additional emission limitations and other control measures for areas designated nonattainment for the 2015 ozone NAAQS will be evaluated by the State and EPA as part of the State's attainment plan under CAA title I part D through a separate process. Thus, EPA found that Colorado does not lack authority to implement the SIP and concluded instead that Colorado's infrastructure SIP satisfied CAA section 110(a)(2)(E)(i).[60]

2. EPA's Revised Analysis on Remand Under CAA Section 110(a)(2)(E)(i)

In its brief filed in the Tenth Circuit litigation, the Center renewed its argument challenging EPA's approval of Colorado's infrastructure SIP submission as meeting CAA section 110(a)(2)(E)(i) for the 2015 ozone NAAQS. The Center argued that EPA erred in approving Colorado's infrastructure SIP submittal under CAA section 110(a)(2)(E)(i) because C.R.S. 25–7–109(8)(A) bars Colorado from regulating agricultural sources other than those that are major sources. In particular, the Center argued that agricultural emissions are largely not from major stationary sources, but rather from fugitive emissions due to pesticide application, gases emitted from soil after fertilizer application, minor stationary sources, and mobile sources. The Center argued that Colorado state law thus is inadequate to provide authority to control these sources of pollution.[61]

As explained in the 2020 final rule, EPA disagreed with the Center's interpretation of the C.R.S. 25–7–109(8)(A) and instead concluded that Colorado is not prohibited under state law from regulating emissions from agricultural sources (however small)[62] as necessary to implement the 2015 ozone NAAQS.[63] In relevant part, the agricultural provision states that ''the [State] shall regulate emissions from [agriculture, horticultural, or floricultural production, including pesticide application] . . . if they are 'major stationary sources', . . . or are required by Part C (prevention of significant deterioration), Part D (nonattainment), or Title V (minimum elements of a permit program), ...''[64] Thus, as stated in the 2020 final rule, the statute plainly *requires* regulation of emissions from agricultural sources, including from nonpoint sources, soils and pesticides, mobile sources, and minor sources, if required under the CAA, including as necessary under Part D for attainment of the NAAQS.

On remand, EPA verified that it properly interpreted Colorado law with respect to the State's authority to regulate agricultural sources, and, in particular, that Colorado law does not limit that regulatory authority to major sources. Indeed, Colorado has confirmed that it agrees with EPA's interpretation of C.R.S. 25–7–109(8)(A). In a letter submitted to EPA on July 29, 2021, Colorado acknowledged that C.R.S. 25–7–109(8)(A) includes a ''limited restriction'' on the State's authority to regulate emissions from agricultural production activities but explains that there are ''important carve-outs'' to that limited restriction. Colorado confirmed that the State has explicit authority to regulate major stationary sources. Colorado further explained that the sources that qualify as ''major stationary sources'' depends on the classification of the nonattainment area at issue—the higher the classification the lower the emissions threshold to qualify as a major stationary source. Additionally, Colorado confirmed in the letter that the State has ''authority to regulate emissions from agricultural production, regardless of the size of the source, to the extent that such regulations are required by Part C (prevention of significant deterioration), Part D (nonattainment), or Title V (minimum elements of a permit program) of the federal [CAA].'' Moreover, Colorado confirmed that the State has explicit authority to regulate emissions from agricultural production to the extent that such regulation is required by CAA section 111 (new source performance standards) and explained that such regulation is conducted through the State's minor source, Prevention of Significant Deterioration, New Source Review, and Title V permitting programs. Finally, Colorado explained that the State has authority to promulgate, administer, and enforce emissions regulations that impact emissions from agricultural production, including mobile sources.[65]

Based on the above analysis and Colorado's July 29, 2021 letter, EPA has now verified its interpretation of the State's authority to regulate agricultural sources, as necessary to meet CAA requirements. Colorado has thus provided necessary assurances of the State's authority to regulate agricultural sources as required in 42 U.S.C. 7410(a)(2)(E)(i). Accordingly, EPA is again proposing to approve Colorado's infrastructure SIP submission for the 2015 ozone NAAQS with respect to the requirements of CAA section 110(a)(2)(E)(i).

[59] Colorado SIP Submission, Attachment 9, Adopted SIP at 6.

[60] 85 FR 20171.

[61] *Center for Biological Diversity* v. *EPA*, No. 20–9560 (Tenth Cir.), Petitioner's Opening Brief at 38–44.

[62] Emissions from agricultural sources make up a very small portion of NO_X and VOC emissions statement in the Denver Metro/Northern Front Range nonattainment area. *See* 2017 NEI NO_X VOC table, which is included in the docket for this action.

[63] 85 FR 20171.

[64] C.R.S. 25–7–109(8)(a).

[65] Letter to Deb Thomas, Regional Administrator (Acting) and Deputy Regional Administrator, U.S. Environmental Protection Agency, Region 8, from Garrison Kaufman, Director, Air Pollution Control Division, July 29, 2021.

III. Proposed Action

In this action, EPA proposes to conclude that Colorado's infrastructure SIP satisfies the interstate transport provision of the CAA, section 110(a)(2)(D)(i)(I), for the 2015 ozone NAAQS, and that the State has provided the necessary assurances of the State's authority to regulate all agricultural sources as may be required by the CAA under section 110(a)(2)(E)(i).

IV. Statutory and Executive Order Reviews

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

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

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

List of Subjects in 40 CFR Part 52

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

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

Dated: April 26, 2022.

K.C. Becker,

Regional Administrator, Region 8.

[FR Doc. 2022–09449 Filed 5–5–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 152

[EPA–HQ–OPP–2019–0701; FRL–7542–03–OCSPP]

RIN 2070–AK56

Pesticides; Proposal To Add Chitosan to the List of Active Ingredients Permitted in Exempted Minimum Risk Pesticide Products; Notice of Data Availability on Chitosan and Chitosan Salts

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of data availability.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting comment on data related to the aquatic toxicity of chitosan salts. The EPA seeks public comment on these data.

DATES: Comments must be received on or before June 6, 2022.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2006–0766, 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.*

Due to the public health concerns related to COVID–19. The EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

The EPA is making two aquatic toxicity reports, submitted by Tidal Vision Products, LLC, available for public comment. The EPA seeks input from stakeholders on how these reports may be used to inform the Agency's assessment of the aquatic toxicity of chitosan and its salts.

On November 2, 2020, the EPA published ''Pesticides; Proposal to Add Chitosan to the List of Active Ingredients Permitted in Exempted Minimum Risk Pesticide Product,'' 85 FR 69307 (FRL–10009–24). The proposed rule addressed the subject matter of a 2018 petition by Tidal Vision Products LLC that requested that the substance commonly known as chitosan (also known by its chemical name poly-D-glucosamine) (CAS Reg. No. 9012–76–4) be added to the list of active ingredients allowed in exempted minimum risk pesticide products under 40 CFR 152.25(f)(1).

Public comments on the proposed rule discussed these salts. The EPA notes that chitosan may form as a salt (*e.g.,* acetate, lactate, hydrochloride, and salicylate) when it is solubilized in acids for end use product formulation and subsequently applied in the environment. The new information submitted by Tidal Vision pertains to these salts.

As authorized by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 25(b), the EPA has exempted from the requirement of registration certain pesticide products if they are composed of specified

ingredients (recognized active and inert substances which are listed in the regulations) and labeled according to the EPA's regulations in 40 CFR 152.25(f). The EPA created the exemption for minimum risk pesticides to eliminate the need for the Agency to expend significant resources to regulate products that were deemed to be of minimum risk to human health and the environment. Prior to submission of these aquatic toxicity reports, the EPA received a petition from Tidal Vision Products, LLC, requesting that the substance commonly known as chitosan (also known by its chemical name poly-D-glucosamine) (CAS Reg. No. 9012–76–4) be added to the list of active ingredients allowed in exempted minimum risk pesticide products under 40 CFR 152.25(f)(1). This matter was the subject of a proposed regulation (85 FR 69307) (FRL–10009–24).

The EPA is considering the information submitted by Tidal Vision in its decision regarding whether to finalize the proposal to add chitosan to the list of permitted active ingredients, and if so, whether and how to address chitosan salts in the exemption.

II. References

The following is a listing of the documents that are specifically referenced in this document. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. Tidal Vision USA. (2019). Aquatic Toxicology Report by Eurofins Environmental Testing Test America. Lab I.D. No. B4345. Report Date: June 17, 2019. EPA Master Record Identification (MRID) 51861901.

2. Tidal Vision USA. (2019). Aquatic Toxicology Report by Eurofins Environmental Testing Test America. Lab I.D. No. B4421. Report Date: August 28, 2019. EPA Master Record Identification (MRID) 51861902.

List of Subjects in 40 CFR Part 152

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

Dated: April 29, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2022–09731 Filed 5–5–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 704

[EPA–HQ–OPPT–2021–0357; FRL–8632–02–OCSPP]

RIN 2070–AK99

Asbestos; Reporting and Recordkeeping Requirements Under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing reporting and recordkeeping requirements for asbestos under the Toxic Substances Control Act (TSCA). EPA proposes to require certain persons that manufactured (including imported) or processed asbestos and asbestos-containing articles (including as an impurity) in the four years prior to the date of publication of the final rule to electronically report certain exposure-related information. This action would result in a one-time reporting obligation. EPA emphasizes that this proposed requirement would include asbestos that is a component of a mixture. The information sought includes quantities of asbestos (including asbestos that is a component of a mixture) and asbestos-containing articles that were manufactured (including imported) or processed, types of use, and employee data. Reported information would be used by EPA and other Federal agencies in considering potential future actions, including risk evaluation and risk management activities. EPA is requesting public comment on all aspects of this proposed rule and has also identified items of particular interest for public input.

DATES: Comments must be received on or before July 5, 2022.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2021–0357, 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.*

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Daniel R. Ruedy, Data Gathering and Analysis Division (Mailcode: 7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–7974; email address: *ruedy.daniel@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (defined by statute to include import) or process asbestos. Any use of the term ''manufacture'' in this document will encompass ''import,'' and the term ''manufacturer'' will encompass ''importer.'' Any use of the term ''asbestos'' will apply to asbestos in bulk form, in an article, or as an impurity, or as a component of a mixture. For a more thorough discussion of the subject asbestos forms, please see Unit III.A. of this document. You may also be potentially affected by this action if you manufacture (including import) or process other chemical substances or mixtures not on the TSCA inventory if they include asbestos.

The following list of North American Industry Classification System (NAICS) codes are provided to assist in determining whether this action might apply to you. This list is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include entities identified in:

- NAICS code 211—Oil and Gas Extraction;
- NAICS code 212—Mining (except Oil and Gas);
- NAICS code 325—Chemical Manufacturing;
- NAICS code 327—Nonmetallic Mineral Product Manufacturing;
- NAICS code 332—Fabricated Metal Product Manufacturing;
- NAICS code 336—Transportation Equipment Manufacturing;
- NAICS code 339—Miscellaneous Manufacturing;

• NAICS code 447—Gasoline Stations; and

• NAICS code 811—Repair and Maintenance.

Additionally, you should carefully examine the proposed regulatory text in this document to determine if your business would be impacted by this rule. If you have any questions regarding the applicability of this action to a particular entity, consult the technical contact person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

EPA is proposing this action under the authority of section 8(a) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2607(a), which generally authorizes EPA to promulgate rules that require each person, other than small manufacturers (including importers) or processors, who manufactures (including import) or processes, or proposes to manufacture (including import) or process, the chemical substance identified in the rule, to maintain such records and submit such reports as the EPA Administrator may reasonably require.

Although TSCA section 8(a)(1) provides an express exemption for small manufacturers (including importers) and processors, TSCA section 8(a)(3) enables EPA to require small manufacturers (including importers) and processors to report under TSCA section 8(a) with respect to a chemical substance that is the subject of a rule proposed or promulgated under TSCA sections 4, 5(b)(4), or 6, or is the subject of an order in effect under TSCA sections 4 or 5(e), a consent agreement under TSCA section 4, or relief that has been granted under a civil action under TSCA sections 5 or 7. Asbestos is subject to TSCA section 6 rulemaking under the Asbestos Ban and Phaseout rule of 1989 (Ref. 1). A portion of this rule was overturned in *Corrosion Proof Fittings* v. *EPA,* 947 F.2d 1201 (5th Cir. 1991), however, a portion remains. The remaining portion of EPA's 1989 asbestos ban and phaseout rule prohibits the manufacture, importation, processing, and distribution in commerce of: Commercial Paper, Corrugated Paper, Rollboard, Specialty Paper, Flooring Felt, and New Uses (the manufacture, importation or processing of which would be initiated for the first time after August 25, 1989). *See* 40 CFR 763.160 *et seq.* Thus EPA proposes to exercise its authority provided under TSCA section 8(a)(3)(A)(ii) to require small manufacturers (including importers) and processors of asbestos or asbestos-containing mixtures (other than Libby Amphibole asbestos) to maintain records and submit reports. Libby Amphibole asbestos is not subject to an applicable proposed or promulgated rule under TSCA sections 4, 5(b)(4) or 6, an order in effect under TSCA section 4 or 5(e), or a consent agreement under TSCA section 4, nor is it the subject of relief that has been granted under a civil action under TSCA section 5 or 7. Therefore, small manufacturers (including importers) and processors of Libby Amphibole asbestos are expected to be exempt from this proposed reporting and recordkeeping rule. For a more thorough discussion of the proposed reporting for small manufacturers (including importers) and processors, see Unit III.B.

TSCA section 8(a)(1)(A) also excludes from the scope of EPA's regulatory authority under that paragraph any manufacturer (including importer) or processor of ''a chemical substance described in subparagraph (B)(ii).'' TSCA section 8(a)(1)(B)(ii), in turn, provides EPA authority to require recordkeeping and reporting by each person (other than a small manufacturer [including importer] or processor) who manufactures (including imports) or processes, or proposes to manufacture (including import) or process, a chemical substance ''in small quantities . . . solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product,'' but only to the extent EPA determines the recordkeeping and/or reporting is necessary for the effective enforcement of TSCA. EPA is not proposing to require recordkeeping or reporting by persons who manufacture (including import) or process, or propose to manufacture (including import) or process, asbestos in small quantities solely for research or analysis for the development of a product as described in TSCA section 8(a)(1)(B)(ii). ''*Small quantities solely for research and development*'' is defined in 40 CFR 704.3 to mean quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that are not greater than reasonably necessary for such purposes.

TSCA section 14 imposes requirements for the assertion, substantiation, and review of information that is claimed as confidential under TSCA (also known as confidential business information or CBI. Some information submitted at the time of the proposed reporting under this rule may be claimed as confidential.

C. What action is the Agency taking?

EPA is proposing to require asbestos manufacturers (including importers) and processors to report to EPA certain information known to or reasonably ascertainable by those entities. For this action, the term ''asbestos'' includes various forms of asbestos, including Libby Amphibole asbestos, as described in more detail in Unit III.A. of this document. The following is a brief list of the primary data requirements being proposed. These proposed requirements are described in detail in Unit III.

1. *Asbestos domestic manufacturers (Asbestos Mine and Mill):* The provisions in this proposed rule would require asbestos domestic manufacturers to provide the quantity manufactured per asbestos type, use, and employee exposure information to EPA. This would include situations in which asbestos is being mined or milled as an intentional or non-intentional impurity, such as in vermiculite and talc.

2. *Asbestos importers:* The provisions in this proposed rule would require importers of asbestos to provide the quantity imported per asbestos type, use, and employee exposure information. This includes importers of mixtures containing asbestos, articles containing asbestos components, and impurities (in articles, bulk materials, or mixtures, such as in talc and vermiculite).

3. *Asbestos processors:* The provisions of the proposed rule would require processors of asbestos (including processors of mixtures or articles) to provide the quantity processed per asbestos type, use, and employee exposure information. This includes both *primary processors* and *secondary processors* of asbestos, as described in Units III.F.3. and 4. This would include situations in which asbestos is appearing as an intentional or non-intentional impurity, such as in vermiculite and talc.

D. Why is the Agency taking this action?

The Agency is proposing this action to obtain certain information known to or reasonably ascertainable by manufacturers (including importers) and processors of asbestos that EPA believes would help the Agency better understand the exposures and uses associated with asbestos, including asbestos in articles and as an impurity (in articles, bulk materials, or mixtures, such as in talc and vermiculite), that fall under the scope of this proposal. Reported information would be used by EPA and other Federal agencies in

considering potential actions involving asbestos, including EPA's TSCA risk evaluation and risk management activities. This action is also subject to a settlement agreement, as discussed in Unit II.C.4. of this document. For a more thorough discussion of the TSCA risk evaluation and risk management process, please see Unit II.C.5. of this document.

E. What are the estimated incremental impacts of this action?

EPA has prepared an economic analysis (Ref. 2) of the potential impacts associated with this proposed rule. The primary purpose of this proposed rule is the collection of detailed data on asbestos uses and exposures. Reported information would be used by EPA and other Federal agencies in considering potential actions involving asbestos, including EPA's TSCA risk evaluation and risk management activities. EPA estimates that at least 18 firms may submit reports for 27 sites based on the intentional manufacturing (including importing) or processing of asbestos, including mixtures and articles containing asbestos. EPA does not currently have information on the extent to which asbestos occurs as an impurity in products that are currently manufactured (including imported) or processed in the U.S., so the number of firms that may report for impurities is not estimated.

The industry is expected to incur one-time burdens and costs associated with rule familiarization, form completion, CBI claim substantiation, recordkeeping, and electronic reporting activities. Where asbestos is intentionally manufactured (including imported) or processed, the estimated average burden and cost per site ranges from approximately 12 hours and $1,146 to 26 hours and $2,265, depending on the type of activities the respondent is engaged in and the information known to or reasonably ascertainable by them. For products where asbestos occurs as an impurity, the estimated average burden and cost per site ranges from approximately 17 hours and $1,573 to 40 hours and $3,334, again depending on the type of activities and the information that is known to or reasonably ascertainable. EPA estimates a total industry quantified burden of approximately 1,157 hours, with a quantified total cost of approximately $99,496.

EPA estimates that at least 14 small firms, which included article importers, will be affected by the proposed rule. Of those small firms, 12 are expected to have cost impacts of less than 1% of annual revenues, one is expected to have impacts between 1–3%, and one is expected to have impacts of more than 3% of annual revenues. Again, these estimates do not include firms that are impacted by the requirement to report for impurities. The Agency is expected to incur a cost of $560,343. The total social burden and cost are therefore estimated to be approximately 1,157 hours and $659,839, respectively (Refs. 2 and 3).

F. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Background

A. What is TSCA section 8(a)?

TSCA section 8(a)(1) generally authorizes EPA to promulgate rules that require entities, other than small manufacturers (including importers) or processors, who manufacture (including import) or process, or propose to manufacture (including import) or process, a chemical substance to maintain such records and submit such reports as the EPA Administrator may reasonably require.

Under TSCA section 8(a)(2), EPA may require reporting and recordkeeping of the following information:

- The common or trade name, chemical identity and molecular structure of each chemical substance or mixture;
- Categories or proposed categories of use for each substance or mixture;
- Total amount of each substance or mixture manufactured (including imported) or processed, the amounts manufactured (including imported) or processed for each category of use, and reasonable estimates of the respective amounts to be manufactured (including imported) or processed for each of its categories of use or proposed categories of use;
- Descriptions of byproducts resulting from the manufacture (including import), processing, use, or disposal of each substance or mixture;
- All existing information concerning the environmental and health effects of each substance or mixture;
- The number of individuals exposed, and reasonable estimates of the number of individuals who will be exposed, to each substance or mixture in their places of employment and the duration of their exposure; and
- The manner or method of disposal of each substance or mixture, and any change in such manner or method.

B. What is asbestos?

Asbestos is one or more of a group of highly fibrous silicate minerals that readily separate into long, thin, strong fibers that have sufficient flexibility to be woven, are heat resistant and chemically inert, are electrical insulators, and are therefore suitable for uses where incombustible, nonconducting, or chemically resistant materials are required.

Asbestos is a mineral fiber that occurs in rock and soil. Because of its fiber strength and heat resistance, asbestos has been used in a variety of building construction materials for insulation and as a fire retardant. Asbestos has also been used in a wide range of manufactured goods, mostly in building materials (roofing shingles, ceiling and floor tiles, paper products, and asbestos cement products), friction products (automobile clutch, brake, and transmission parts), heat-resistant fabrics, packaging, gaskets, and coatings (Ref. 3).

For purposes of this proposed rule, EPA considers ''asbestos'' to include the asbestiform varieties included in the definition of asbestos in TSCA Title II (added to TSCA in 1986), section 202 and Libby Amphibole asbestos. ''Asbestos'' is defined in TSCA Title II, section 202 as the asbestiform varieties of six fiber types—chrysotile (serpentine), crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite or actinolite. The general CAS Registry Number (CASRN) of asbestos is 1332–21–4; this is the only asbestos on the TSCA Inventory. However, CASRNs are also available for specific fiber types. See Unit III.A.1. for additional discussion.

In addition, EPA is proposing to include reporting for Libby Amphibole asbestos (mainly consisting of tremolite ([CASRN 77536–68–6], winchite

[CASRN 12425–92–2], and richterite [CASRN 17068–76–7]) to identify if this particular type of asbestos continues to be manufactured (including imported) or processed in the United States. The term ''Libby Amphibole asbestos'' is used in this document to identify the naturally occurring mixture of amphibole mineral fibers of varying elemental composition (winchite, richterite, tremolite, etc.) that have been identified in the Rainy Creek complex near Libby, Montana (Ref. 4). EPA does not anticipate that there is ongoing manufacture (including import) or processing of the Libby Amphibole asbestos, but to help confirm this understanding has included this substance in the scope of this proposed rule.

EPA requests comment on whether reporting on Libby Amphibole asbestos' component parts, winchite and richterite, which are not asbestos types but are indicative of the presence of Libby Amphibole asbestos in a substance, should be included in the scope of this TSCA section 8(a) data collection and be reported on individually in addition to reporting on Libby Amphibole asbestos (Ref. 5). Any reporting on Libby Amphibole asbestos would improve EPA's understanding of this substance and would inform risk evaluation activities involving asbestos.

Asbestos is a hazard to human health (Ref. 6). Some of the health effects caused by exposure to asbestos are:

- Lung cancer;
- Ovarian cancer;
- Laryngeal cancer; and
- Mesothelioma, a cancer of the thin lining of the lung, chest and the abdomen and heart.

As part of the TSCA Risk Evaluation of chrysotile asbestos published in December 2020 (Ref. 6). EPA evaluated the database of health effects associated with asbestos exposure cited in U.S. and international data sources and reviewed and evaluated scientific information on toxicity, exposure, and hazard. Many authorities have established that there are causal associations between asbestos exposures and cancer (Ref. 7).

For a more thorough discussion on the asbestos types addressed by this proposed rule, see Unit III.A. of this document.

C. What are relevant past and ongoing EPA TSCA actions on asbestos?

1. 1982 Asbestos Reporting Requirements Rule

In 1982, EPA finalized a rule entitled: ''Asbestos Reporting Requirements'' (47 FR 33198, August 30, 1982) (TSH–FRL–2124–4), under the authority of TSCA section 8(a) that required one-time reporting to EPA by asbestos manufacturers, importers, and processors. The information sought included data on the quantities of asbestos used in making products, employee exposure data, and waste disposal and pollution control equipment data. Reported information was used by EPA and other Federal agencies in considering the regulation of asbestos.

The information gathered as a result of the 1982 data collection rule was used in the drafting of the 1989 rule entitled ''Asbestos: Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions'' (54 FR 29460, July 12, 1989) (FRL–3476–2). In that action, EPA used TSCA section 6 authority to ban most asbestos-containing products. However, most of the ban was overturned in 1991 by the Fifth Circuit Court of Appeals. *Corrosion Proof Fittings* v. *EPA,* 947 F.2d 1201 (5th Cir. 1991). As a result, the 1989 asbestos regulation only bans new uses of asbestos in products that would be initiated ''for the first time'' after 1989 and five other specific product types (40 CFR part 763, subpart I).

It has been nearly 40 years since the 1982 rule was implemented, and EPA needs an updated data collection to better understand the universe of asbestos types in commerce and the specific entities presently manufacturing (including importing) and processing asbestos, including asbestos-containing products. This proposal is modeled after the 1982 data collection but requires more detailed information from manufacturers (including importers) and processors in addition to information about asbestos appearing as an impurity.

2. Chemical Data Reporting (CDR) Rule

In limited circumstances, asbestos has been reported under the Chemical Data Reporting (CDR) rule (40 CFR part 711). The CDR rule requires manufacturers (including importers) to provide EPA with information on the production and use of chemicals in commerce. (Ref. 8). Under CDR, naturally occurring substances (including asbestos), impurities, and chemical substances when imported as part of articles are exempted from reporting (Ref. 9). This proposed rule differs from the existing CDR universe of data collected as it would: (a) Be a one-time data collection as opposed to a reoccurring data collection; (b) require reporting for naturally-occurring asbestos; (c) require processors of asbestos to report (*i.e.,* sites manufacturing (including importing) and/or processing asbestos would be subject to this rule); and (d) require reporting by entities who are manufacturing (including importing), and/or processing asbestos and to whom the asbestos content is known or reasonably ascertainable (see TSCA section 8(b)(2)). ''Known to or reasonably ascertainable by'' would be defined to include ''all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.'' EPA acknowledges that it is possible that an importer, particularly an importer of articles containing asbestos, may not have knowledge that they have imported asbestos and thus not report under this rule, even after they have conducted their due diligence under this reporting standard as described in this paragraph. Such an importer should document its activities to support any claims it might need to make related to due diligence. EPA is asking for public comment on importers' anticipated ability to know or reasonably ascertain whether those entities import asbestos. This proposed rule would also differ from CDR data collection as it would apply to impurities and articles, both of which are exempted from CDR data collection (40 CFR 711.10(b) & (c)) (Ref. 9, Ref. 10).

3. 2019 Significant New Use Rule (SNUR) for Discontinued Uses of Asbestos

In 2019, EPA promulgated a SNUR (84 FR 17345, April 25, 2019) (FRL–9991–33) for the manufacturing (including import) or processing of asbestos for use in adhesives, sealants, and roof and nonroof coatings; arc chutes; beater-add gaskets; cement products; extruded sealant tape and other tape; filler for acetylene cylinders; friction materials (with certain exceptions); high-grade electrical paper; millboard; missile liner; packings; pipeline wrap; reinforced plastics; roofing felt; separators in fuel cells and batteries; vinyl-asbestos floor tile; woven products; any other building material; and any other use of asbestos that was not already prohibited under TSCA or under evaluation in the TSCA Risk Evaluation for Asbestos Part 1: Chrysotile Asbestos.

Activities that were under evaluation in the TSCA Risk Evaluation for Asbestos Part 1: Chrysotile Asbestos were not subject to the SNUR since there was ongoing manufacturing (including importing) or processing for those uses. Those activities not subject to the SNUR were manufacturing (including importing) or processing for

the use of chrysotile in asbestos diaphragms; sheet gaskets; oilfield brake blocks; aftermarket automotive brakes/linings; other vehicle friction products; and other gaskets. Because all the ongoing uses of asbestos identified in the SNUR were of chrysotile, any use of crocidolite, amosite, anthophyllite, tremolite, or actinolite would be considered a significant new use.

A person wishing to begin manufacturing, importing, or processing asbestos (including as part of an article) for a significant new use must first submit a Significant New Use Notice (SNUN) to EPA. Before any significant new use of asbestos begins, EPA must evaluate it for potential risks to health and the environment and take any necessary regulatory action, which may include a prohibition.

4. TSCA Section 21 Petitions on Asbestos

On September 27, 2018, and January 31, 2019, respectively, petitioners Asbestos Disease Awareness Organization et al. (ADAO) (Ref. 11), and Attorneys General from ten states and the District of Columbia (the States) (Ref. 12) submitted petitions under TSCA section 21 (15 U.S.C. 2620) requesting EPA to amend the CDR Rule in ways that petitioners asserted would increase reporting of asbestos. Both petitions sought to close alleged asbestos CDR reporting gaps (including immediate submission of asbestos reports), remove the naturally occurring and byproduct exemptions, lower the reporting threshold, require reporting by processors, and eliminate the ability to claim information as confidential, in order to maximize the information reported to aid the Agency in conducting the ongoing TSCA section 6 risk evaluation of asbestos and subsequent TCSA Section 6(a) risk management rule (see Unit II.C.3. for more information). EPA denied the petitions on December 21, 2018, and April 30, 2019, respectively, and issued associated explanations for the denials in the **Federal Register** on February 12, 2019 (84 FR 3396) (FRL–9988–56) and May 8, 2019 (84 FR 20062) (FRL–9992–67), respectively, asserting that the petitioners failed to demonstrate that it is necessary to amend the CDR rule. EPA's denial was also in part due to a timing issue with the asbestos risk evaluation. Petitioners filed lawsuits on February 18, 2019, and June 28, 2019, respectively, in the U.S. District Court in the Northern District of California, reiterating concerns about the need to amend the CDR rule to increase asbestos reporting. *Asbestos Disease Awareness Organization* v. *EPA,* No. 19–CV–00871; *State of California et al.* v. *EPA,* No. 19–CV–03807. The cases were consolidated. On December 22, 2020, after full briefing and oral argument, the Court issued an opinion granting summary judgment to Plaintiffs and denying summary judgment to EPA.

Following the litigation, EPA reached an agreement with the Plaintiffs on June 7, 2021. The parties agreed that no later than nine months from the effective date of the agreement (Ref. 13), EPA will sign for publication in the **Federal Register**, a notice of proposed action to promulgate a rule pursuant to TSCA section 8(a), 15 U.S.C. 2607(a), for the maintenance of records and submission to EPA of reports by manufacturers (including importers) and processors of asbestos (including asbestos that is a component of a mixture), and articles containing asbestos (including as an impurity) that address the information-gathering deficiencies identified in the Court's Summary Judgment Order. Additionally, the parties agreed that no later than eighteen months from the effective date of the agreement (Ref. 13), EPA will sign for publication in the **Federal Register** a notice of final action regarding the proposed TSCA section 8(a) rule.

5. TSCA Risk Evaluation for Asbestos

Pursuant to TSCA section 6(b)(4)(A), EPA conducts risk evaluations to determine whether a chemical substance presents unreasonable risk of injury to health or the environment, without consideration of costs or non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by the Agency, under the conditions of use. (15 U.S.C. 2605(b)(4)(A)).

EPA is developing the TSCA Risk Evaluation on asbestos in two parts. In December 2020, EPA released the TSCA Risk Evaluation for Asbestos Part 1: Chrysotile Asbestos (Ref. 6), which determined that chrysotile asbestos presents an unreasonable risk of injury to health based upon the following conditions of use: Processing and industrial use of chrysotile asbestos diaphragms in the chlor-alkali industry; processing and industrial use of chrysotile asbestos-containing sheet gaskets in chemical production; industrial use and disposal of chrysotile asbestos-containing brake blocks in the oil industry; commercial use and disposal of aftermarket automotive chrysotile asbestos-containing brakes/linings; commercial use and disposal of other chrysotile asbestos-containing vehicle friction products; commercial use and disposal of other asbestos-containing gaskets; consumer use and disposal of aftermarket automotive chrysotile asbestos-containing brakes/linings; and consumer use and disposal of other asbestos-containing gaskets.

EPA initially focused the risk evaluation for asbestos on chrysotile asbestos as this is the only asbestos type that EPA believes is currently imported, processed, or distributed in the U.S. EPA informed the public of this decision to focus on ongoing uses of asbestos and exclude legacy uses and associated disposals in the Scope of the Risk Evaluation for Asbestos document, published in June 2017 (Ref. 14). However, in late 2019, the court in *Safer Chemicals, Healthy Families* v. *EPA,* 943 F.3d 397, 426–27 (9th Cir. 2019) held that EPA's Risk Evaluation Rule (82 FR 33726, July 20, 2017) (FRL–9964–38) should not have excluded ''legacy uses'' (*i.e.,* uses without ongoing or prospective manufacturing (including importing), processing, or distribution) or ''associated disposals'' (*i.e.,* future disposal of legacy uses) from the definition of conditions of use, although the court did uphold EPA's exclusion of ''legacy disposals'' (*i.e.,* past disposal). Following this court ruling, EPA continued development of the risk evaluation for chrysotile asbestos and determined that the complete TSCA Risk Evaluation for Asbestos would be issued in two parts. The TSCA Risk Evaluation for Asbestos Part 1: Chrysotile Asbestos was released in December 2020, allowing the Agency to expeditiously move into risk management for the unreasonable risk identified in Part 1.

EPA is currently conducting the TSCA Risk Evaluation for Asbestos Part 2: Supplemental Evaluation Including Legacy Uses and Associated Disposals of Asbestos. EPA intends to include in Part 2 of the risk evaluation the legacy uses and associated disposal of asbestos. For the purposes of scoping and risk evaluation, EPA has adopted the definition of asbestos as defined by TSCA Title II (added to TSCA in 1986), section 202 definition as the ''asbestiform varieties of six fiber types—chrysotile (serpentine), crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite or actinolite,'' The TSCA Title II definition identified five amphibole types of asbestos (crocidolite, amosite, anthophyllite, tremolite, and actinolite) plus a serpentine type (chrysotile). Part 2 will also consider Libby Amphibole Asbestos as well as asbestos present as an impurity in talc and other substances. EPA expects that the data collected from this proposed rule will

be used in Part 2 of the TSCA Risk Evaluation for asbestos and will also inform risk management actions for asbestos under TSCA section 6(a).

D. How will EPA use the information proposed to be collected?

Reported information would be used by EPA and other Federal agencies in considering potential actions on asbestos, including EPA's TSCA risk evaluation and risk management activities. Reporting requirements may provide EPA with baseline information needed to assess whether certain ''conditions of use'' of asbestos pose an unreasonable risk to health or the environment under TSCA section 6(b). EPA must consider reasonably available information as part of the risk evaluation process under TSCA section 6(b), and as part of any subsequent risk management rulemaking efforts under TSCA section 6(a). Reported information would be useful in the risk management stage because EPA would consider potential risk management actions taking into account relevant information obtained through this rulemaking. Understanding the health risks of asbestos and protecting the public, including potentially exposed or susceptible subpopulations, from these risks is a priority for EPA.

As part of the risk evaluation process under TSCA section 6(b), EPA must determine whether asbestos presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including unreasonable risk to relevant potentially exposed or susceptible subpopulations, under the conditions of use. EPA must also use scientific information and approaches in a manner that is consistent with the requirements in TSCA for the best available science, and ensure decisions are based on the weight of scientific evidence. See TSCA section 26(h) and (i), 15 U.S.C. 2625(h) and (i). In order to follow this framework, EPA shall take into consideration reasonably available information to inform the Part 2 risk evaluation. Data collected by this rule could help to fill potential data gaps that EPA may have for asbestos that could better inform Part 2 of the asbestos risk evaluation. Following risk evaluation, TSCA mandates that EPA take action if the Agency determines that asbestos presents unreasonable risk of injury to health or the environment. EPA needs to ensure that sufficient information is reasonably available on the uses and trends of asbestos activities to develop a risk management rule that eliminates the unreasonable risk. The information collected in this rulemaking may be available to support the Part II risk evaluation and the final risk evaluation document expected by December 1, 2024. Additionally, the information collected in this rulemaking will help inform risk management following the risk evaluation process.

For these reasons, EPA believes that the reporting and recordkeeping requirements proposed in this document are reasonable. See TSCA section 8(a)(1)(A).

III. Summary of Proposed Reporting and Recordkeeping Requirements

A. What chemical substances would be reportable under this rule?

EPA is proposing to require the reporting of information on specific asbestos forms, or if specific information is not known or reasonably ascertainable, reporting on ''asbestos'' as it is more generally listed on the TSCA Inventory. EPA is also proposing to require the reporting of information related to asbestos as it is manufactured (including imported) or processed in bulk, as a component of a mixture, in an article, or as an impurity in bulk materials or products.

See Units III.A.2 and 3 for more details.

1. Asbestos Forms

EPA is proposing to obtain manufacturing (including importing) and processing information associated with the following different asbestos forms, and therefore is proposing to require that reporting be completed for each of the forms, to the extent that the information is known or reasonably ascertainable. If the specific asbestos type is unknown, a submitter would provide information under the general asbestos form (CASRN 1332–21–4). See Unit II.B. for more information about what is considered asbestos:

- Asbestos—CASRN 1332–21–4;
- Chrysotile—CASRN 132207–32–0;
- Crocidolite—CASRN 12001–28–4;
- Amosite—CASRN 2172–73–5;
- Anthophyllite—CASRN 77536–67–5;
- Tremolite—CASRN 77536–68–6;
- Actinolite—CASRN 77536–66–4;
- Libby Amphibole Asbestos—CASRN not applicable (mainly consisting of tremolite [CASRN 77536–68–6], winchite [CASRN 12425–92–2], and richterite [CASRN 17068–76–7]).

2. Asbestos as an Impurity

Impurity means a chemical substance which is unintentionally present with another chemical substance (40 CFR 704.3). Asbestos may occur naturally as an impurity in other products such as talc, vermiculite, and potentially other substances. These products are distributed and used in commerce in the United States. For example, talc, a hydrous magnesium silicate mineral, is used in a wide variety of applications. Talc deposits can contain asbestos as an impurity that poses a risk to human health (Ref. 15). If all other reporting conditions are met, these products would be subject to reporting under this rule. EPA proposes to collect data on asbestos as an impurity because EPA may lack data on the extent to which asbestos as an impurity occurs in products under TSCA jurisdiction that are currently being manufactured (including imported) or processed. In particular, data on asbestos as an impurity could better inform the Part 2 asbestos risk evaluation where EPA will determine and then evaluate the relevant conditions of use of asbestos in talc.

3. Articles Containing Asbestos

This rule would require reporting on articles containing asbestos (including as an impurity). An ''article'' is defined in 40 CFR 704.3 as ''a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end-use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.'' EPA proposes to collect more data on imported articles containing asbestos; this data could inform Part 2 of the TSCA Risk Evaluation for Asbestos where EPA will determine and then evaluate the relevant conditions of use of such articles containing asbestos. Articles included in Part 1 of the TSCA Risk Evaluation for Asbestos included brake blocks for use in the oil industry, rubber sheets for gaskets used to create a chemical-containment seal in the production of titanium dioxide, certain other types of preformed gaskets, and some vehicle friction products (Ref. 18); EPA is interested in identifying if there are other articles or if there is information about specific forms of asbestos in these articles.

4. Asbestos That Is a Component of a Mixture

Under TSCA section 3(10) (15 U.S.C. 2602(10)), the term ''mixture'' means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured (including imported) for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined. EPA proposes to collect data on asbestos in circumstances where it is a component of a mixture to inform Part 2 of the TSCA Risk Evaluation for Asbestos. In the Part 2 Evaluation, EPA will determine the relevant conditions of use of asbestos in talc; EPA will use the results to evaluate asbestos exposures and associated risks.

Legislative history affirms that EPA can conduct risk evaluations on a chemical substance when the substance is present as a component of a mixture (See Senate Congressional Record, S3511, June 7, 2016): ''In section 6(b) of TSCA, as amended by the Frank R Lautenberg Chemical Safety for the 21st Century Act, EPA is directed to undertake risk evaluations on chemical substances in order to determine whether they pose an unreasonable risk to health or the environment. Some have questioned whether the failure to explicitly authorize risk evaluations on mixtures calls into question EPA's authority to evaluate the risks from chemical substances in mixtures. The definition of 'conditions of use' . . . plainly covers all uses of a chemical substance, including its incorporation in a mixture, and thus would clearly enable and require, where relevant, EPA to evaluate the risks of the chemical substance as a component of a mixture.''

B. Will small businesses need to report?

Although TSCA section 8(a)(1) provides an exemption for small manufacturers (including importer) and processors, TSCA section 8(a)(3) enables EPA to require small manufacturers (including importers) and processors to report pursuant to TSCA section 8(a) with respect to a chemical substance that is the subject of a rule proposed or promulgated under TSCA sections 4, 5(b)(4), or 6, an order in effect under TSCA sections 4 or 5(e), a consent agreement under TSCA section 4, or relief that has been granted under a civil action under TSCA sections 5 or 7. Six of the asbestos types subject to this proposal (chrysotile, crocidolite, amosite, anthophyllite, tremolite, and actinolite) are subject to a TSCA section 6 rule under the Asbestos Ban and Phaseout rule of 1989 (Ref. 1) (40 CFR 763.160 *et seq.*) and therefore EPA is proposing that these forms of asbestos are not eligible for a small manufacturer (including importer) or processor exemption. Although most of the original ban was overturned in 1991 by the Fifth Circuit Court of Appeals, a portion of the section 6 rulemaking remains in effect (*See* 40 CFR 763.160 *et seq.*) Libby Amphibole asbestos, however, is not subject to an applicable proposed or promulgated rule under TSCA sections 4, 5(b)(4), or 6; an order under TSCA sections 4 or 5(e); or a consent agreement under TSCA section 4; and is not the subject of relief that has been granted under a civil action under TSCA section 5 or 7. Therefore, EPA is proposing that Libby Amphibole asbestos continue to be eligible for such an exemption.

EPA's experience with TSCA Risk Evaluation for Asbestos Part 1: Chrysotile Asbestos, indicates that small businesses are associated with certain identified conditions of use associated with asbestos. For some conditions of use, EPA identified a single business engaged in each of the activities and, in two cases, the companies were small businesses. In addition, EPA identified multiple conditions of use for which it was unable to identify a single company engaged in the condition of use. Because of the low number of companies found to be involved in specific conditions of use, it is possible that companies associated with other conditions of use that need to be considered in the Part 2 TSCA Risk Evaluation, are small businesses.

Because EPA has much less information on the activities of small businesses, the Agency is concerned that certain conditions of use for which the Agency lacks detailed information may be conducted largely or entirely by small businesses. Given EPA's experience and the petitioners' concerns (Refs. 11 and 12), the Agency believes that exempting all small businesses from reporting may exclude most or all of the reporting for some conditions of use which could severely hinder EPA's risk evaluation or risk management activities. As a result, EPA is proposing that small businesses—small manufacturers (including importers) and processors of asbestos, and asbestos mixtures (other than Libby Amphibole asbestos)—will need to maintain records and report under this action.

As discussed previously, at the time of this proposal, Libby Amphibole asbestos is not the subject of any of the activities described in TSCA section 8(a)(3) (Unit III.B.) and therefore manufacturers (including importers) and processors of that substance may be eligible for a small business exemption.

EPA proposes to use the small manufacturer (including importer) definition already established at 40 CFR 704.3. Thus, any entity manufacturing (including importing) Libby Amphibole asbestos would be considered a small manufacturer and exempt from reporting if it meets either of these two standards (as adjusted by an inflation index):

- Total sales during the most recent year of the reporting period, combined with those of the parent company, domestic or foreign (if any), are less than $120 million and the annual production and importation volume of that chemical substance (*i.e.,* asbestos) does not exceed 100,000 pounds at any individual plant site. If the annual production and importation volume of the chemical substance (*i.e.,* asbestos) at any individual site owned or controlled by the submitter is greater than 100,000 pounds, the submitter is required to report for that particular site unless it qualifies as small under the following standard.
- Total sales during the most recent year of the reporting period, combined with those of the parent company, domestic or foreign (if any), are less than $12 million regardless of the quantity of asbestos produced or imported.

The small manufacturer (including importer) exemption as written in *Small manufacturer* and *Small government* definitions (40 CFR 704.3) applies to domestic manufacturers and importers, but does not cover processors. Therefore, EPA proposes a definition for small processors, functionally identical to that established in 40 CFR 704.20—Chemical substances manufactured or processed at the nanoscale (Ref. 16). EPA proposes this definition because it is most similar to the small manufacturing (including importing) definition already promulgated. This definition would state: ''Small processor means any processor whose total annual sales, when combined with those of its parent company (if any), are less than $12 million.'' Note that in the nanoscale rule, the total annual sales threshold is $11 million. EPA increased the threshold to $12 million to align with the non-volume portion of the TSCA small manufacturer definition, which

was updated in 2020. The small manufacturer definition has a second standard that exempts companies on a chemical-by-chemical volume basis (*i.e.,* 100,000-pound threshold when company sales are less than $120 million), thus exempting small manufacturers for some chemicals but not for others. The second standard would not be appropriate to include in the small processor definition because the amount of asbestos in products may vary drastically. It is also not appropriate because EPA is not basing reporting requirements on volumes for this rule. Thus, the volume of asbestos is less applicable as a measure than sales.

EPA requests additional comment on how to best provide guidance for small processors of Libby Amphibole asbestos.

C. What is the reporting standard?

EPA is proposing that this rule would use the reporting standard used for certain other TSCA section 8(a) reporting requirements, including CDR. This standard requires that manufacturers (including importers) and processors report information to the extent that the information is known to or reasonably ascertainable by the manufacturer (including importer) or processor (see TSCA section 8(a)(2)). ''Known to or reasonably ascertainable by'' includes ''all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know'' (40 CFR 704.3). This reporting standard requires reporting entities to evaluate their current level of knowledge of their manufactured products (including imports) or processed products, as well as evaluate whether there is additional information that a reasonable person, similarly situated, would be expected to know, possess, or control. This standard carries with it an exercise of due diligence, and the information-gathering activities that may be necessary for manufacturers (including importers) and processors to achieve this reporting standard may vary from case-to-case.

This standard requires that submitters conduct a reasonable inquiry within the full scope of their organization (not just the information known to managerial or supervisory employees). This standard may also entail inquiries outside the organization to fill gaps in the submitter's knowledge. Such activities may, though not necessarily, include phone calls or email inquiries to upstream suppliers or downstream users or employees or other agents of the manufacturer (including importer) or processor, including persons involved in the research and development, import or production, or marketing of asbestos.

Examples of types of information that are considered to be in a manufacturer's (including importer's) or processor's possession or control, or that a reasonable person similarly situated might be expected to possess, control, or know include: Files maintained by the manufacturer (including importer) or processor such as marketing studies, sales reports, or customer surveys; information contained in standard references showing use information or concentrations of chemical substances in mixtures, such as a Safety Data Sheet (SDS) or a supplier notification; and information from the Chemical Abstracts Service (CAS) or from Dun & Bradstreet (D–U–N–S). This information may also include knowledge gained through discussions, conferences, and technical publications.

EPA has provided CDR reporting guidance materials on this reporting standard, including hypothetical examples of applying the ''known to or reasonably ascertainable by'' reporting standard in the context of collecting processing and use data for CDR, which would be instructive for reporting under this rule as well (Ref. 9). Therefore, EPA anticipates some submitters under this proposed rule will be familiar with this reporting standard, and resources are available to support those submitters who may not be familiar with the standard.

EPA acknowledges that it is possible that a manufacturer (including importer) or processor, particularly an importer of articles containing asbestos (including as an impurity), may not have knowledge that they have imported asbestos and thus not report under this rule, even after they have conducted their due diligence under this reporting standard as described previously. Such an importer should document its activities to support any claims it might need to make related to due diligence.

In the event that a manufacturer (including importer) or processor does not have actual data (*e.g.,* measurements or monitoring data) to report to EPA, the manufacturer (including importer) or processor would be required to make ''reasonable estimates'' of such information. ''Reasonable estimates'' may rely, for example, on approaches such as mass balance calculations, emissions factors, or best engineering judgment.

D. When would reporting be required?

This proposed rule would result in a one-time reporting obligation. EPA proposes reporting for persons who have manufactured (including imported) or processed asbestos at any time during the four complete calendar years prior to the effective date of the final rule. EPA anticipates that the four calendar years would be 2019 to 2022. These entities would report to EPA during a three-month submission period, which EPA proposes would begin six months following the effective date of the final rule. Therefore, manufacturers (including importers) and processors would have up to nine months following the effective date of the final rule to collect and submit all required information to EPA.

EPA believes that providing six months between the effective date of the rule and the start of the submission period would allow sufficient time for both the Agency to finalize the reporting tool and for submitters to familiarize themselves with the rule and compile the required information. Since this TSCA section 8(a) reporting rule would result in the collection of similar information to that collected under CDR, EPA anticipates some submitters would be familiar with the types of information requested and how to report. EPA believes that three months would be adequate time for submissions, in addition to the six-month period between the effective date and the start of the submission period.

EPA is asking for public comment on the submission period start date and duration (see Unit IV.), as well as alternative compliance timelines for small businesses.

E. How would information be reported?

EPA is proposing different reporting requirements based on a two-part knowledge-based reporting approach in order to obtain as complete a picture as possible of the manufacturing (including importing), processing, and use of asbestos. Because asbestos can be included in small quantities in some products, having a threshold concentration for reporting would be expected to eliminate much of the information that may be useful to support EPA's TSCA risk evaluation and risk management efforts. Therefore, EPA is proposing that reporting would be required whenever the presence of asbestos is known or reasonably ascertainable.

However, EPA is also aware that there may be circumstances under which a manufacturer (including importer), or processor is unable to provide a reliable quantity of the asbestos in their products because the percentage of asbestos in their products is not known or reasonably ascertainable by them. For those situations, EPA is proposing a

short form (Form A) for attestation purposes. For other situations, submitters that can determine or estimate the quantity would provide more detailed information in the full form (Form B). EPA anticipates that most submitters would know or be able to estimate the quantity of the asbestos and would complete the full form.

1. Determining the Need To Report Using Form A

For entities that are aware of asbestos in their product, but unable to determine or estimate the quantity manufactured (including imported) or processed, submitters would provide a subset of the information required on Form B. This subset would consist of information related to manufacturing (including importing) or processing asbestos, including as an impurity, in an article, or as a component of a mixture, and information about the employees involved with such activities.

One of the goals of this rule is to ensure EPA has a complete picture of the status of asbestos in the U.S. Therefore, EPA is proposing a reporting approach that would ensure that even circumstances where asbestos appears in smaller or unknown quantities are captured. Some entities manufacturing (including importing) or processing asbestos as a component of a mixture or articles containing asbestos (*e.g.,* the importers of articles), may be aware of asbestos in their products but unable to determine or estimate the quantity of the asbestos for reporting purposes. Therefore, EPA is proposing to include a short form (Form A) for such entities that are aware of a quantity of asbestos in their products, but unable to determine (or estimate) the quantity manufactured (including imported) or processed of asbestos to report.

For a more detailed discussion of the data elements, please see Unit III.F. EPA anticipates that Form A will be the less common option of the two reporting forms.

2. Determining the Need To Report Using Form B

EPA proposes that if a quantity of asbestos in a product is known to or reasonably ascertainable by the submitter then the submitter must provide the more detailed reporting information required by Form B. For example, if submitters are able to determine that their quantity is close to 25 pounds (or another quantity value), they would be required to report using Form B.

Form B would require specific quantity information per asbestos type, more detailed processing information, and employee information (including employee exposure information). EPA is requesting public comments on whether other information, such as waste and disposal information, should be reported. For a more detailed discussion on specifics included in Form B, see Unit III.C.2.

EPA is requesting comment on whether there should be a threshold for the amount of asbestos when determining whether to report using Form B and, if so, whether the threshold should be concentration-based (*e.g.,* a certain percentage of asbestos in the product) or annual volume-based (*e.g.,* the total volume of asbestos manufactured [including imported] or processed). In addition, EPA is requesting comment on whether any submitter under the threshold should alternatively report using Form A. Having a threshold for Form B but reporting using Form A for entities under the reporting threshold may decrease burden on certain submitters while still allowing EPA to obtain information on all instances where asbestos is a component of a mixture and all articles with known asbestos content. Asbestos can occur naturally as impurities in other products that may be handled in very large volumes, such as talc, vermiculite, and potentially other substances. A *de minimis* concentration could reduce the compliance determination and reporting burdens. Comments suggesting threshold levels should include the justification for that particular level.

F. What information would be reported in Form A and Form B?

EPA is proposing certain information to be reported in either Form A or Form B. Unit III.E. describes how to choose which form to use for reporting. This unit provides a more in-depth overview of the information to be reported. Each form has sections about respondent identification, mined or milled bulk asbestos, imported bulk asbestos, primary processor production, secondary processor production, importation of mixtures, and importation of articles. Form A is a subset of Form B. If a data element is included in Form B only, it is indicated by ''(Form B only)'' following the name of the data element.

1. Respondent Identification Information

EPA is proposing that both Form A and B will include information associated with identifying the respondent company and site and information about contacts at the company or site who can respond to any clarifying or other follow up questions. Specifically, EPA is proposing that submitters report the following information (proposed 40 CFR 704.180(e)(3)):

- U.S. Parent Company Information;
- Authorized Official Contact Information;
- Technical Contact Information; and
- Site Information (including NAICs codes and total number of employees at site).

In addition, submitters would identify the activity for which they are reporting, selecting from the list provided in proposed 40 CFR 704.180(e)(4)(i). If more than one activity applies, the submitter would indicate all that apply. Each activity and the associated data elements are described in the remainder of this Unit.

2. Mined, Milled, or Imported Bulk Asbestos or Bulk Materials Containing Asbestos, Including as an Impurity

An asbestos mine or mill is an entity that either mines or mills asbestos. Mined or extracted asbestos-containing ore is further milled to produce bulk asbestos. Milling involves the separation of the fibers from the ore, grading and sorting the fibers, or fiberizing crude asbestos ore. An importer of Bulk Asbestos imports bulk asbestos into the customs territory of the U.S. EPA anticipates that companies that are mining, milling, or importing bulk asbestos will report using Form B, because the volume of asbestos is likely to be known or reasonably ascertainable by them.

For companies that are mining, milling, or importing talc, vermiculite, or another bulk material where asbestos can be found as an impurity, EPA anticipates that they would report using either Form A or Form B, based upon their knowledge of the amount of asbestos in their bulk material.

Specifically, EPA is proposing that sites involved in mining, milling, or importing asbestos or bulk materials containing asbestos report certain information associated with those activities, as listed in proposed 40 CFR 704.180(e)(4)(ii) and (iii), and (e)(5). All submitters would report the applicable asbestos form associated with the mining, milling, or importing activity.

a. Bulk asbestos. In addition, EPA is proposing that sites involved in mining, milling, or importing bulk asbestos, for each asbestos type and for each year, report the quantity of asbestos and the disposition of asbestos. Table 3 in proposed 40 CFR 704.180(e)(4)(ii)(B) provides a list of dispositions from which to select, including: Used on site, sent to another U.S. site, exported, or

disposed of. EPA is proposing that a site selecting ''Disposed of within the U.S.'' would provide additional explanation to indicate the quantity and type of disposal (*e.g.,* disposed in a landfill).

b. Bulk materials containing asbestos. EPA is proposing that sites involved in mining, milling, or importing bulk materials containing asbestos also report the type of bulk material that is manufactured (including imported) or processed, and for each type of bulk material and year, report:

- The quantity of bulk material quantity by weight (Form B only);
- The percentage of asbestos in the bulk material (Form B only);
- The most specific identity of asbestos (Form B only);
- Information describing how you know the amount of asbestos in the bulk material (Form B only); and
- The disposition of the bulk material as described in Unit III.F.2.a.

3. Primary Processors of Asbestos (Bulk Processing Material, Other Than Milling), Including as an Impurity

A primary processor starts with bulk asbestos or bulk materials containing asbestos and makes a mixture that contains asbestos. A primary processor may simply mix or repackage different types or sizes of fibers and then sell that product. Mixtures that contain asbestos are products to which asbestos has been intentionally added and which can be used or processed further and incorporated into other products. For example, asbestos cement, asbestos paper, and asbestos-reinforced plastics are instances where asbestos is contained in a mixture. Primary processors are defined in the proposed 40 CFR 704.180(a), a definition adapted from the definition of primary processor in the 1982 *Asbestos Reporting Requirements* Rule (see Unit II.C.1.).

EPA anticipates that primary processors starting with bulk asbestos are more likely to report using Form B while those starting with bulk materials containing asbestos may report using either Form A or Form B.

EPA is proposing that primary processors report, for each year, the total quantity of asbestos processed (Form B only) and the end product type (selected from Table 4 in proposed 40 CFR 704.180(e)(4)(iv)(B)). For each product type, report by year:

- The most specific identity of asbestos (Form B only);
- The total annual production quantity of end product, using the unit of measure as listed in Table 4 in proposed 40 CFR 704.180(e)(4)(iv)(B);
- The percentage of asbestos in the end product (Form B only);
- If the asbestos content is an impurity, how you know about the presence, amount, and type of asbestos (*i.e.,* do you have test results (provide the results), how often is testing conducted, other methods for identifying the asbestos content); and
- The disposition of the end product (Form B only) as described in Unit III.F.2.a.

4. Secondary Processor Production (Processing Asbestos When a Component of a Mixture and Articles Containing Asbestos), Including as an Impurity

Secondary processors are those who start with asbestos when it is a component of a mixture and incorporate the mixture into their own products. For example, persons who fabricate asbestos cement sheet by cutting the sheet to make an electrical switch board, or persons who make garments by cutting an asbestos-containing textile, are secondary processors. Secondary processors are defined in the proposed 40 CFR 704.180(a), a definition adapted from the definition of primary processor in the 1982 *Asbestos Reporting Requirements Rule* (see Unit II.C.1.).

EPA anticipates that secondary processors may report using either Form A or Form B. EPA is proposing that secondary processors report, for each year, the total quantity of asbestos processed (Form B only) and the end product type (selected from Table 4 in proposed 40 CFR 704.180(e)(4)(iv)(B)). For each product type, report by year:

- The most specific identity of asbestos and the quantity of asbestos (Form B only);
- The total annual production quantity of end product, using the unit of measure as listed in Table 4 in proposed 40 CFR 704.180(e)(4)(iv)(B);
- The percentage of asbestos in the end product (Form B only);
- If the asbestos content is an impurity, how you know about the presence, amount, and type of asbestos (*i.e.,* do you have test results [provide the results], how often is testing conducted, other methods for identifying the asbestos content); and
- The disposition of the end product (Form B only) as described in Unit III.F.2.a.

5. Importation of Asbestos as a Component of a Mixture or Articles That Contain Asbestos, Including as an Impurity

An importer of asbestos contained in a mixture or articles that contain asbestos, including as an impurity, imports these substances into the customs territory of the U.S.

EPA anticipates that an importer of products may report using either Form A or Form B. EPA is proposing that importers report, for each year, the total quantity of asbestos processed (Form B only) and the imported product type (selected from Table 4 in proposed 40 CFR 704.180(e)(4)(iv)(B)). For each product type, report by year:

- Whether the imported product including asbestos is contained in a mixture or a part of an article;
- The most specific identity of asbestos and the quantity of asbestos (Form B only);
- The total annual import quantity of the imported product, using the unit of measure as listed in Table 4 of proposed 40 CFR 704.180(e)(4)(iv)(B);
- The percentage of asbestos in the imported product (Form B only);
- Information about how you know about the presence, amount, and type of asbestos (*i.e.,* do you have test results (provide the results), how often is testing conducted, other methods for identifying the asbestos content); and
- The disposition of the imported product (Form B only) as described in Unit III.F.2.a.

6. Employee Information

For each activity reported, EPA is proposing that submitters also report certain information about the number of employees involved with the activity. Specifically, EPA is proposing that submitters report the number of employees associated with the activity, whether personal protective equipment was used and, if yes, the type of equipment used, and any workplace exposure measurement assessments such as monitoring data. When supplying the measurement assessment data, also include information about how the assessment was conducted and other explanations to help EPA better understand and use the data.

G. Did EPA consider additional data elements for the proposal?

When evaluating which data elements to include in this proposal, EPA also considered potentially requiring reporting on additional information related to current employee exposures, wastewater treatment, disposal information, and customer sites. EPA presently believes the additional information might be useful for a more in-depth analysis of the potential exposures associated with asbestos. However, EPA also presently believes that the proposed data elements described in Unit III.F. would provide sufficient information for use by EPA and other Federal agencies in potential actions involving asbestos, including

EPA's TSCA risk evaluation and risk management activities. EPA chose not to include these additional data elements in this proposed rule in the interest of maintaining a manageable level of burden for reporting entities, while also considering the need for creating a manageable reporting tool.

EPA is seeking public comment on whether any additional data (particularly, information related to current employee exposures, wastewater treatment information, additional disposal information, and customer sites) should be added as required data elements on Form B.

1. Employee Data

EPA considered collecting a more detailed breakdown of the number and types of employees by work category. This information would enable the agency to consider exposures to employees conducting different types of work at a site, including those conducting production, shipping or receiving, maintenance, waste management, or other activities.

EPA also considered collecting employee exposure information, including 8-hr time-weighted average exposures, 15- or 30-minute peak or maximum exposures, related statistical data (medians, arithmetic means, standard deviations, etc.), levels of detection and non-detectable measurements, and descriptions of sampling and analysis, such as sampling and analytical chemistry methods. Due to the anticipated burden for reporters in contrast to the usefulness of the data that the agency could collect, EPA is not including reporting on these additional employee data elements in this proposed rule.

2. Wastewater Discharge and Waste Disposal Data

EPA considered collecting information related to asbestos or asbestos-containing discharges, including releases, wastes, and disposal data. These data included a description of any discharges, such as to water or to off-site public treatment facilities, and descriptions of solids disposal, such as to land-based facilities. Wastewater related information included volumes of wastewater, amount of asbestos in the wastewater, on-site treatment methods (if any), National Pollutant Discharge Elimination System (NPDES) permit numbers and copies of reports, transport to off-site treatment, and removed solids management. General waste and disposal information included the identity of the end product being disposed, the form of the waste, the quantity of asbestos in the waste, the type of land disposal facility (*e.g.,* impoundment, waste pile, landfill, injection well), and whether the disposal is on- or off-site. Note, however, that EPA is proposing that a site reporting ''Disposed of within the U.S.'' in response to Table 3 would provide additional explanation to indicate the quantity, address of the disposal facility, and type of disposal (*e.g.,* disposed in a landfill). EPA believes this level of reporting on waste disposal data is sufficient for purposes of this data collection. Due to the anticipated burden for reporters in contrast to the usefulness of the data that the agency could collect, EPA is not including reporting on additional data elements related to wastewater discharge and waste disposal in this proposed rule beyond the disposal explanation that would be included in response to reporting ''Disposed of within the U.S.'' in response to Table 3.

3. Air Emissions Data

EPA considered collecting information related to air emissions at facilities that manufacture (including import) or process asbestos or asbestos-containing mixtures and products. The information included sources of emissions, methods of air pollution control, descriptions of control devices, and pollution control equipment operation and testing frequency and methods. Due to the anticipated burden for reporters in contrast to the usefulness of the data that the agency could collect, EPA is not including reporting on these additional data elements in this proposed rule.

4. Customer Sites Data

EPA also considered requiring additional information about the number of customers respondents have. As proposed, this action would only collect information about asbestos manufacturers (including importers) and processors. Additional customer information from companies selling a product could be useful in understanding the universe of asbestos users. For the reasons described previously, EPA is not including reporting on these additional employee data elements in this proposed rule, however, EPA is requesting comment on requiring manufactures (including importers) and processors of asbestos that are selling a product that contains asbestos to report the number of customer sites they have.

H. How would information be submitted to EPA?

EPA is proposing to require electronic reporting similar to the requirements established in 2013 for submitting other information under TSCA (see 40 CFR 704.20(e)). EPA is proposing to require submitters to use EPA's CDX (Central Data Exchange), the Agency's electronic reporting portal, for all reporting under this rule. In 2013, EPA finalized a rule to require electronic reporting of certain information submitted to the Agency under TSCA sections 4, 5, 8(a), and 8(d) (78 FR 72818) (FRL–2013–28510). The final rule followed two previous rules requiring similar electronic reporting of information submitted to EPA for TSCA CDR and for premanufacture notices (PMNs). In proposing to require similar electronic reporting under this rule, EPA expects that electronic reporting would save time, improve data quality, and increase efficiencies for both the submitters and the Agency.

EPA developed the Chemical Information Submission System (CISS) for use in submitting data electronically to the Agency for TSCA sections 4, 5, 6, 8(a), 8(b), 8(d), 8(e), and Title VI. CISS, a web-based reporting tool housed within the CDX environment, provides submitters with user-friendly applications to build and submit data packages to EPA within a secure, encrypted environment. CISS applications provide for the capture of both fielded data as well as the attachment of additional information using a wide variety of file types. Submitted information is rendered into PDF and XML formats, which are provided to submitters in the form of a Copy of Record.

EPA is proposing to require submitters to follow the same submission procedures used for other TSCA submissions, *i.e.,* to register with EPA's CDX and use CISS to prepare a data file for submission. Registration enables CDX to authenticate user identity. To submit electronically to EPA via CDX, individuals must first register with CDX at *http://cdx.epa.gov/.* To register in CDX, the CDX registrant (also referred to as ''Electronic Signature Holder'' or ''Public/Private Key Holder'') agrees to the Terms and Conditions, provides information about the submitter and organization, selects a username and password, and follows the procedures outlined in the guidance document for CDX available at *https://cdx.epa.gov/FAQ#CSPP.*

Within CDX, CISS is available under the ''Submission for Chemical Safety and Pesticide Program (CSPP)'' CDX flow. Users who have previously submitted under TSCA through CDX, including submitting information under TSCA sections 4 and 5, CDR, or reporting under the TSCA Inventory Notification (Active-Inactive)

Requirements rule (82 FR 37520, Aug. 11, 2017) (FRL–9964–22), will already have the CSPP flow linked to their account. Users reporting to EPA using other CDX housed applications, including the Toxics Release Inventory TRI–MEweb, would be able to add the CSPP flow to their existing CDX accounts.

All submitters would be required to use CISS to prepare their submissions. CISS guides users through a ''hands-on'' process of creating an electronic submission. Once a user completes the relevant data fields and attaches appropriate PDF files, or other file types, such as XML files, the web-based tool validates the submission by performing a basic error check and makes sure all the required fields and attachments are provided and complete. Further instructions for uploading PDF attachments or other file types, such as XML, and completing metadata information would be available through CISS reporting guidance.

CISS also allows the user to choose to ''Preview,'' ''Save,'' or ''Submit'' the data package. Once the submission process is initiated, the user is asked to certify the information and provide requested information to complete the submission process. The data package is then sent, in an encrypted state, to the Agency. The user can login to the application and check the submission status of their data package. Upon successful receipt of the submission by EPA, the submission status of the submissions will be flagged as ''Completed'' and a confirmation email will be sent to the submitter's CDX inbox. The CDX inbox is used to notify the users when submissions are received by EPA or to notify users when a submission-specific communication has been received and how to locate and access the communication. Information on accessing the CDX user inbox is provided in the guidance document for CDX at *https://cdx.epa.gov/FAQ#CSPP.* To access CISS log into CDX using the link: *https://cdx.epa.gov/* and click on the appropriate user role associated with the CSPP data flow. For further instructions, visit *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/electronic-reporting-requirements-certain-information.* Procedures for reporting under this proposed rule would be similar.

EPA believes that electronic reporting reduces the reporting burden for submitters by reducing the cost and time required to review, edit, and transmit data to the Agency. It also allows submitters to share a draft submission within their organization, and more easily save a copy for their records or future use. Additionally, EPA believes that some of the anticipated submitters under this proposed rule have experience with reporting electronically to EPA through CDX. The resource and time requirements to review and process data by the Agency will also be reduced and document storage and retrieval will require fewer resources. EPA expects to benefit from receiving electronic submissions and communicating electronically with submitters.

I. How does the rule address claims for treatment of confidential information?

In a separate rulemaking under development, EPA plans to propose new provisions concerning the assertion and treatment of CBI claims for information reported to or otherwise obtained by EPA under TSCA. Unless otherwise stated in specific TSCA regulations (such as those proposed here), EPA intends the proposed provisions to govern how CBI claims made for information submitted under TSCA, including information submitted under this part, will be asserted, reviewed, and maintained.

In this rulemaking, EPA is proposing in proposed 40 CFR 704.180(h) that a person submitting a reporting form under this action may claim some information in the form as confidential at the time of submission, consistent with TSCA section 14. EPA is also proposing that certain data elements cannot be claimed as confidential:

- Site NAICS code in proposed 40 CFR 704.180(e)(3)(v), because it represents a general description associated with the manufacture (including import) or processing of a chemical substance.
- Chemical and bulk material identities (as identified in proposed 40 CFR 704.180(h)(1)(ii)(B)), because the chemical identities are listed in the asbestos definition in proposed 40 CFR 704.180(a) or are general identities of bulk materials that are already publicly known.
- Responses that are blank or ''not known or reasonably ascertainable'' (as identified in proposed 40 CFR 704.180(h)(1)(ii)(C)) because there is no data to claim as confidential.
- Health and safety study data (as identified in proposed 40 CFR 704.180(h)(1)(ii)(D)), because, under TSCA section 14(b)(2), such information is not protected from disclosure. Note, however, that CBI claims may be asserted to the extent that disclosure of data from studies would reveal certain information as provided in proposed 40 CFR 704.180(h)(1)(ii)(D)(1)–(3). The electronic reporting tool described in proposed 40 CFR 704.180(i) enables the submitter of a health and safety study containing CBI claims to attach a public copy of the study, as described in proposed 40 CFR 704.180(h)(2)(vi).

TSCA section 14 also requires that the submitter attest to a statement concerning the confidential status of the information, that they have a reasonable basis to conclude that release of the information would likely result in substantial harm to the competitive position of their business and that the information is not readily discoverable through reverse engineering. The submitter must certify that this statement and any substantiation provided are true and correct. This certification statement will be incorporated into the electronic reporting tool identified in proposed 40 CFR 704.180(i).

TSCA section 14(c)(3) further requires that substantiation be provided at the time a confidentiality claim is asserted. However, TSCA section 14(c)(2) exempts certain information from that substantiation requirement (*e.g.,* specific production volume). Under the proposed rule, CBI claims for specific production or import volumes of the manufacturer need not be substantiated, as identified in proposed 40 CFR 704.180(h)(2)(iv). For all other information submitted under this proposed rule, submitters are required to substantiate their confidentiality claims at the time of submission. Substantiation questions are listed in proposed 40 CFR 704.180(h)(2)(iii) and will be incorporated into the electronic reporting tool identified in proposed section 704.180(i). Responses to the substantiation questions that are not specific to the data element for which a claim of confidentiality is being substantiated may be inadequate to justify confidential protection.

Any information which is claimed as confidential will be disclosed by EPA only in accordance with the procedures and requirements of TSCA section 14 and 40 CFR part 2, or any TSCA-specific CBI provisions that may in the future replace or supplement portions of 40 CFR part 2. TSCA section 14(b)(2) limits confidentiality protections for health and safety studies and information from health and safety studies regarding chemical substances that have been offered for commercial distribution, except to the extent such studies or information reveals ''information that discloses processes used in the manufacturing (including importing) or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the

mixture''. Additionally, in some cases EPA may consider information contained in a study as not part of a *health and safety study* as defined in TSCA section 3(8). The workplace exposure measurement data listed in proposed 40 CFR 704.180(e)(5)(iii) are from studies pertaining to human exposure in the workplace and therefore are considered health and safety study data. Submitters asserting a confidentiality claim for such information in health and safety studies (as well as for other information claimed as confidential) will be required to submit a sanitized copy of the study, removing only that information which is claimed as confidential. See proposed 40 CFR 704.180(h)(1)(ii)(D) for additional information regarding health and safety studies and proposed 40 CFR 704.180(h)(2)(vi)) regarding public copies.

J. What are the recordkeeping requirements?

EPA is proposing that each person who reports under this part must maintain records that document information reported under this part and, in accordance with TSCA, permit access to and the copying of such records by EPA officials. Consistent with the CDR rule, EPA is proposing a five-year recordkeeping period, beginning on the last date of the submission period. The five-year retention requirement generally corresponds with the statute of limitations for TSCA violations. Information in this one-time data collection will be used by EPA for risk evaluation and risk management activities, and the companies must maintain the records for five years in the event that EPA has follow-up questions as the agency activities are completed. Further, EPA believes the burden of retaining these records, which are likely electronic, is minimal.

IV. Request for Comments

EPA requests comment on the content of this proposed rule and the Economic Analysis prepared in support of this proposed rule (Ref. 2). In addition, EPA is providing a list of issues on which the Agency is specifically requesting public comment. EPA encourages all interested persons to submit comments on these issues, and to identify any other relevant issues as well. This input will assist the Agency in developing a final rule that successfully addresses information needs while minimizing potential reporting burdens associated with the rule. EPA requests that commenters making specific recommendations include supporting documentation where appropriate.

1. EPA is soliciting comment on the total number of manufactures (including importers) and processors that will be impacted by the promulgation of this rule, and on the related burden and costs for reporting. In addition, due to the lack of information on the extent to which asbestos occurs as an impurity, EPA was unable to determine the number of potential manufacturers (including importers) or processors of asbestos as an impurity that would report under this rule. EPA is soliciting public comment on the number of manufacturers (including importers) and processors that may be subject to the proposed rule due to the presence of impurities in their products, and on the related burden and cost for reporting.

2. As described further in Unit III.B., because there is no existing small processers definition that would be applicable under TSCA section 8(a), EPA is requesting comment on how to best provide guidance for small processors of Libby Amphibole asbestos.

3. As described further in Unit III.C.2, EPA is seeking comment on what additional guidance, if any, might be useful for helping entities, including small businesses, understand the reporting standard, as well as to how the reporting standard would apply to impurities.

As described further in Unit III.D., EPA is requesting public comment on the submission start date and duration, including for small businesses.

4. As described further in Unit III.E.2., EPA is requesting comment on whether there should be a threshold for reporting using Form B and, if so, whether the threshold should be concentration-based (*e.g.,* a certain percentage) or annual volume-based. In addition, EPA is requesting comment on whether any submitter under the threshold should alternatively report using Form A. Having a threshold for Form B may decrease burden on certain submitters while still allowing EPA to obtain information on all bulk materials, mixtures, and articles with known asbestos content. The substances subject to the rule can occur naturally as impurities in other products that may be handled in very large volumes, such as talc, vermiculite, and potentially other substances. A *de minimis* concentration could reduce the compliance determination and reporting burdens. Comments suggesting threshold levels should include the justification for that particular level.

5. As described further in Unit III.F. and first mentioned in Unit III.F.3., EPA is requesting comment on whether there should be other end product types listed in Table 4 in proposed 40 CFR 704.180(e)(4)(iv)(B). In addition, EPA is interested in whether the units of measure listed with the product types are appropriate.

6. As described further in Unit III.G., EPA identifies additional data elements related to employee data, wastewater discharge and waste disposal, air emissions data and customer sites data, considered for this proposed rule and is soliciting public comment on whether any of the additional data elements should be included in the action. While EPA believes the proposed data elements in Unit III.F provide sufficient information for use by EPA and other Federal agencies in potential actions involving asbestos, EPA is seeking comment on whether any additional data elements should be included in this action.

7. As described further in Unit III.AC.2, EPA is seeking comment on what additional guidance, if any, might be useful.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Final Rule; Asbestos: Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions. **Federal Register**. 54 FR 29460. July 12, 1989. (FRL–3476–2).
2. EPA, OPPT. Economic Analysis for the Proposed TSCA Section 8(a) Reporting and Recordkeeping Requirements for Asbestos. February 4, 2022.
3. EPA. Learn About Asbestos. EPA website. *https://www.epa.gov/asbestos/learn-about-asbestos.*
4. EPA. IRIS Toxicological Review of Libby Amphibole Asbestos (Final Report). U.S. Environmental Protection Agency, Washington, DC, EPA/635/R–11/002F, 2014. *https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1026tr.pdf.*

5. Agency for Toxic Substances and Disease Registry (ATSDR). Summary Report: Exposure to Asbestos-Containing Vermiculite from Libby, Montana, at 28 Processing Sites in the United States. U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, Atlanta, GA, 2008. *https://www.atsdr.cdc.gov/asbestos/sites/national_map/Summary_Report_102908.pdf* and *https://hero.epa.gov/hero/index.cfm/reference/details/reference_id/783510.*
6. EPA. Risk Evaluation for Asbestos, Part 1: Chrysotile Asbestos. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). Washington, DC, EPA–740–R1–8012, 2020. *https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_asbestos_part_1_chrysotile_asbestos.pdf.*
7. National Toxicology Program (NTP). Asbestos, CAS No. 1332–21–4. In *Report on Carcinogens* (15th ed.).: U.S. Department of Health and Human Services, Public Health Service, Research Triangle Park, NC, 2001. *https://ntp.niehs.nih.gov/ntp/roc/content/profiles/asbestos.pdf.*
8. EPA. Determining If You Are a Manufacturer or Importer for Reporting. EPA website. *https://www.epa.gov/chemical-data-reporting/determining-if-you-are-manufacturer-or-importer-required-report.*
9. EPA. Instructions for Reporting 2020 TSCA Chemical Data Reporting (pp. 45–47).: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics (OPPT) Washington, DC, 2020. *https://www.epa.gov/sites/default/files/2020-12/documents/instructions_for_reporting_2020_tsca_cdr_2020-11-25.pdf.*
10. EPA. TSCA Chemical Data Reporting Fact Sheet: Articles. U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics (OPPT) Washington, DC, 2012. *https://www.epa.gov/sites/default/files/documents/articlesfactsheetforcdr_reporting_080312.pdf.*
11. Asbestos Disease Awareness Organization (ADAO), American Public Health Association (APHA), Center for Environmental Health (CEH), Environmental Health Strategy Center (EHSC), Environmental Working Group (EWG), Safer Chemicals, Healthy Families (SCHF) to Andrew Wheeler, Administrator, U.S. Environmental Protection Agency. Petition under TSCA Section 21 to Require Reporting on Asbestos Manufacture, Importation and Use under TSCA Section 8(a). September 27, 2018. *https://www.epa.gov/sites/default/files/2018-10/documents/adao-asbestos-cdr-petition-all.pdf.*
12. The Attorneys General of Massachusetts, California, Connecticut, Hawaii, Maine, Maryland, Minnesota, New Jersey, New York, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and the District of Columbia to Andrew Wheeler, Administrator, U.S. Environmental Protection Agency. Petition Under TSCA Section 21(a) for EPA to Issue an Asbestos Reporting Rule to Require Reporting under TSCA Section 8(a). January 31, 2019. *https://www.epa.gov/sites/default/files/2019-02/documents/tsca_section_21_rulemaking_petiton_for_asbestos_reporting_1_31_2019_2.pdf.*
13. Settlement Agreement, Case Nos. 3:19–CV–00871–EMC; 3:19–CV–03807–EMC. *Asbestos Disease Awareness Organization, et al.,* Plaintiffs, v. *U.S. Environmental Protection Agency, et al.,* Defendants. June 7, 2021.
14. EPA. Scope of the Risk Evaluation for Asbestos. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP), Washington, DC, EPA–740–R1–7008, 2017. *https://www.epa.gov/sites/default/files/2017-06/documents/asbestos_scope_06-22-17.pdf.*
15. Occupational Safety and Health Administration (OSHA). OSHA Occupational Chemical Database, Talc (Containing Asbestos). United States Department of Labor. *https://www.osha.gov/chemicaldata/276.*
16. Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements, 40 CFR part 704 (2017). *https://www.federalregister.gov/documents/2017/01/12/2017-00052/chemical-substances-when-manufactured-or-processed-as-nanoscale-materials-tsca-reporting-and.*
17. EPA. Information Collection Request (ICR) for the TSCA Section 8(a) Reporting and Recordkeeping Requirements for Asbestos (Proposed Rule). EPA ICR No. 2711.01 and OMB No. 2070–[NEW]. February 4, 2022.
18. U.S. Geological Survey (USGS). Asbestos Statistics and Information: Mineral Commodity Summaries. 2021. *https://pubs.usgs.gov/periodicals/mcs2021/mcs2021-asbestos.pdf.*

VI. 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 a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Order 12866 (58 FR 51735, October 4, 1993) and Executive Order 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket. EPA prepared an economic analysis of the potential costs and benefits associated with this action (Ref. 2), which is available in the docket and summarized in Unit I.E. (Ref. 2).

B. Paperwork Reduction Act (PRA)

The information collection requirements in this proposed rule have been submitted to OMB for review and comment under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA has been assigned the EPA ICR No. 2711.01 (Ref. 17). You can find a copy of the ICR in the docket for this action, and it is briefly summarized here.

The information collection activities in the proposed rule include a one-time reporting requirement and recordkeeping requirements. Companies that manufacture (including import) or process asbestos must report certain information to EPA and maintain corresponding records.

Respondents/affected entities: Chrysotile asbestos manufacturers (including importers) and processors. See Unit I.A. for a list of potentially affected entities.

Respondent's obligation to respond: Mandatory. TSCA section 8(a) and proposed 40 CFR 704.180.

Estimated number of respondents: 27.

Frequency of response: One time.

Total estimated burden: 1,157 hours (per report). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $99,496 (per report), which includes no annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at *www.reginfo.gov/public/do/PRAMain.* Find this particular ICR by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later

than June 6, 2022. The EPA will respond to any ICR-related comments in the final rule.

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, 5 U.S.C. 601 *et seq.* The small entities subject to the requirements of this action are persons who have manufactured (including imported), or processed asbestos, including asbestos as a component of a mixture, asbestos in articles, and asbestos as an impurity in the four full calendar years prior to the effective date of this rule. EPA estimates that at least 14 small firms will be affected by the proposed rule. Of those small firms, which include importers of articles and processors, 12 are expected to have cost impacts of less than 1% of annual revenues, one is expected to have impacts between 1–3%, and one is expected to have impacts of more than 3% of annual revenues. These estimates do not include firms that are impacted by the requirement to report for impurities, which EPA was unable to identify. Based on information available to EPA, the Agency does not believe there are a substantial number of such firms. Further, EPA believes that impacts to any such firms would not significantly alter the Agency's analysis under the RFA. Details of this analysis are presented in the Economic Analysis (Ref. 2).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). In EPA's experience, states do not engage in the activities that would make them subject to the requirements in the proposed rule. As such this action 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 (65 FR 67249, November 9, 2000). It does not have substantial direct effects on tribal government because asbestos is not manufactured (including imported) or processed by tribes and would not impose substantial direct compliance costs on tribal governments.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045, because it is a data gathering rulemaking and does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution in Commerce, or Use

This action is not a ''significant energy action'' under Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy and has not otherwise been designated by the Administrator of OMB's Office of Information and Regulatory Affairs as a ''significant energy action.'' This action is not expected to affect energy use, energy supply or energy prices.

I. National Technology Transfer and Advancement Act (NTTAA)

This proposed rulemaking does not involve technical standards. As such, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

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 this action does not establish an environmental health or safety standard. The collected information, however, will be used by EPA and other Federal agencies to inform considerations of potential future actions involving asbestos, potentially including risk evaluation and risk management activities that could benefit underserved communities and indigenous peoples.

List of Subjects in 40 CFR Part 704

Chemicals, Confidential business information, Environmental protection, Hazardous substances, Reporting and recordkeeping requirements.

Dated: April 22, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

For the reasons set forth in the preamble, it is proposed that 40 CFR chapter I be amended as follows:

PART 704—REPORTING AND RECORDKEEPING REQUIREMENTS

■ 1. The authority citation for part 704 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

■ 2. Add § 704.180 to subpart B to read as follows:

Subpart B—Chemical-Specific Reporting and Recordkeeping Rules

* * * * *

§ 704.180 Asbestos.

(a) *Definitions.*

The definitions in subpart A of this part apply to § 704.180 unless otherwise specified in this section.

Asbestos is a collective term meaning any of the substances listed in Table 1 of this paragraph.

TABLE 1 IN § 704.180(a)—CASRN OF ASBESTOS TYPES

CASRN	Asbestos type
1332–21–4	Asbestos.
132207–32–0	Chrysotile.
12001–28–4	Crocidolite.
2172–73–5	Amosite.
77536–67–5	Anthophyllite.
77536–68–6	Tremolite.

TABLE 1 IN § 704.180(a)—CASRN OF ASBESTOS TYPES—Continued

CASRN	Asbestos type
77536–66–4	Actinolite.
NA	Libby Amphibole (mainly consisting of tremolite [CASRN 77536–68–6], winchite [CASRN 12425–92–2], and richterite [CASRN 17068–76–7]).

Bulk asbestos means any quantity of asbestos fiber of any type or grade, or combination of types or grades, that is mined or milled with the purpose of obtaining asbestos. This term does not include asbestos that is produced or processed as a contaminant or an impurity.

Bulk materials containing asbestos means bulk materials in which asbestos is being mined or milled as a contaminant or an impurity, such as in vermiculite or talc.

Chemical Information Submission System or *CISS* means EPA's electronic, web-based reporting tool for the completion and submission of CDR data, reports, and other information, or its successors.

Form A means an abbreviated form for persons that know or can reasonably ascertain that they manufactured (including imported) or processed asbestos, including as an impurity, during the reporting period described in paragraph (f) but do not know and cannot reasonably ascertain the amount of asbestos manufactured (including imported) or processed by them.

Form B means the standard form to be used by persons that know or can reasonably ascertain that they manufactured (including imported) or processed asbestos, including as an impurity, during the reporting period described in paragraph (f) and know or can reasonably ascertain how much asbestos they manufactured (including imported) or produced.

Primary processor means a person that starts with bulk asbestos or bulk materials containing asbestos and makes a mixture that contains asbestos as a component.

Secondary processor means a person that further processes asbestos, after primary processing of asbestos is completed, as a component of a mixture, or an article containing asbestos.

Small processor means any processor whose total annual sales, when combined with those of its parent company (if any), are less than $12 million.

(b) *Substance for which reports must be submitted.*

The requirements of this section apply to asbestos, including asbestos in bulk form, as a component of a mixture, in an article, and as an impurity.

(c) *Persons who must report.*

Persons who have manufactured (including imported), or processed asbestos, including asbestos as a component of a mixture, asbestos in articles, and asbestos as an impurity in the four full calendar years prior to the effective date of this rule must report under this subpart.

(d) *Persons exempt from reporting.*

A person who is subject to reporting requirements pursuant to paragraph (c) is exempt from the requirements in this subpart to the extent that the person and that person's use of asbestos is described in this paragraph.

(1) *Non-isolated intermediate.* A person who manufactures or proposes to manufacture asbestos, as described in paragraph (c), solely as a non-isolated intermediate is exempt from the reporting requirements of this subpart.

(2) *Research and development.* A person who manufactures (including imports), processes, or proposes to manufacture (including import), or process asbestos, as described in paragraph (c), only in small quantities solely for research and development is exempt from the reporting requirements of this subpart.

(3) *Small manufacturers (including importers) and processors.* Small manufacturers (including importers) and processors are exempt from the reporting requirements of this subpart for the substance Libby Amphibole only.

(e) *Reporting information to EPA.*

Persons described in paragraph (c) of this section must report to EPA the following information, to the extent known to or reasonably ascertainable by them. In the event that specific numeric data is not known or is not reasonably ascertainable by the submitter, then reasonable estimates may be submitted.

(1) *Required forms.* Report using the appropriate Form, based on whether you know or can reasonably ascertain a quantity for asbestos.

(i) *Form A.* Report using Form A if you know or can reasonably ascertain that asbestos is a component of a mixture or article but are unable to determine the asbestos quantity by weight.

(ii) *Form B.* Report using Form B if you know or can reasonably ascertain a quantity for asbestos.

(2) *A certification statement signed and dated by an authorized official of the submitter company.* The authorized official must certify that the submitted information has been completed in compliance with the requirements of this part and that the confidentiality claims made on Form A or Form B are true and correct. The certification must be signed and dated by the authorized official for the submitter company, and provide that person's name, official title, and email address.

(3) *Company and plant site information.* The following currently correct company and plant site information must be reported for each site at which a reportable chemical substance is manufactured (including imported) or processed (see § 704.3 for the ''site'' for importers):

(i) *Company name.* The highest-level U.S. parent company name, address, and Dun and Bradstreet D–U–N–S® (D&B) number. A submitter under this part must obtain a D&B number for the U.S. parent company if none exists.

(ii) *Authorized official.* The name of a person who will serve as Authorized Official for the submitter company, and who will be able to sign the certification statement as described in paragraph (e)(1), the Authorized Official's full mailing address, telephone number, and email address.

(iii) *Point of contact.* The name of a person who will serve as technical contact for the submitter company, and who will be able to answer questions about the information submitted by the company to EPA, the contact person's full mailing address, telephone number, and email address.

(iv) *Site information.* The site name, full street address, including the county or parish (or other jurisdictional indicator) in which the plant site is located. Also report the following:

(A) The appropriate D&B number for the plant site. If none exists, you must obtain a D&B number for the reported site.

(B) Other site identification numbers, including the Facility Registry Service (FRS) identification number, if they exist.

(v) *Applicable NAICS code.* The six-digit North American Industry Classification System (NAICS) code(s) of the site.

(vi) *Number of employees.* The total number of employees at the site. Select from among the ranges of employees listed in Table 2 of this paragraph and report the corresponding code (*i.e.,* W1 through W8):

TABLE 2 IN § 704.180(e)(3)(vi)—CODES FOR REPORTING NUMBER OF EMPLOYEES

Code	Range
W1	Fewer than 10 employees.
W2	At least 10 but fewer than 25 employees.
W3	At least 25 but fewer than 50 employees.
W4	At least 50 but fewer than 100 employees.
W5	At least 100 but fewer than 500 employees.
W6	At least 500 but fewer than 1,000 employees.
W7	At least 1,000 but fewer than 10,000 employees.
W8	At least 10,000 employees.

(4) *Activity information.* The following activity information must be reported.

(i) *Type of activity at reporting site.* Report all that apply.

(A) Mining of bulk asbestos or bulk materials containing asbestos.

(B) Milling of bulk asbestos or bulk materials containing asbestos.

(C) Importing of bulk asbestos or bulk materials containing asbestos.

(D) Primary processing of bulk asbestos or bulk materials containing asbestos.

(E) Secondary processing of mixtures or articles containing asbestos.

(F) Importing of mixtures or articles containing asbestos.

(ii) *Form B only.* For mining, milling, or importing of bulk asbestos reported under activity in paragraph (e)(4)(i)(A) through (C), report by year:

(A) The most specific asbestos type that applies. Select from among the asbestos types listed in Table 1 of paragraph (a) in this section. If the specific asbestos type is not known or reasonably ascertainable, report the general listing, asbestos CASRN 1332–21–4.

(B) For each asbestos type, report

(1) Quantity of asbestos, in pounds.

(2) Disposition of asbestos (see Table 3 in paragraph (e)(4)(ii)(B) of this section).

TABLE 3 IN § 704.180(e)(4)(ii)(B)—DISPOSITION

Code	Disposition description
1	Used on-site, including further processed.
2	Stored on-site.
3	Sent to another U.S. site (including intra-company transfer) for use or processing.
4	Stored at another U.S. site (including intra-company transfer).
5	Exported outside of the U.S. without further processing.
6	Disposed of within the U.S. (explain).
7	Other (explain).

(iii) Reporting information for mining, milling, or importing of bulk materials containing asbestos. For mining, milling, or importing of bulk materials containing asbestos reported under the activity identified in paragraph (e)(4)(i)(A) through (C), report by year:

(A) Bulk material type manufactured or processed (*e.g.,* talc, vermiculite).

(B) For Form B only, for each bulk material type:

(1) Quantity of bulk material manufactured or processed.

(2) Percent asbestos by weight in bulk material.

(3) The most specific asbestos type that applies. Select from among the asbestos types listed in Table 1 in paragraph (a) of this section. If the specific asbestos type is not known or reasonably ascertainable, report the general listing, asbestos CASRN 1332–21–4.

(4) Any testing of or test results assessing the asbestos content of your bulk material in the applicable reporting years.

(i) If testing was conducted, specify how often testing was conducted on the presence of asbestos in your bulk material and what method and type of test was used for determining asbestos content, and provide the test results.

(ii) If testing was not conducted, explain how you knew or reasonably ascertained the presence and amount of asbestos in the bulk materials.

(C) For each bulk material type, the disposition of bulk material (see Table 3 in paragraph (e)(4)(ii)(B) of this section).

(iv) *Reporting information for primary processors.* For primary processing reported under activity identified in paragraph (e)(4)(i)(D) of this section, report by year:

(A) For Form B only, the total quantity of asbestos processed.

(B) End product type, selecting from products listed in Table 4 in paragraph (e)(4)(iv)(B) of this section. If your end product is not listed, report ''other'' and provide a brief description. For each end product type, report:

(1) For Form B only, the most specific asbestos type that applies. Select from among the asbestos types listed in Table 1 in paragraph (a) of this section. If the specific asbestos type is not known or reasonably ascertainable, report the general listing, asbestos CASRN 1332–21–4. Report also the total annual quantity of asbestos type processed.

(2) The total annual production quantity of end products produced, using the associated unit of measure listed in Table 4 in paragraph (e)(4)(iv)(B) of this section. If a unit of measure is not listed, provide the unit of measure associated with the quantity reported.

(3) For Form B only, the percentage of asbestos in the end product.

(4) For Form B only, the disposition of the end product (see Table 3 in paragraph (e)(4)(ii)(B) of this section).

(5) For Form B only, explain if you tested or received test results assessing the asbestos content of your end product in the applicable reporting years.

(i) If testing was conducted, specify how often testing was conducted on the presence of asbestos in your end product and what method and type of test was used for determining asbestos content, and provide the test results.

(ii) If testing was not conducted, explain how you knew or reasonably ascertain the presence and amount of asbestos in the end product.

TABLE 4 IN § 704.180(e)(4)(iv)(B)—END PRODUCT TYPES

Code	Name	Unit of measure
	Papers, Felts, or Related Products	
01	Commercial paper	Short Tons.
02	Rollerboard	Short Tons.
03	Millboard	Short Tons.

TABLE 4 IN § 704.180(e)(4)(iv)(B)—END PRODUCT TYPES—Continued

Code	Name	Unit of measure
04	Pipeline wrap	Short Tons.
05	Beater-add gasketing paper	Short Tons.
06	High-grade electrical paper	Short Tons.
07	Unsaturated roofing felt	Short Tons.
08	Saturated roofing felt	Short Tons.
09	Flooring felt	Short Tons.
10	Corrugated paper	Short Tons.
11	Specialty paper (specify generic name)	Short Tons.
12	Other (specify generic name)	(Specify).
Floor Coverings		
13	Vinyl asbestos floor tile	Square yards.
14	Asbestos felt backed vinyl flooring	Square yards.
15	Other (specify generic name)	(Specify).
Asbestos Cement Products		
16	A/C pipe and fittings	Short Tons.
17	A/C sheet, flat	100 sq. ft.
18	A/C sheet corrugated	100 sq. ft.
19	A/C shingle	Squares.
20	Other (specify generic name)	(Specify).
Transportation Friction Materials (Including Aircrafts, Marine Vessels, Railroad Engine and Railcars, and Other Vehicles)		
21	Drum brake lining (light-medium vehicle)	Pieces.
22	Disc brake pads (light-medium vehicle)	Pieces.
23	Disc brake pads (heavy vehicle)	Pieces.
24	Brake block (heavy equipment)	Pieces.
25	Clutch facings (all)	Pieces.
26	Automatic transmission friction components	Pieces.
27	Friction materials (industrial and commercial)	Pieces.
28	Custom automotive body filler	Pieces.
29	Transmissions	Pieces.
30	Mufflers	Pieces.
31	Radiator top insulation	Pieces.
32	Radiator sealant	Pieces.
33	Other (specify generic name)	(Specify).
Appliances		
34	Appliance Industrial and consumer (specify generic name)	Pieces.
35	Other (specify generic name)	(Specify).
Construction Products		
36	Boiler and furnace baffles	Pieces.
37	Decorated building panels	Pieces.
38	Asbestos cement sheet	Pieces.
39	Flexible Air Conductor	Pieces.
40	Hoods and Vents	Pieces.
41	Portable construction building	Pieces.
42	Roofing, saturated	Pieces.
43	Roof shingles	Pieces.
44	Wallboard	Pieces.
45	Wall/roofing panels	Pieces.
46	Other (specify generic name)	(Specify).
Electrical Products and Components		
47	Cable insulation	Pieces.
48	Electronic motor components	Pieces.
49	Electrical resistance supports	Pieces.
50	Electrical switchboard	Pieces.
51	Electrical switch supports	Pieces.
52	Electrical wire insulation	Pieces.
53	Motor armature	Pieces.
54	Other (specify generic name)	(Specify).

TABLE 4 IN § 704.180(e)(4)(iv)(B)—END PRODUCT TYPES—Continued

Code	Name	Unit of measure
	Fire and Heat Shielding Equipment and Components	
55	Arc deflectors	Pieces.
56	Fire doors	Pieces.
57	Fireproof absorbent paper	Short tons.
58	Heat shields	Pieces.
59	Molten metal handling equipment	Pieces.
60	Oven and stove insulation	Short tons.
61	Pipe wrap	Pieces.
62	Stove lining, wood and coal	Pieces.
63	Stove pipe rings	Pieces.
64	Sleeves	Pieces.
65	Thermal Insulation	Short tons.
66	Other (specify generic name)	(Specify).
	Textiles and Clothing	
67	Cloth	Pounds.
68	Thread, yarn, lap, roving, cord, rope, or wick	Pounds.
69	Aprons	Pieces.
70	Boots	Pieces.
71	Gloves and mittens	Pieces.
72	Hats and helmets	Pieces.
73	Overgaiters	Pieces.
74	Suits	Pieces.
75	Aluminized cloth	Short Tons.
76	Rope or braiding	Short Tons.
77	Yarn, lap or roving	Short Tons.
78	Wicks	Short Tons.
79	Bags	Pieces.
80	Belting	Short Tons.
81	Blankets	Pieces.
82	Carpet padding	Short Tons.
83	Commercial/industrial dryer felts	Short Tons.
84	Draperies	Pieces.
85	Drip cloths	Pieces.
86	Fire hoses	Pieces.
87	Ironing board pads and insulation	Pieces.
88	Mantles, lamp or catalytic heater	Pieces.
89	Packing and packaging components	Pieces.
90	Piano and organ felts	Pieces.
91	Rugs	Pieces.
92	Tape	Pieces.
93	Theater curtains	Pieces.
94	Umbrellas	Pieces.
95	Other (specify generic name)	(Specify).
	Gaskets	
96	Sheet gasketing, rubber encapsulated beater addition	Pieces.
97	Sheet gasketing, rubber encapsulated compressed	Pieces.
98	Compressed sheet gasketing (other)	Pieces.
99	Metal reinforced gaskets	Pieces.
100	Automotive gaskets	Pieces.
101	Other (specify generic name)	(Specify).
	Marine Equipment and Supplies	
102	Caulks, marine	Pounds.
103	Liners, pond or canal	Pieces.
104	Marine bulkheads	Pieces.
105	Other (specify generic name)	(Specify).
	Paints, Coatings, Sealants and Compounds	
106	Asphaltic compounds	Pounds.
107	Automotive/truck body coatings	Gallons.
108	Buffing and polishing compounds	Pounds.
109	Caulking and patching compounds	Pounds.
110	Drilling fluid	Gallons.
111	Flashing compounds	Pounds.
112	Furnace cement	Pounds.

TABLE 4 IN § 704.180(e)(4)(iv)(B)—END PRODUCT TYPES—Continued

Code	Name	Unit of measure
113	Glazing compounds	Pounds.
114	Plaster and stucco	Pounds.
115	Pump valve, flange and tank sealing components	Pieces.
116	Roof coatings	Gallons.
117	Textured paints	Gallons.
118	Tile cement	Pounds.
119	Other (specify generic name)	(Specify).
	Other Products	
120	Sheet gasketing (other than beater-add)	Square Yards.
122	Packing	Pounds.
123	Paints and surface coatings	Gallons.
124	Adhesives and sealants	Gallons.
125	Asbestos-reinforced plastics	Pounds.
126	Insulation materials not elsewhere classified (specify generic name)	(Specify).
127	Mixed or repackaged asbestos	Short Tons.
128	Aerial distress flares	Pieces.
129	Acoustical product	Pieces.
130	Ammunition wadding	Pieces.
131	Ash trays	Pieces.
132	Baking sheets	Pieces.
133	Blackboards	Pieces.
134	Candlesticks	Pieces.
135	Chemical tanks and vessels	Pieces.
136	Filters	Pieces.
137	Grommets	Pieces.
138	Gun grips	Pieces.
139	Jewelry making equipment	Pieces.
140	Kilns	Pieces.
141	Lamp sockets	Pieces.
142	Light bulbs (all types)	Pieces.
143	Linings for vaults, safes, humidifies and filing cabinets	Pieces.
144	Phonograph records	Pieces.
145	Pottery clay	Pounds.
146	Welding rod coatings	Pieces.
147	Other (specify generic name)	(Specify).

(v) *Reporting information for secondary processors.* For secondary processing reported under the activity identified in paragraph (e)(3)(i)(E) of this section, report by year:

(A) For Form B only, the estimated total quantity of asbestos processed.

(B) End product type listed in Table 4 in paragraph (e)(4)(iv)(B) of this section. For each product type, report:

(1) For Form B only, the most specific asbestos type that applies. Select from among the asbestos types listed in Table 1 in paragraph (a) of this section. If the specific asbestos type is not known or reasonably ascertainable, report the general listing, asbestos CASRN 1332–21–4. Also report the quantity of asbestos.

(2) The total annual production quantity of the end products produced, using the associated unit of measure listed in Table 4 in paragraph (e)(4)(iv)(B) of this section.

(3) For Form B only, the percentage of asbestos in the end product.

(i) If testing was conducted, specify how often testing was conducted on the presence of asbestos in your products and what method and type of test was used for determining asbestos content, and provide the test results.

(ii) If testing was not conducted, explain how you knew or reasonably ascertained the presence and amount of asbestos in the end product.

(4) For Form B only, the disposition of the end product (see Table 3 in paragraph (e)(4)(ii)(B) of this section).

(vi) *Reporting information for importers.* For importing reported under activity identified in paragraph (e)(4)(i)(F) of this section, report by year:

(A) For Form B only, the estimated total quantity of asbestos imported.

(B) Imported product type (Table 4 (e)(4)(iv)(B). For each imported product type, report:

(1) Whether the imported product is a mixture or an article.

(2) For Form B only, the most specific asbestos type that applies. Select from among the asbestos types listed in Table 1 in paragraph (a) of this section. If the specific asbestos type is not known or reasonably ascertainable, report the general listing, asbestos CASRN 1332–21–4. Also report the quantity of asbestos type.

(3) The total annual import quantity of the imported product, using the associated unit of measure listed in Table 4 in paragraph (e)(4)(iv)(B) of this section.

(4) For Form B only, the percentage of asbestos in the product.

(5) For Form B only, explain if you tested or received test results assessing the asbestos content of your imported product in the applicable reporting years.

(i) If testing was conducted, specify how often testing was conducted on the presence of asbestos in your imported product and what method and type of test was used for determining asbestos content, and provide the test results.

(ii) If testing was not conducted, explain how you knew or reasonably ascertained the presence and amount of asbestos in the imported product.

(6) For Form B only, the disposition of the imported product (see Table 3 in paragraph (e)(4)(ii)(B) of this section).

(5) *Employee information.* For each activity reported, report the following information about employees at the associated site:

(i) Number of employees involved with activity. Select from among the ranges of employees listed in Table 2 in paragraph (e)(3)(vi) of this section and report the corresponding code (*i.e.,* W1 through W8).

(ii) Is personal protective equipment used? If yes, identify the type(s) of personal protective equipment used.

(iii) For Form B only, submit any workplace exposure measurement assessments and data (*e.g.,* monitoring).

(f) *When to report.*

All information reported to EPA under this section must be submitted during the applicable submission period. The submission period shall begin six months following the effective date of this rule and last for three months.

(g) *Recordkeeping requirements.*

Each person who reports under this part must maintain records that document information reported under this part and in accordance with TSCA, permit access to, and the copying of such records by EPA officials. Relevant records must be retained for a period of five years beginning on the last day of the submission period.

(h) *Confidentiality claims.*

(1) *Assertion of confidentiality claims*—(i) *Generally.* Any person submitting information under this part may assert a confidentiality claim for that information, except for information described in paragraph (h)(1)(ii) of this section. Any such confidentiality claims must be asserted electronically, pursuant to § 704.180(i), at the time the information is submitted. Information claimed as confidential in accordance with this section will be treated and disclosed in accordance with the procedures in 40 CFR part 2 and section 14 of TSCA.

(ii) *Exceptions.* Confidentiality claims may not be asserted with respect to the following:

(A) Site NAICS code required by § 704.180(e)(3)(v);

(B) For chemical identities and bulk material forms required by §§ 704.180(e)(4)(ii)(A), (iii)(A), (iii)(B)(*3*), (iv)(B)(*1*), (v)(B)(*1*), and (vi)(B)(*2*);

(C) Any data element that is left blank or designated as ''not known or reasonably ascertainable;'' or

(D) Health and safety data required by § 704.180(e)(5)(iii), except that the following information may be claimed as confidential:

(*1*) Information that would reveal processes used in the manufacturing, importing, or processing of the substance or mixture, or the portion of a mixture comprised by any of the substances in the mixture, provided that the information is expressly identified as revealing processing information or portion of a mixture;

(*2*) Company name or address, financial statistics, and product codes used by a company and contained in a study; and

(*3*) Information other than company name or address, financial statistics, and product codes used by a company, which is contained in a study, the disclosure of which would clearly be an unwarranted invasion of personal privacy (such as individual medical records).

(iii) *Certification statement for claims.* An authorized official representing a person asserting a claim of confidentiality must certify that the submission complies with the requirements of this part by signing and dating the following certification statement:

> ''I certify that all claims for confidentiality asserted with this submission are true and correct, and all information submitted herein to substantiate such claims is true and correct. Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. 1001. I further certify that: (1) I have taken reasonable measures to protect the confidentiality of the information; (2) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law; (3) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and (4) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.''

(2) *Substantiation.*—(i) *Requirement to substantiate.* Confidentiality claims must be substantiated at the time of submission to EPA, unless exempt under paragraph (h)(2)(v) of this section.

(ii) *Information in substantiations may be claimed as confidential.* Such claims must be accompanied by the certification described in paragraph (h)(1)(iii),but need not be themselves substantiated.

(iii) *Substantiation questions for all claims.* Answers to the following questions must be provided for each confidentiality claim in a TSCA submission:

(A) Please specifically explain what harm to the competitive position of your business would be likely to result from the release of the information claimed as confidential. How would that harm be *substantial?* Why is the substantial harm to your competitive position *likely* (*i.e.,* probable) to be caused by release of the information rather than just *possible*? If you claimed multiple types of information to be confidential (*e.g.,* site information, exposure information, environmental release information), explain how disclosure of each type of information would be likely to cause substantial harm to the competitive position of your business.

(B) Has your business taken precautions to protect the confidentiality of the disclosed information? If yes, please explain and identify the specific measures, including but not limited to internal controls, that your business has taken to protect the information claimed as confidential. If the same or similar information was previously reported to EPA as non-confidential (such as in an earlier version of this submission), please explain the circumstances of that prior submission and reasons for believing the information is nonetheless still confidential.

(C)(*1*) Is any of the information claimed as confidential required to be publicly disclosed under any other Federal law? If yes, please explain.

(*2*) Does any of the information claimed as confidential otherwise appear in any public documents, including (but not limited to) safety data sheets; advertising or promotional material; professional or trade publications; state, local, or Federal agency files; or any other media or publications available to the general public? If yes, please explain why the information should be treated as confidential.

(*3*) Does any of the information claimed as confidential appear in one or more patents or patent applications? If yes, please provide the associated patent number or patent application number (or numbers) and explain why the information should be treated as confidential.

(D) Is the claim of confidentiality intended to last less than 10 (ten) years (see TSCA section 14(e)(1)(B))? If yes, please indicate the number of years (between 1 (one) and 10 (ten) years) or the specific date after which the claim is withdrawn.

(E) Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this chemical substance? If yes, please provide the circumstances associated with the prior determination, whether the information was found to be entitled to confidential treatment, the entity that made the decision, and the date of the determination.

(iv) *Exemptions from the substantiation requirement.*

Confidentiality claims are exempt from the requirement to substantiate the claim at the time of submission for the data elements required pursuant to paragraphs (e)(4)(ii)(B)(*1*), (iii)(B)(*1*), (iv)(A), (iv)(B)(*2*), (v)(A), (v)(B)(*2*), (vi)(A), and (vi)(B)(3) of this section.

(v) *No claim of confidentiality.* Information not claimed as confidential in accordance with the requirements of this section may be made public without further notice.

(vi) *Public copies.* Submissions and their accompanying attachments that include a confidentiality claim must be accompanied, at the time of submission, by a public version of the submission and any attachments, with all information that is claimed as confidential removed. Only information that is claimed as confidential may be redacted or removed. Generally, a public copy that removes all or substantially all of the information would not meet the requirements of this paragraph.

(A) Where the electronic reporting tool contains a checkbox or other means of designating with specificity what information is claimed as confidential, no further action by the submitter is required to satisfy this requirement.

(B) For all other information claimed as confidential, including but not limited to information in attachments and in substantiations required under paragraph (h) of this section, the submitter must prepare and attach a public copy. Submissions with public or sanitized copies that are entirely blank or that are substantially reduced in length as compared to the CBI version will not meet the requirements of this paragraph (h)(2)(vi) of this section.

(i) *Electronic reporting.*

You must use the EPA Central Data Exchange (CDX) to complete and submit the information required under this section. Submissions may only be made as set forth in this paragraph. Submissions must be sent electronically to EPA using the asbestos reporting tool in CDX. The information submitted and all attachments (unless the attachment appears in scientific literature) must be in English. All information must be true and correct. Access the asbestos reporting tool and instructions, as follows:

(1) *By website.* Access the asbestos reporting tool via the CDX homepage at *https://cdx.epa.gov/* and follow the applicable instructions.

(2) *By phone or email.* Contact the EPA TSCA Hotline at (202) 554–1404 or *TSCA-Hotline@epa.gov*.

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Notices

Federal Register
Vol. 87, No. 88
Friday, May 6, 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.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Notice of May 23, 2022 Meeting of the Board for International Food and Agricultural Development

AGENCY: Agency for International Development.

ACTION: Notice of meeting; request for comment.

Pursuant to the Federal Advisory Committee Act, notice is hereby given of a public meeting of the Board for International Food and Agricultural Development (BIFAD), *The Global Food Security Crisis: Exploring the Evidence Base and Lessons from the Past to Strengthen Agricultural, Nutrition, and Food Systems in the Face of Shocks.* The meeting will be held on May 23, 2022 from 12:00 to 2:30 EDT online, with designated times for public comment from 1:30–1:50 p.m. EDT and from 2:15–2:20 p.m. EDT. The meeting will be livestreamed via Zoom (registration required) and accessible at the following link: *https://us06web.zoom.us/webinar/register/WN_vCZ3oZYDTAyEEcq14OwKIA.*

The BIFAD is a seven-member, presidentially appointed advisory board to USAID established in 1975 under Title XII of the Foreign Assistance Act, as amended, to ensure that USAID brings the assets of U.S. universities to bear on development challenges in agriculture and food security and supports their representation in USAID programming. This will be the first public meeting of BIFAD members appointed by President Joseph Biden on January 14, 2022 and will include an introduction to newly appointed BIFAD members, a briefing on BIFAD's current work plan priorities, and an overview of key upcoming initiatives. Public comment is invited to further inform BIFAD's work.

In the face of short-term and long-term shocks, fragile food systems are driving increases in poverty, hunger, and child stunting. The global effort to end hunger and poverty is at a critical moment, with Russia's invasion of Ukraine adding to an already-compounded global food crisis as countries struggle to recover from the impacts of COVID–19, humanitarian emergencies and climate change.

What does it mean to get ahead of future crises and to build resilient food systems? What are the lessons learned from previous crises, including the COVID–19 pandemic and the 2007–2008 global food price crisis? BIFAD will take stock of evidence around these questions and identify weak links in food systems that must be strengthened to respond to global food security crises and to mitigate the impacts of current and future shocks. Food systems, nutrition, and humanitarian assistance experts will share lessons learned about resilience in the face of these disruptions. Evidence-based recommendations from these deliberations will inform USAID strategy implementation, policy, and programming.

For questions about registration, please contact Carol Chan at *carol.chan@tetratech.com.* For questions about BIFAD, or to submit written public comments in advance, please contact Clara Cohen, Designated Federal Officer for BIFAD in the Bureau for Resilience and Food Security at USAID. Interested persons may email her at *ccohen@usaid.gov* or telephone her at (202) 712–0119.

Clara Cohen,

Designated Federal Officer, BIFAD.

[FR Doc. 2022–09707 Filed 5–5–22; 8:45 am]

BILLING CODE 6116–01–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by June 6, 2022 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number, and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal and Plant Health Inspection Service

Title: Control of African Swine Fever; Restrictions on the Movement of Swine Products and Swine Byproducts from Puerto Rico and the U.S. Virgin Islands.

OMB Control Number: 0579–0480.

Summary of Collection: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*) the Secretary of the U.S. Department of Agriculture (USDA) is authorized to protect the health of the livestock, poultry, and aquaculture populations in the United States by preventing the introduction and interstate spread of serious diseases and pests, and for eradicating such diseases and pests from the United States, when feasible. Within the USDA, the Animal and Plant Health Inspection Service (APHIS Veterinary Services (VS) is tasked with preventing foreign animal disease outbreaks in the United States, and monitoring, controlling, and eliminating a disease outbreak should

one occur. In the past several years, there have been significant worldwide outbreaks of African swine fever (ASF), a highly contagious and deadly viral disease affecting domestic and feral pigs. APHIS is committed to working with State and industry partners to keep the disease out of the United States.

Need and Use of the Information: To certify compliance with the restriction guidelines in the Federal Order for the interstate movement of swine products and byproducts from Puerto Rico and the U.S. Virgin Islands, commercial producers must meet the requirements as listed in the Federal Order or complete a VS Form 16–3, an application for a permit to import or transport controlled material or organisms or vectors. The collection of this information prevents unhealthy swine products and byproducts from being imported into the United States.

Description of Respondents: State animal health officials, and commercial producers of swine products and byproducts.

Number of Respondents: 22.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 60.

Dated: May 5, 2022.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–09733 Filed 5–5–22; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

[Docket ID FSA–2022–0005]

Notice of Funds Availability; Cotton and Wool Apparel Program

AGENCY: Commodity Credit Corporation, and Farm Service Agency; Department of Agriculture (USDA).

ACTION: Notification of funding availability.

SUMMARY: The Farm Service Agency (FSA) is announcing the availability of $50 million for the new Cotton and Wool Apparel Program (CAWA), which will support the domestic markets for wool and Pima cotton by assisting eligible apparel manufacturers of men's and boys' worsted wool suits, sport coats, pants, or Pima cotton dress shirts; Pima cotton spinners; and wool fabric manufacturers and wool spinners. The COVID–19 pandemic dramatically reduced the demand for these types of clothing, textiles, and threads, and in turn, the market for the raw commodities. CAWA will assist in the development and restoration of the market for domestically produced cotton and wool products and ultimately for the underlying commodities. To be eligible for CAWA, an applicant must have experienced a decrease of at least 15 percent in calendar year 2020 gross sales or consumption of eligible products described in this document compared to the applicant's gross sales or consumption in any selected calendar years 2017, 2018, or 2019. Payments to eligible entities will be based on their pre-pandemic market share relative to other similar applicants subject to payment limitations. The eligibility requirements, payment calculation, and application procedure for CAWA are included in this document.

DATES:

Funding Availability: Implementation will begin May 6, 2022.

Applications Start Date: We will accept applications for funding starting on May 16, 2022.

Applications Due Date: We will accept applications for funding through June 17, 2022.

FOR FURTHER INFORMATION CONTACT: Kimberly Graham; telephone: (202) 720–6825; email: *Kimberly.Graham@usda.gov.* Persons with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 (voice) or (844) 433–2774 (toll-free nationwide).

SUPPLEMENTARY INFORMATION:

Background

Since the onset of the COVID–19 pandemic in March 2020, millions of Americans transitioned from working in offices to working from home. Two years later, the pandemic has persisted, and many employees have continued to work remotely. This transition toward remote work has led to a dramatic decrease in consumer demand for worsted wool suits, sport coats, dress pants, and Pima cotton dress shirts. Manufacturers of these products, mainly small and medium-sized businesses, had to temporarily shut down or reduce their hours of production through the early months of the pandemic due to a dramatic decline in demand. Although many of these manufacturers shifted to the production of personal protective equipment (PPE), the industry has struggled to recover from a persistent and significant reduction in sales and many of these businesses are now struggling to avoid bankruptcy.

Without additional support, some of these companies will cease operations or be unable to restore full production, negatively impacting American workers, the supply chain, and ultimately the market for domestic cotton growers and wool producers that rely on the American apparel manufacturing industry to support the market for their raw products. Like other industries, the supply chain between the production of raw Pima cotton or wool to the ultimate consumer has become globalized and does not track the origin of the raw material in most cases. Many imported wool and Pima cotton fabrics contain domestically produced raw materials and ultimately support the markets for those domestic agricultural commodities. By excluding synthetic fabrics and targeting specific apparel, CAWA further ensures assistance to support and rebuild key domestic and global markets for the domestic producers of raw Pima cotton and wool.

In accordance with 15 U.S.C. 714c, the Secretary is using $50 million of the Commodity Credit Corporation (CCC) funds that were previously transferred for pandemic-related assistance to establish a new program to indirectly support Pima cotton and wool producers by providing assistance to wool and Pima cotton manufacturers and spinners whose consumption and gross sales of raw Pima cotton and wool in 2020 were impacted by the COVID–19 pandemic and that filed an affidavit for a payment in any year from calendar year 2017 to calendar year 2021 in accordance with sections 12602 or 12603 of the Agriculture Improvement Act of 2018 (2018 Farm Bill; Pub. L. 115–34), which authorizes the Wool Apparel Manufacturers Trust Fund and the Pima Agriculture Cotton Trust Fund, respectively. CAWA is using the eligibility for the trust funds established in the 2018 Farm Bill because the entities that meet these eligibility criteria encompass the known universe of domestic apparel manufacturers of men's and boys' worsted wool suits, sport coats, pants, or Pima cotton dress shirts; Pima cotton spinners; and wool fabric manufacturers and wool spinners. This group of companies represents one of the few markets for Pima cotton and wool materials in the United States and an opportunity to indirectly support wool and Pima cotton producers. While CAWA defines eligibility partially based on eligibility for, and participation in, these trust funds, CAWA and the trust fund programs are otherwise distinct and separate with regard to purpose and authority. Since the entities targeted for payment in both CAWA and the trust funds have been determined to be the same, using the same base eligibility criteria, as previously demonstrated

through participation in the trust fund programs provides for a streamlined delivery of CAWA. Since CAWA is a pandemic assistance program focused on restoring and improving a distinct market, CAWA participants must meet additional eligibility criteria to ensure assistance through CAWA is tied to demonstrable pandemic-induced market challenges.

CAWA will provide assistance to several subsets of the wool and Pima cotton industries. There are no publicly available breakdowns of the relative size or degree of need among the different segments; therefore, USDA conducted research and leveraged appropriate industry resources with specific knowledge of the Pima cotton and wool apparel markets. USDA research and these industry resources provided the information necessary for USDA to determine the level of pandemic-related market challenges for each subset of the wool and Pima cotton industries, along with the support needed to restore and increase these markets for Pima cotton and wool in the United States. This information was subsequently used to determine the funding levels for each industry subset. As a result, USDA determined that approximately $35 million will be available for eligible apparel manufacturers; approximately $5 million will be available for eligible Pima cotton spinners; and approximately $10 million will be available for eligible wool fabric manufacturers and yarn wool spinners. USDA also determined that a minimum payment of $50,000 would be used to both ensure that each recipient received sufficient assistance to provide a meaningful amount to restore or help expand the domestic market and as a way to target small businesses for a proportionately larger benefit than if market share was used alone.

Funds available to CCC will be used as authorized by section 5(e) of the CCC Charter Act (15 U.S.C. 714c(e)). As outlined above, the assistance to these wool and Pima cotton domestic apparel and textile industries will help increase and restore the domestic consumption of agricultural commodities in the form of raw Pima cotton and wool by aiding in the recovery of the domestic market for the use of Pima cotton and wool products. Without this assistance, several companies have indicated that they may cease operation or remain at lower production levels for a substantially longer period of time, impairing the demand for Pima cotton and wool materials from domestic markets. The specific CCC authority will be used to restore and ultimately improve the viability of this key domestic market for Pima cotton and wool materials beyond pre-pandemic levels.

FSA is implementing CAWA as a part of the Secretary's USDA Pandemic Assistance for Producers initiative. While each applicant must meet the minimum eligibility requirement of a 15 percent decline in gross sales or consumption compared to pre-pandemic levels, the payments themselves will be based on each applicant's pre-pandemic market share and are not indemnities for past losses. Through CAWA, FSA will make payments to:

- Apparel manufacturers that have experienced at least a 15 percent decrease in calendar year 2020 in gross sales of eligible products, when comparing calendar year 2020 gross sales to gross sales in any one of calendar years 2017, 2018, or 2019; gross sales is used in the case of apparel manufacturers because there is not a readily available conversion to consumption of the raw materials.
- Pima cotton spinners that have experienced at least a 15 percent decrease in calendar year 2020 in:
  - Gross sales of eligible products when comparing calendar year 2020 gross sales to gross sales in any one of calendar years 2017, 2018, or 2019; or
  - Consumption of eligible products when comparing calendar year 2020 consumption to consumption in any one of calendar years 2017, 2018, or 2019; and
- Wool fabric manufacturers and wool spinners that experienced at least a 15 percent decrease in calendar year 2020 in:
  - Gross sales for of eligible products when comparing calendar year 2020 gross sales to gross sales in any one of calendar years 2017, 2018, or 2019; or
  - Consumption of eligible products, when comparing calendar year 2020 consumption to consumption in any one of calendar years 2017, 2018, or 2019.

On behalf of the CCC, FSA is administering the direct payments under the general supervision and direction of the FSA Administrator, with assistance from the Foreign Agriculture Service (FAS) to ensure applicants are eligible.

Definitions

The definitions in 7 CFR parts 718 and 1400 apply to CAWA, except as otherwise provided in this document. The following definitions also apply:

Apparel manufacturers means domestic manufacturers and producers that use imported Pima cotton fabric (80s or higher count and 2-ply in warp) to manufacture men's and boys' woven Pima cotton shirts or domestic manufacturers and producers of men's and boys' worsted wool suits, suit-type jackets, or trousers that use imported fabrics containing 85 percent or more by weight of wool.

Consumption means for:

- Pima Cotton—the number of pounds of Pima cotton processed for U.S. ring spun Pima cotton yarns measuring less than 83.33 decitex (exceeding 120 metric number).
- Worsted Wool—the number of pounds of wool top spun into worsted yarn and the number of pounds of wool yarn processed into worsted woven wool fabric, converted into wool top.

Member of a controlled group means a subsidiary or otherwise affiliated company of a parent or holding company that has a history of participating in the wool and cotton trust fund programs. The applicant would be the parent or holding company for the purposes of this program.

Deputy Administrator means Deputy Administrator for Farm Programs, Farm Service Agency, U.S. Department of Agriculture, or their designee.

Gross sales means the direct sale or wholesale of eligible products only in dollars.

Pima cotton spinner means a spinner that produces domestic ring spun Pima cotton yarns measuring less than 83.33 decitex (exceeding 120 metric number) in single and plied form.

Unique entity identifier (SAM UEI) means a number used to identify a specific entity. A System for Award Management (SAM) UEI number replaced the DUNS UEI number. The number can be obtained on *SAM.gov*, and is used to make payments to entities receiving government payments.

Wool fabric manufacturers and wool spinners means domestic manufacturers and producers of woven worsted wool fabrics containing 85 percent or more by weight of wool or processors of imported wool yarn, fiber, and top that use such wool yarn, fiber, or top to manufacture in the United States.

Wool top means wool fiber used for worsted manufacturing. It has undergone all major preprocessing steps and is ready for yarn spinning. To convert wool yarn to wool top, applicants should use the following conversion: 1 pound of wool yarn equates to 1.11 pounds of wool top.

United States means all 50 states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States.

Eligible Products

For apparel manufacturers, eligible products are:

- Men's and boys' worsted wool suits, sport coats, or pants; or
- Men's and boys' Pima cotton dress shirts.

The products must have been cut and sewn in the United States at a facility owned by the applicant or a member of its controlled group in the United States.

For Pima cotton spinners, the eligible product is Pima cotton for U.S. ring spun Pima cotton yarns measuring less than 83.33 decitex (exceeding 120 metric number) in single and plied form.

For wool fabric manufacturers and wool spinners, eligible products are:

- Yarn spun in the United States of a type used for worsted woven wool fabric;
- Worsted wool fabric woven in the United States; or
- Wool top spun into worsted yarn in the United States.

Eligibility

To be eligible for a CAWA payment, an applicant must:

(1) Have filed an affidavit for a payment in any year from 2017 to 2021 from the trust funds authorized by sections 12602 and 12603 of the 2018 Farm Bill.

(2) At the time of application, be in operation or have plans to restart domestic operations within a reasonable timeframe as an apparel manufacturer, Pima cotton spinner, wool fabric manufacturer, or wool spinner and submit a business plan showing the use of the assistance determined acceptable by the Deputy Administrator.

(3) Have had at least a 15 percent decrease in calendar year 2020, compared to calendar year 2017, 2018, or 2019, in:

(a) Gross sales; or

(b) Consumption of the eligible products, except for apparel manufacturers.

(4) Be an active entity on *https://SAM.gov* and have a SAM UEI.

An eligible applicant is a legal entity with production and facilities located in the United States.

Any entity that did not file an affidavit for a payment in any year from 2017 to 2021 under sections 12602 and 12603 of the 2018 Farm Bill is ineligible for CAWA.

An entity is considered eligible if it is manufacturing on the date of application or has plans to restart domestic operations within a reasonable timeframe and submits a business plan showing the use of the assistance determined acceptable by the Deputy Administrator. An entity remains eligible if it acquired a manufacturer or producer during any year in which gross sales or consumption is reported on an application, or if there is a change in ownership and the entity continues to manufacture the same products as a predecessor manufacturer that participated in a trust fund. In the case of an entity that continues to manufacture the same products as a predecessor manufacturer, the entity may use gross sales or consumption data of its predecessor in its application at the discretion of the Deputy Administrator.

If an entity is under common control with another manufacturer or producer during any year in which sales or consumption would be reported on an application, any application must be submitted through the parent or holding company unless otherwise permitted by the Deputy Administrator.

Application Process

FSA will accept applications from May 16, 2022, through June 17, 2022. To apply for CAWA, eligible applicants must submit a completed form CCC–917, Cotton and Wool Apparel Program (CAWA) Application. Applications may be submitted to the FSA National Office by email to *CAWA@usda.gov.* All applicants must be an active entity on *https://SAM.gov* and are required to enter their SAM UEI number on the application form to receive payment.

The program requires the applicant to show a 15 percent or greater reduction in calendar year 2020 when comparing calendar year 2017, 2018, or 2019 to calendar 2020, for:

- Apparel manufacturers, gross sales of eligible products.
- Pima cotton spinners, either:
  - Gross sales of eligible products, or
  - Consumption of eligible products.
- Wool fabric manufacturers and/or spinner, either:
  - Gross sales of eligible products, or
  - Consumption of eligible products.

The applicant only needs to report the applicable percentage decrease on the CCC–917 but should be prepared to provide actual calculations and documentation upon request.

Eligible apparel manufacturers will report gross sales of eligible products for the year of their choice during calendar years 2017, 2018, or 2019 on form CCC–917. These data will be used to approximate each company's pre-pandemic market share relative to other applicants in order to calculate the proportionate share of funding within the apparel manufacturer funding category after an initial flat-rate payment is made to each eligible entity and subject to payment limitations.

To estimate the pre-pandemic market share and calculate proportionate payment shares within the other funding categories, Pima cotton spinners, wool spinners, and wool fabric manufacturers must report total consumption on form CCC–917 for calendar year 2017, 2018, or 2019. When reporting consumption, a wool yarn spinner will report the total number of wool top pounds processed, and a wool fabric manufacturer will convert total pounds of wool yarn processed into wool top and then report the total number of wool top pounds processed.

FSA will cross-check applicant information with the most recent affidavits on file with FAS for the trust funds. If there is not a match, applicants will be required to provide documentation to verify they are authorized to represent the eligible entity, executed in accordance with any State laws that designate what officers, members, or managers are authorized signatories for signature authority on the form CCC–917. Documentation may include, but is not limited to, corporate charter, bylaws, articles of organization, partnership papers, signed corporate minutes, or resolution of the corporation's board of directors.

Gross sales and consumption are based on the applicant's certification and are subject to spot check.

If requested by FSA, the applicant must provide supporting documentation to verify the accuracy of information provided on the application, including to substantiate the gross sales or consumption, and documentation that demonstrates the application is not for an entity that is under common control with another manufacturer or producer during any year in which gross sales or consumption are reported on an application. If any supporting documentation is requested, the documentation must be submitted to FSA within 30 days from the request or the application will be disapproved by FSA. Supporting documentation should be maintained for a period of 3 years.

Payments

For all eligible applicants, the payment amount will be calculated as follows:

- A payment of $50,000;
- Plus, a proportionate share of the remaining balance of funds in the applicant's funding category based on each applicant's pre-pandemic market share adjusted for payment limitations.

The funds available for eligible apparel manufacturers, Pima cotton spinners, and wool fabric manufacturers and wool spinners are as follows:

- Approximately $35 million will be available for eligible apparel manufacturers. Eligible apparel manufacturers will receive a minimum payment of $50,000 plus the proportionate share of the balance of funds available based on pre-pandemic market share measured by gross sales and adjusted for remaining applicants in the funding category as entities reach the payment limit. Payments will be capped at $8 million per applicant.
- Approximately $5 million will be available for eligible Pima cotton spinners. Eligible Pima cotton spinners will receive a minimum payment of $50,000 plus the proportionate share of the balance of funds available based on pre-pandemic market share measured by consumption and adjusted for remaining applicants in the funding category as entities reach the payment limit. Payments will be capped at $2.5 million per applicant.
- Approximately $10 million will be available for eligible wool fabric manufacturers and wool spinners. Eligible wool fabric manufacturers and wool spinners will receive a minimum payment of $50,000 plus the proportionate share of the balance of funds available based on pre-pandemic market share measured by consumption and adjusted for remaining applicants in the funding category as entities reach the payment limit. Payments will be capped at $5 million per applicant.

Within each funding category payments will be determined using the same procedures. First, the $50,000 minimum payment will be allocated to each eligible applicant, and then the remaining available funding will be apportioned. For example, if there are 20 eligible apparel manufacturer applicants, minimum payments would total $1 million. Second, the remaining funding within each funding category will be allocated proportionately based on each entity's pre-pandemic market share. This is calculated based on either relative gross sales or consumption, depending on funding category, reported in three pre-pandemic years, 2017, 2018, or 2019. Applicants can choose the year of gross sales or consumption reported for this market share calculation, but the proportionate shares will be calculated without regard for which of the three years is reported by each entity. In other words, within each of the three categories, the total across all eligible applicants will be a sum of the individual submissions and not broken down by year. An entity's total payment will be capped by applicable payment limitations. Once an entity reaches a payment limitation, that entity's proportional share of funding above the payment limit will be reallocated to any entities in that funding category that have not reached the payment limitation based on their proportional pre-pandemic market shares. Continuing the earlier example, there would be $34 million remaining in the apparel manufacturer category after the minimum per entity payment of $50,000. Therefore, if an entity has a 30 percent pre-pandemic market share ($10.2 million), it would receive $7,950,000 from the proportionate funding (in addition to the $50,000 that every eligible applicant receives) and the remaining $2,250,000 of its share above the payment limitation would be reallocated based on the proportional pre-pandemic market shares of any entities that have not yet reached the payment limitation in the apparel manufacturer funding category.

Provisions Requiring Refund to FSA

In the event that any application for a CAWA payment resulted in an incorrect payment due to erroneous information reported by the applicant, the payment will be recalculated, and the applicant must refund any excess payment to FSA, including interest, to be calculated from the date of the disbursement to the applicant. If, for any reason, FSA determines that the applicant misrepresented the gross sales or consumption difference, the application will be disapproved, and the applicant must refund the full CAWA payment to FSA, with interest, from the date of disbursement. Any required refunds must be resolved in accordance with 7 CFR part 3.

Miscellaneous Provisions

All applicants must provide the name and address of the entity along with their active SAM UEI. Provisions of 7 CFR 718.6, which address ineligibility for benefits for offenses involving controlled substances, apply to CAWA. Appeal regulations specified in 7 CFR parts 11 and 780, and equitable relief and finality provisions specified in 7 CFR part 718, subpart D, apply to determinations under CAWA. The determination of matters of general applicability cannot be appealed if they are not in response to, or result from, an individual set of facts in an individual participant's application for payment. Such matters of general applicability include, but are not limited to, the determination of applicable time periods and the payment calculation for CAWA.

Participants are required to retain documentation in support of their application for 3 years after the date of approval. Participants receiving CAWA payments or any other person furnishing such documentation to USDA must permit authorized representatives of USDA or the Government Accountability Office, during regular business hours, to enter the participant's business and to inspect, to examine, and to allow representatives to make copies of books, records, or other items for the purpose of confirming the accuracy of the information provided by the participant.

Applicants have a right to a decision in response to their application. If an applicant files a late CAWA application, the application is subject to the following conditions:

- A late CAWA application will be considered a request to waive the deadline.
- Requests to waive or modify program provisions are at the discretion of the Deputy Administrator. The Deputy Administrator has the authority to waive or modify application deadlines and other requirements or program provisions not specified in law in cases where the Deputy Administrator determines it is (1) equitable to do so; and (2) where the lateness or failure to meet other requirements or program provisions do not adversely affect the operation of CAWA.
- Applicants who request to waive or modify CAWA program provisions do not have a right to a decision on those requests.
- The Deputy Administrator's refusal to exercise discretion on requests to waive or modify CAWA program provisions will not be considered an adverse decision and is, by itself, not appealable.

The regulations governing offsets in 7 CFR part 3 apply to CAWA payments.

In either applying for or participating in CAWA, or both, the applicant is subject to laws against perjury (including but not limited to 18 U.S.C. 1621). If the applicant willfully makes and represents as true any verbal or written declaration, certification, statement, or verification that the applicant knows or believes not to be true, in the course of either applying for or participating in CAWA, or both, then the applicant may be found to be guilty of perjury. Except as otherwise provided by law, if guilty of perjury the applicant may be fined, imprisoned for not more than 5 years, or both, regardless of whether the applicant makes a verbal or written declaration, certification,

statement, or verification within or outside the United States.

Paperwork Reduction Act Requirements

In accordance with the Paperwork Reduction Act, the information collection request that supports CAWA was submitted to OMB for emergency approval. OMB approved the 6-month emergency information collection under OMB control number 0560–0308. The CAWA Program will be available for up to 6 months for making the payments to the eligible apparel manufacturers, Pima cotton spinners, and wool fabric manufacturers and wool spinners that have experienced a decrease of at least 15 percent in gross sales or consumption in calendar year 2020, compared to any one of calendar years 2017, 2018, or 2019.

Environmental Review

The environmental impacts have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321–4347), the regulations of the Council on Environmental Quality (40 CFR parts 1500–1508), and the FSA regulation for compliance with NEPA (7 CFR part 799).

As previously stated, CAWA will provide payment to the eligible apparel manufacturers, Pima cotton spinners, and wool fabric manufacturers and wool spinners that experienced a decrease of at least 15 percent in gross sales or consumption in calendar year 2020, compared to any one of calendar years 2017, 2018, or 2019. The limited discretionary aspects of CAWA do not have the potential to impact the human environment as they are administrative. Accordingly, these discretionary aspects are covered by the FSA Categorical Exclusion specified in 7 CFR 799.31(b)(6)(vi) that applies to safety net programs.

No Extraordinary Circumstances (§ 799.33) exist. As such, the implementation of CAWA and the participation in CAWA do not constitute major Federal actions that would significantly affect the quality of the human environment, individually or cumulatively. Therefore, FSA will not prepare an environmental assessment or environmental impact statement for this action and this document serves as documentation of the programmatic environmental compliance decision for this Federal action.

Federal Assistance Programs

The title and number of the Federal assistance programs, as found in the Assistance Listing,[1] to which this document applies is 10.149, Cotton and Wool Apparel Program (CAWA).

USDA Non-Discrimination Policy

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family or parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (for example, braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA TARGET Center at (202) 720–2600 or (844) 433–2774 (toll-free nationwide). Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint* and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410 or email: *OAC@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

Zach Ducheneaux,

Administrator, Farm Service Agency.

[FR Doc. 2022–09730 Filed 5–5–22; 8:45 am]

BILLING CODE 3410–05–P

[1] See *https://sam.gov/content/assistance-listings.*

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Special Milk Program for Children

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This collection is an extension without change of a currently approved collection which FNS employs to determine public participation in Special Milk Program for Children.

DATES: Written comments must be received on or before July 5, 2022.

ADDRESSES: Comments may be sent to: Kevin Maskornick, Operational Support Branch, Program Monitoring and Operational Support Division, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, Alexandria, VA 22314 or submitted via email to *kevin.maskornick@usda.gov.* Comments will primarily be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically. All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Kevin Maskornick via phone at 703–305–2537 or via email at *kevin.maskornick@usda.gov.*

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: 7 CFR part 215, Special Milk Program for Children.

Form Number: FNS–10 and FNS–777.

OMB Number: 0584–0005.

Expiration Date: July 31, 2022.

Type of Request: Extension without change of a currently approved collection.

Abstract: Section 3 of the Child Nutrition Act (CNA) of 1966, (42 U.S.C. 1772) authorizes the Special Milk Program (SMP). It provides for the appropriation of such sums as may be necessary to enable the Secretary of Agriculture to encourage the consumption of fluid milk by children in the United States in: (1) Nonprofit schools of high school grade and under; and (2) nonprofit nursery schools, child care centers, settlement houses, summer camps, and similar nonprofit institutions devoted to the care and training of children, which do not participate in a food service program authorized under the CNA or the National School Lunch Act.

Section 10 of the CNA (42 U.S.C. 1779) requires the Secretary of Agriculture to prescribe such regulations as deemed necessary to carry out this Act and the National School Lunch Act. Pursuant to that provision, the Secretary has issued 7 CFR part 215, which sets forth policies and procedures for the administration and operation of the SMP. State and local operators of the SMP are required to meet Federal reporting and accountability requirements. This information collection is required to administer and operate this program. The Program is administered at the State, school food authority (SFA), and child care institution levels; and operations include the submission of applications and agreements, submission and payment of claims, and maintenance of records. The reporting and record keeping burden associated with this revision has remained the same at 13,325 hours. All reporting and recordkeeping requirements associated with the SMP are currently approved by the Office of Management and Budget and are in force. This is an extension without change of the currently approved information collection.

Forms FNS–10 and FNS–777 collect information that are associated with this information collection; however, these forms are approved under another FNS information collection. Forms FNS–10 and FNS–777 are used by the State agencies to report program data. These forms, and the reporting burden associated with them, are approved under OMB# 0584–0594 Food Programs Reporting System (FPRS) (expiration date 7/31/23). The recordkeeping burden associated with these forms is covered in this collection.

Affected Public: State, Local, and Tribal Government and Not-for-profit institutions. Respondent groups identified include State agencies and Non-profit Institutions.

Number of Respondents: 3,499 (54 State Agencies, 3,445 Non-profit Institutions).

Estimated Number of Responses per Respondent (Reporting): 1.35.

Total Annual Responses (Reporting): 4,741.

Reporting Time per Response (Reporting): .25.

Estimated Annual Reporting Burden: 1,185.

Number of Recordkeepers: 3,499 (54 State Agencies, 3,445 Non-profit Institutions).

Estimated Number of Responses per Respondent (Recordkeeping): 23.91.

Estimated Total Number of Records to Keep: 83,666.

Estimated Time per Response (Recordkeeping): 0.15.

Total Estimated Recordkeeping Burden: 12,140.

Total Annual Responses for Reporting/Recordkeeping: 88,407.

Annual Recordkeeping and Reporting Burden: 13,325.

Current OMB Inventory for Part 215: 14,914.

Difference (change in burden with this renewal): 0.

Refer to the table below for estimated total annual burden for each type of respondent.

Affected public	Estimated number respondents	Number of responses per respondent	Total annual responses	Estimated total hours per response	Estimated total burden
Reporting					
State agencies	54	24	1,296	0.25	324
Non-profit Institutions	3,445	1	3,445	0.25	861
Total Estimated Reporting Burden	3,499	1.35	4,741	0.25	1,185
Recordkeeping					
State agencies	54	861.8	46,537	0.10	4,714
Non-profit Institutions	3,445	10.78	[1] 37,129	0.20	7,426
Total Estimated Recordkeeping Burden	3,499	[2] 23.91	83,666	0.15	12,140
Total Reporting and Recordkeeping					
Reporting	3,499	1.35	4,741	0.25	1,185
Recordkeeping	3,499	23.91	83,666	0.15	12,140
Total	3,499	25.27	88,407	0.15	13,325

[1] Certain procurement requirements only apply to the 2,679 school food authorities and residential child care institutions participating in the Special Milk Program.

[2] Rounded from 23.91146.

Cynthia Long,

Administrator, Food and Nutrition Service.

[FR Doc. 2022–09809 Filed 5–5–22; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Generic Clearance for the Development of Nutrition Education Messages and Products for the General Public

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This is a revision of a currently approved collection. This notice announces the Center for Nutrition Policy and Promotion's (CNPP) intention to request the Office of Management and Budget's approval of the information collection processes and instruments to be used during consumer research while testing nutrition education messages and products developed for the general public. The purpose of performing consumer research is to identify consumers' understanding of potential nutrition education messages and obtain their reaction to prototypes of nutrition education products, including internet-based tools. The information collected will be used to refine messages and improve the usefulness of products as well as aid consumer understanding of *Dietary Guidelines*-grounded messages and related materials.

DATES: Written comments must be received on or before July 5, 2022.

ADDRESSES: Comments may be sent to: Jessica Larson, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, Fourth Floor, Alexandria, VA 22314. Comments may also be submitted via email to *SM.FN.CNPPSupport@usda.gov*. Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Jessica Larson at 703–305–7600.

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Generic Clearance for the Development of Nutrition Education Messages and Products for the General Public.

Form Number: Not applicable.

OMB Number: 0584–0523.

Expiration Date: 11/30/2022.

Type of Request: Revision of a currently approved collection.

Abstract: The Center for Nutrition Policy and Promotion (CNPP) of the U.S. Department of Agriculture (USDA) conducts consumer research to identify key issues of concern related to the public understanding the consumer translation of key guidance from the *Dietary Guidelines for Americans* (*Dietary Guidelines* or *Guidelines*) into consumer messages, tools and resources.

As background, the *Dietary Guidelines* is a primary source of dietary health information in the form of technical publication written for use by professional audiences, not consumers. Users include Federal agencies, health professionals, policy makers, and nutrition educators. Issued jointly by the USDA and Health and Human Services (HHS) every five years, the *Guidelines* serve as the cornerstone of Federal nutrition policy and form the basis for these agencies' development of consumer nutrition education efforts (nutrition messaging and development of consumer materials). Translation of key guidance from the technically written *Dietary Guidelines* into consumer messages and resources is essential so that the public has resources to help them make healthier eating choices. After the release of the *2010 Dietary Guidelines* for use by professional audiences, a consumer communication initiative built around USDA's new *MyPlate* icon, including the resources at *www.MyPlate.gov,* was launched. *MyPlate* is a visual cue supported by messages and resources to help consumers make better food choices; these consumer materials are consistent with the *Dietary Guidelines.* It illustrates the five food groups and uses a familiar mealtime visual, a place setting, to prompt Americans to eat more healthfully. Information collected from consumer research will be used in further development of consumer nutrition messages and related resources to be communicated through *MyPlate.* These may include:

1. Messages and resources that help consumers make healthier food choices, grounded in the latest *Dietary Guidelines;*
2. Additions and enhancements to the *www.MyPlate.gov* website;
3. Materials relaying consumer messages supporting *MyPlate,* grounded in the latest *Dietary Guidelines,* for special population groups; and
4. New policy, messages, resources, and tools that might be developed as a result of the most current *Dietary Guidelines,* as well as the most currently available technologies.

CNPP works to improve the health and well-being of Americans by developing and promoting dietary guidance that links scientific research to the nutrition needs of consumers across the lifespan.

CNPP has among its major functions the development and coordination of nutrition guidance within USDA and is involved in the investigation of techniques for effective nutrition communication. Under Subtitle D of the National Agriculture Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3171–3175), the Secretary of Agriculture is required to develop and implement a national food and human nutrition research and extension program, including the development of techniques to assist consumers in selecting food that supplies a nutritionally adequate diet. Pursuant to 7 CFR 2.19(a)(3), the Secretary of Agriculture has delegated authority to CNPP for, among other things, developing materials to aid the public in selecting food for good nutrition; coordinating nutrition education promotion and professional education projects within the Department; and consulting with the Federal and State agencies, the Congress, universities, and other public and private organizations and the general public regarding food consumption and dietary adequacy.

Under Section 301 of Public Law 101–445 (7 U.S.C. 5341, the National

Nutrition Monitoring and Related Research Act of 1990, Title III) the Secretaries of USDA and HHS are directed to publish the *Dietary Guidelines for Americans* jointly at least every five years. The law instructs that this publication shall contain nutritional and dietary information and guidelines for the general public, shall be based on the preponderance of scientific and medical knowledge current at the time of publication, and shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program. Recent editions of the *Dietary Guidelines* provide dietary advice for Americans across the lifespan. By translating the *Dietary Guidelines* into consumer friendly nutrition education communication materials, CNPP and partnering agencies are able to help Americans make better or healthier food and beverage choices that can help improve health. One of the primary ways CNPP helps Americans apply the nutrition guidance in their daily lives is by developing and maintaining interactive, digital tools. CNPP's digital resources and tools provide hands-on learning opportunities that empower Americans to think critically about their food and health choices. Maintaining and enhancing CNPP's digital resources and tools are key in reversing the trend of childhood obesity and building a healthier next generation.

USDA's *MyPlate* icon is supported by a robust consumer nutrition education program to assist Americans in selecting foods for a dietary pattern that is consistent with the *Dietary Guidelines.*

Ensuring that *MyPlate* resources and related tools are useful to intended audiences is critical to CNPP's work and is a major activity included in its 5-year strategic plan in fulfillment of the Government Performance and Results Act of 1993 (31 U.S.C. 9701).

Affected Public: Individual/Households.

Estimated Number of Respondents: 57,700.

Estimated Number of Responses per Respondent: 1.006932 (One for focus group screeners, interview screeners, focus groups, journaling, interviews, web-based collections and consent forms. Three for consumer panels.).

Estimated Total Annual Responses: 58,100.

Estimated Time per Response: 12.759 minutes (0.21265 hours).

Estimated Total Annual Burden on Respondents: 12,354.96 rounded up to 12,355 hours. See the table below for estimated total annual burden for each type of respondent.

Testing instrument	Estimated number of individual respondents	Number of responses per respondent	Estimated total annual responses per respondent	Estimated time per response in hours	Estimated total annual burden in hours
Focus Group Screeners	7,500	1	7,500	.25	1,875
Interview Screeners	7,500	1	7,500	.25	1,875
Focus Groups	500	1	500	2	1,000
Journaling	500	1	500	.25	125
Interviews	500	1	500	1	500
Consumer Panels	200	3	600	.50	300
Web-based Collections	20,000	1	20,000	.25	5,000
Consent Form	21,000	1	21,000	.08	1,680
Total	57,700		58,100	0.21265	12,355

The total estimated annual burden is 12,355 hours and 58,100 responses. Thus, we are requesting 37,065 three year burden estimates and 174,300 total responses for three year approval period. Current estimates are based on both historical numbers of respondents from past projects as well as estimates for projects to be conducted in the next three years.

Cynthia Long,

Administrator, Food and Nutrition Service.

[FR Doc. 2022–09724 Filed 5–5–22; 8:45 am]

BILLING CODE 3410–30–P

CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: (87 FR 23164), April 19, 2022, FR Doc. 2022–08473.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: May 5, 2022, 1:00 p.m. EDT (4 hours) on Zoom.

CHANGES IN THE MEETING: The Chemical Safety Board (CSB) unanimously voted on May 3, 2022, to cancel the meeting on the Loy-Lange Box Company Investigation Report previously scheduled for May 5, 2022.

CONTACT PERSON FOR MORE INFORMATION: Hillary Cohen, Communications Manager, at *public@csb.gov* or (202) 446–8094. Further information about this public meeting can be found on the CSB website at: *www.csb.gov.*

Dated: May 4, 2022.

Tamara Qureshi,

Assistant General Counsel, Chemical Safety and Hazard Investigation Board.

[FR Doc. 2022–09897 Filed 5–4–22; 4:15 pm]

BILLING CODE 6350–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–106]

Wooden Cabinet and Vanities and Components Thereof From the People's Republic of China: Preliminary Results and Partial Rescission of the Antidumping Duty Administrative Review; 2019–2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily finds that Qufu Xinyu Furniture Co., Ltd. (Qufu Xinyu), did not make sales of subject merchandise at less than normal value (NV) during the period of review (POR) October 9, 2019, through March 31, 2021; Shanghai Beautystar Cabinetry Co., Ltd. (Beautystar), is part of the China-wide entity; and Jiang Su Rongxin Wood Industry Co., Ltd. (Rongxin Wood), is the successor-in-interest to Jiangsu Rongxin Cabinets Co., Ltd. (Rongxin Cabinets). Commerce is also rescinding the review with respect

to 40 companies. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable May 6, 2022.

FOR FURTHER INFORMATION CONTACT: Jacob Keller, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4948.

SUPPLEMENTARY INFORMATION:

Background

On April 21, 2020, the Department of Commerce published in the **Federal Register** the antidumping duty (AD) order on wooden cabinets and vanities and components thereof from the People's Republic of China (China).[1] On April 1, 2021, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order*.[2] On June 11, 2021, based on timely requests for an administrative review, Commerce initiated the administrative review of the *Order*.[3] The administrative review covers 66 companies, including three mandatory respondents, Beautystar, Qufu Xinyu, and Rongxin Cabinets.[4]

Scope of the Order

The products covered by this *Order* are wooden cabinets and vanities that are for permanent installation (including floor mounted, wall mounted, ceiling hung or by attachment of plumbing), and wooden components thereof. A full description of the scope of the *Order* is provided in the Preliminary Decision Memorandum.[5]

Rescission of Review in Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested a review withdraws its request within 90 days of the date of publication of the notice of initiation. The requests for an administrative review of the 40 companies listed in Appendix II to this notice were withdrawn within 90 days of the date of publication of the Initiation Notice.[6] As a result, Commerce is rescinding this review with respect to these companies, in accordance with 19 CFR 351.213(d)(1).

Separate Rates

Commerce preliminarily determines that 15 companies, not individually examined, are eligible for separate rates in this administrative review.[7] The Tariff Act of 1930, as amended (the Act) and Commerce's regulations do not address the establishment of a separate rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for separate-rate respondents which Commerce did not examine individually in an administrative review. For the preliminary results of this review, Commerce has determined the estimated dumping margin for Qufu Xinyu to be zero. For the reasons explained in the Preliminary Decision Memorandum, we are assigning this rate to the non-examined respondents which qualify for a separate rate in this review.

China-Wide Entity

Under Commerce's policy regarding the conditional review of the China-wide entity,[8] the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity in this review, the entity is not under review, and the entity's rate (*i.e.,* 251.64 percent) is not subject to change.[9] Commerce considers all other companies for which a review was requested (none of which filed a separate rate application) listed in Appendix II to this notice, to be part of the China-wide entity.[10] We find mandatory respondent Beautystar to be a part of the China-wide entity in the instant review because it withdrew from participation and failed to submit a response to the initial AD questionnaire, thereby failing to establish its eligibility for a separate rate.[11]

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Act. For a full description of the

[1] *See Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Antidumping Duty Order,* 85 FR 22126 (April 21, 2020) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 86 FR 17137 (April 1, 2021).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 31282, 31296 (June 11, 2021) (*Initiation Notice*).

[4] *See* Memoranda, ''Antidumping Duty Administrative Review of Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Respondent Selection,'' dated August 6, 2021; ''Antidumping Duty Administrative Review of Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Second Respondent Selection,'' dated September 17, 2021; and ''Antidumping Duty Administrative Review of Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Third Respondent Selection,'' dated October 20, 2021.

[5] *See* Memorandum, ''Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Decision Memorandum for Preliminary Results and Partial Rescission of the First Antidumping Duty Administrative Review,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *See* Company Letters, ''Wooden Cabinets and Vanities from the People's Republic of China: Withdrawal of Request for Administrative Review,'' dated June 29, 2021; ''Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China—Withdrawal of Fujian Senyi's Request for Administrative Review,'' dated July 9, 2021; ''Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China; Withdrawal of Request for Review,'' dated July 12, 2021; ''Wooden Cabinets and Vanities from the People's Republic of China: Withdrawal of Request for Administrative Review,'' dated July 13, 2021; ''Wooden Cabinets and Vanities from the People's Republic of China: Withdrawal of Request for Administrative Review,'' dated July 21, 2021; ''Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China—Withdrawal of Request for Administrative Review,'' dated August 27, 2021; ''Wooden Cabinets and Vanities from the People's Republic of China: Withdrawal of Request for Administrative Review,'' dated August 30, 2021; ''Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China, A–570–106; Withdrawal of Request for Review,'' dated September 3, 2021; ''Antidumping Duty Administrative Review of Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Withdrawal of Administrative Review Request—Jiangsu Beichen Wood Co., Ltd.,'' dated September 7, 2021; ''Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China; Withdrawal of Administrative Review Request,'' dated September 7, 2021; ''Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Withdrawal of Request for Administrative Review,'' dated September 8, 2021; ''Wooden Cabinets and Vanities from the People's Republic of China: Withdrawal of Request for Administrative Review,'' dated September 8, 2021; ''Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China—Withdrawal of Request for Administrative Review,'' dated September 8, 2021; and ''Wooden Cabinets and Vanities and Components Thereof from The People's Republic of China: Withdrawal of Request for Administrative Review,'' dated September 9, 2021; *see also* Petitioner's Letter, ''Wooden Cabinets and Vanities and Components Thereof from: Withdrawal of Review Request for The Ancientree Cabinet Co., Ltd.,'' dated August 26, 2021.

[7] *See* Appendix II; *see also* Preliminary Decision Memorandum at the ''Separate Rate Determination'' section for more details.

[8] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[9] *See Order.*

[10] *See Initiation Notice* (''All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below.''); *see also* Appendix II for the list of companies that are subject to this administrative review that are considered to be part of the China-wide entity.

[11] *See* Preliminary Decision Memorandum at 13–14.

methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* A list of topics discussed in the Preliminary Decision Memorandum is included as an appendix to this notice. In addition, a complete version of the Preliminary Decision Memorandum can be found at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Rescission of the Administrative Review

As discussed in the Preliminary Decision Memorandum and as expounded upon in the *Bona Fides* Memorandum, Commerce preliminarily finds that the sale made by Dalian Hualing Wood Co., Ltd. (Hualing) serving as the basis for administrative review is not a *bona fide* sale of cabinets.[12] Commerce reached this conclusion based on the totality of the record information surrounding Hualing's reported sale, including, but not limited to, the price and quantity of the sale, the timing of the sale, the resale price and profit, and other relevant factors such as the single sale made during the POR, the ''specialty'' nature of the product, and the likelihood of future sales.[13]

Because the non-*bona fide* sale was the only reported sale of subject merchandise during the POR, we preliminarily find that Hauling had no reviewable transactions during this POR and is ineligible for an administrative review. Accordingly, we intend to rescind this administrative review with respect to Hualing if our determination remains the same in the final results of this administrative review.[14]

Regarding Rongxin Cabinets, as discussed in the Preliminary Decision Memorandum, we preliminarily find that Rongxin Wood, is the successor-in-interest to Rongxin Cabinets. Consequently, we are preliminarily rescinding the review with respect to Rongxin Cabinets based on Rongxin Wood's timely withdrawal of its review request and because there are no other outstanding requests for review of Rongxin Cabinets or Rongxin Wood. For the complete successor-in-interest analysis, *see* the Preliminary Decision Memorandum.

Should the final results of review remain the same as these preliminary results of review, we intend to rescind the review of Rongxin Cabinets and in accordance with 19 CFR 351.213(d)(1). Additionally, effective the date of publication of the final results of review, we will instruct U.S. Customs and Border Protection (CBP) to apply the AD cash deposit rate applicable to Rongxin Cabinets to entries of subject merchandise exported by Rongxin Wood.

Preliminary Results of the Administrative Review

Commerce preliminarily determines that the following weighted-average dumping margin exists for the administrative review covering the period October 9, 2019, through March 31, 2021:

Exporter	Weighted-average dumping margin (percent)
Qufu Xinyu Furniture Co., Ltd	0.00
Non-Selected Companies Under Review Receiving a Separate Rate[15]	0.00

Disclosure

Commerce intends to disclose to parties to the proceeding the calculations performed for these preliminary results of review within five days of the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Public Comment

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than seven days after the date for filing case briefs.[16] Pursuant to 19 CFR 351.309(d)(2), rebuttal briefs must be limited to issues raised in the case briefs.[17] Commerce modified certain of its requirements for serving documents containing business proprietary information until further notice.[18] Parties who submit case briefs or rebuttal briefs in this proceeding 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.[19]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the publication of this notice. Requests should contain the party's name, address, telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Unless the deadline is extended, Commerce intends to issue the final results of this review, including the results of its analysis of the issues raised in any written briefs, no later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Assessment Rates

Upon issuing the final results, Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[20] If the preliminary results are

[12] *Id.* at 6–11; *see also* Memorandum, ''Antidumping Duty Administrative Review of Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Preliminary *Bona Fides* Sale Analysis for Dalian Hualing Wood Co., Ltd.,'' dated concurrently with this notice (*Bona Fides* Memorandum).

[13] *Id.*

[14] *Id.*

[15] *See* Appendix II.

[16] *See* 19 CFR 351.309(d); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006, 17007 (March 26, 2020) (''To provide adequate time for release of case briefs via ACCESS, E&C intends to schedule the due date for all rebuttal briefs to be 7 days after case briefs are filed (while these modifications remain in effect).'').

[17] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[18] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[19] *See* 19 CFR 351.309(c)(2) and (d)(2); *see also* 19 CFR 351.303 (for general filing requirements).

[20] *See* 19 CFR 351.212(b)(1).

unchanged for the final results, we will instruct CBP to apply an *ad valorem* assessment rate of 251.64 percent to all entries of subject merchandise during the POR which were exported by the companies considered to be a part of the China-wide entity listed in Appendix II of this notice. If Commerce determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the China-wide rate.[21]

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).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this review for shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For the subject merchandise exported by the company listed above that has a separate rate, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this administrative review (except, if the rate is zero or *de minimis,* then zero cash deposit will be required); (2) for previously investigated or reviewed Chinese and non-Chinese exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the China-wide entity; and (4) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

[21] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65695 (October 24, 2011).

Notification to Importers

This notice 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 these PORs. 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

Commerce is issuing and publishing the preliminary results of this review in accordance with sections 751(a)(1)(B), 751(a)(3) and 777(i) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: May 2, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Partial Rescission of Administrative Review
IV. Scope of the Order
V. No-Shipment Certifications
VI. Discussions of the Methodology
VII. Currency Conversion
VIII. Adjustment Under Section 777A(f) of the Act
IX. Recommendation

Appendix II

Companies Subject to Rescission of Review

1. Anhui Swanch Cabinetry Co., Ltd.
2. Anhui Xinyuanda Cupboard Co., Ltd.
3. Dalian Jiaye Wood Products Co., Ltd.
4. Dandong Laroyal Cabinetry Co., Ltd.
5. Foremost Worldwide Company Limited
6. Fujian Senyi Kitchen Cabinet Co., Ltd.
7. Fuzhou CBM Import & Export Co., Ltd.
8. Fuzhou Minlian Wood Industry Co., Ltd.
9. Hangzhou Entop Houseware Co., Ltd.
10. Hangzhou Hoca Kitchen & Bath Products Co., Ltd.
11. Hangzhou Home Dee Sanitary Ware Co., Ltd.
12. Hangzhou Royo Import & Export Co., Ltd.
13. Heyond Cabinet Co., Ltd.
14. Honsoar New Building Material Co., Ltd.
15. HS Furniture Industrial Co., Ltd.
16. Jiang Su Rongxin Wood Industry Co., Ltd.
17. Jiangsu Beichen Wood Co., Ltd.
18. Jiangsu Sunwell Cabinetry Co., Ltd.
19. Jiangsu Weisen Houseware Co., Ltd.
20. Kunshan Baiyulan Furniture Co., Ltd.
21. Linyi Bonn Flooring Manufacturing Co., Ltd.
22. Linyi Kaipu Furniture Co., Ltd.
23. Morewood Cabinetry Co., Ltd.
24. Pizhou Ouyme Import & Export Trade Co., Ltd.
25. Qingdao Shousheng Industry Co., Ltd.
26. Rizhao Foremost Woodwork Manufacturing Company Ltd.
27. Shandong Huanmei Wood Co., Ltd.
28. Shanghai Zifeng International Trading Co., Ltd.
29. Sheen Lead International Trading (Shanghai) Co., Ltd.
30. Shouguang Jinxiangyuan Home Furnishing Co., Ltd.
31. Shouguang Sanyang Wood Industry Co., Ltd.
32. Tech Forest Cabinetry Co., Ltd.
33. The Ancientree Cabinet Co., Ltd.
34. Weifang Fuxing Wood Co., Ltd.
35. Weihai Jarlin Cabinetry Manufacture Co., Ltd.
36. Xiamen Adler Cabinetry Co., Ltd.
37. Xiamen Goldenhome Co., Ltd.
38. Xuzhou Yihe Wood Co., Ltd.
39. Yichun Dongmeng Wood Co., Ltd.
40. Yixing Pengjia Cabinetry Co., Ltd.

Companies Considered To Be Part of the China-Wide Entity

1. Deqing Meisheng Import and Export Co., Ltd.
2. Fuzhou Pyrashine Trading Co., Ltd.
3. Jiang Su Rongxin Import and Export Co., Ltd.
4. Linshu Meibang Furniture Co., Ltd.
5. Shanghai Beautystar Cabinetry Co., Ltd.
6. Shanghai Zifeng Industries Development Co., Ltd.
7. ZBOM Cabinets Co., Ltd.
8. Zhongshan KM Cabinetry Co., Ltd.

Non-Selected Companies Under Review Receiving a Separate Rate

1. Dalian Meisen Woodworking Co., Ltd.
2. Fujian Dushi Wooden Industry Co., Ltd.
3. Guangzhou Nuolande Import and Export Co., Ltd.
4. Jiangsu Xiangsheng Bedtime Furniture Co., Ltd.
5. KM Cabinetry Co., Ltd.
6. Linyi Bomei Furniture Co., Ltd.
7. Nantong Aershin Cabinets Co., Ltd.
8. Senke Manufacturing Company
9. Shandong Longsen Woods Co., Ltd.
10. Shenzhen Pengchengzhirong Trade Co., Ltd.
11. Shouguang Fushi Wood Co., Ltd.
12. Suzhou Siemo Wood Import & Export Co., Ltd.
13. Taishan Oversea Trading Company Ltd.
14. Zhangzhou OCA Furniture Co., Ltd.
15. Zhoushan For-strong Wood Co., Ltd.

[FR Doc. 2022–09813 Filed 5–5–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–904]

Certain Activated Carbon From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review, Preliminary Determination of No Shipments; 2020–2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that Jilin Bright Future Chemicals Co., Ltd. (Jilin Bright), an exporter of certain activated carbon from the People's Republic of China (China), sold subject merchandise in the United States at prices below normal value (NV) during the period of review (POR) April 1, 2020, through March 31, 2021. Further, Commerce preliminarily determines that Datong Juqiang Activated Carbon Co., Ltd. (Datong Juqiang), an exporter of certain activated carbon from China, did not sell subject merchandise in the United States at prices below NV during the POR. Interested parties are invited to comment on these preliminary results.

DATES: Applicable May 6, 2022.

FOR FURTHER INFORMATION CONTACT: Jinny Ahn or Joshua Simonidis, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0339 or (202) 482–0608, respectively.

SUPPLEMENTARY INFORMATION:

Background

This administrative review is being conducted in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this administrative review on June 11, 2021.[1] On November 15, 2021, Commerce extended the preliminary results deadline until April 29, 2021.[2]

Scope of the Order [3]

The merchandise subject to the *Order* is certain activated carbon. The products are currently classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) subheading 3802.10.00. Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the *Order* remains dispositive.[4]

Continuation of Administrative Review for Jacobi [5]

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if a party who requested the review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. On August 26, 2021, Jacobi timely withdrew its request for review.[6] However, because there is still an active review request for Jacobi,[7] we are not rescinding this review with respect to Jacobi, pursuant to 19 CFR 351.213(d)(1).

Preliminary Determination of No Shipments

Based on our analysis of U.S. Customs and Border Protection (CBP) information, and the no shipment certifications submitted by Beijing Pacific Activated Carbon Products Co., Ltd., Shanxi Dapu International Trade Co., Ltd, and Tianjin Channel Filters Co., Ltd., Commerce preliminarily determines that these companies had no shipments of subject merchandise during the POR.

Jacobi submitted an untimely no shipment certification, which Commerce consequently rejected.[8] For additional information regarding this determination, *see* the Preliminary Decision Memorandum.

Consistent with our practice in non-market economy (NME) cases, we are not rescinding this review but instead intend to complete the review with respect to these three companies for which we have preliminarily found no shipments and issue appropriate instructions to CBP based on the final results of the review.[9]

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Act. We calculated export prices and constructed export prices in accordance with section 772 of the Act. Because China is an NME country within the meaning of section 771(18) of the Act, NV has been calculated in accordance with section 773(c) of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. A list of the topics discussed in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum is available at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Results of the Review

Commerce preliminarily finds that six companies for which a review was

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 31282 (June 11, 2021).

[2] *See* Memorandum, ''Certain Activated Carbon from the People's Republic of China: Extension of Deadline for Preliminary Results of the Fourteenth Antidumping Duty Administrative Review,'' dated November 15, 2021.

[3] *See Notice of Antidumping Duty Order: Certain Activated Carbon from the People's Republic of China,* 72 FR 20988 (April 27, 2007) (*Order*).

[4] For a complete description of the scope of the *Order, see* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Certain Activated Carbon from the People's Republic of China; 2020–2021,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] In the third administrative review of the *Order,* Commerce found that Jacobi Carbons AB, Tianjin Jacobi International Trading Co. Ltd. (Tianjin Jacobi), and Jacobi Carbons Industry (Tianjin) (Jacobi Carbons) (collectively, Jacobi) should be treated as a single entity, and because there were no facts presented on the record of this review which would call into question our prior finding, we continue to treat these companies as part of a single entity for this administrative review, pursuant to sections 771(33)(E), (F), and (G) of the Act, and 19 CFR 351.401(f). *See Certain Activated Carbon from the People's Republic of China: Final Results and Partial Rescission of Third Antidumping Duty Administrative Review,* 76 FR 67142, 67145, n.25 (October 31, 2011); Further, in a changed circumstances review of the order, Commerce determined that Jacobi should be collapsed with its new wholly-owned Chinese affiliate, Jacobi Adsorbent Materials (JAM), and the single entity, inclusive of JAM, should be assigned the same antidumping (AD) cash deposit rate assigned to Jacobi for purposes of determining AD liability in this proceeding. *See Certain Activated Carbon from the People's Republic of China: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 86 FR 58874 (October 25, 2021). Therefore, for these final results of this administrative review, we intend to assign the new Jacobi single entity, inclusive of JAM, the same AD rate as the rate assigned to Jacobi (*i.e.,* the China-wide rate (2.42 dollars per kilogram)) for purposes of cash deposit and assessment.

[6] *See* Jacobi's Letter, ''Jacobi's Withdrawal of Request for Administrative Review,'' dated August 26, 2021.

[7] *See* Calgon Carbon Corporation and Cabot Norit Americas Inc.'s (collectively, the petitioners) Letter, ''Petitioners' Request for Initiation of fourteenth Annual Administrative Review,'' dated April 30, 2021.

[8] *See* Jacobi's Letter, ''Jacobi's Withdrawal of Request for Administrative Review and No Shipment Certification,'' dated August 11, 2021; *see also* Commerce's Letter, ''Notification of Untimely Filed No Shipment Letter,'' dated August 18, 2021.

[9] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65694–95 (October 24, 2011) (*NME Practice*).

requested, including Jacobi,[10] did not establish eligibility for a separate rate because they failed to provide either a separate rate application or separate rate certification. As such, we preliminarily determine that these six companies are part of the China-wide entity.[11]

For those companies that have established their eligibility for a separate rate,[12] Commerce preliminarily determines that the following weighted-average dumping margins exist for the POR:

Exporter	Weighted-average dumping margin (U.S. dollars per kilogram)[13]
Datong Juqiang Activated Carbon Co., Ltd	0.00
Jilin Bright Future Chemicals Co., Ltd	0.35
Carbon Activated Tianjin Co., Ltd	0.35
Datong Municipal Yunguang Activated Carbon Co., Ltd	0.35
Ningxia Guanghua Cherishmet Activated Carbon Co., Ltd	0.35
Ningxia Huahui Environmental Technology Co., Ltd. (formerly Ningxia Huahui Activated Carbon Co., Ltd.)[14]	0.35
Ningxia Mineral & Chemical Limited[15]	0.35
Shanxi Industry Technology Trading Co., Ltd	0.35
Shanxi Sincere Industrial Co., Ltd	0.35
Tancarb Activated Carbon Co., Ltd	0.35

In these preliminary results, of the two mandatory respondents, only Jilin Bright, has a calculated weighted-average dumping margin which is not zero, *de minimis,* or based entirely on facts available. Therefore, in accordance with section 735(c)(5)(A) of the Act, we have preliminarily assigned Jilin Bright's calculated rate as the separate rate for the respondents that were not selected for individual examination in this administrative review but qualified for a separate rate.

Disclosure and Public Comment

Commerce intends to disclose the calculations performed for these preliminary results to the parties no later than five days after the date of publication of this notice in accordance with 19 CFR 351.224(b). Pursuant to 19 CFR 351.309(c)(ii), interested parties may submit case briefs no later than 30 days after the date of publication of these preliminary results of review. Parties who submit case briefs or rebuttal briefs in this proceeding 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. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the case briefs are filed.[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), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues parties intend to discuss. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs.[18] If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.[19] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

All submissions to Commerce must be filed electronically using ACCESS[20] and must also be served on interested parties.[21] An electronically filed document must be received successfully in its entirety by ACCESS, by 5 p.m. Eastern Time (ET) on the date that the document is due.

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, within 120 days of publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results, Commerce will determine, and CBP

[10] *See* Appendix II of this notice for a full list of the six companies.

[11] Because no interested party requested a review of the China-wide entity and Commerce no longer considers the China-wide entity as an exporter conditionally subject to administrative reviews, we did not conduct a review of the China-wide entity. Thus, the rate for the China-wide entity is not subject to change as a result of this review. *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963, 65969–70 (November 4, 2013). The China-wide entity rate of 2.42 U.S. dollars per kilogram was last reviewed in *Certain Activated Carbon from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2012–2013,* 79 FR 70163 (November 25, 2014).

[12] *See* Preliminary Decision Memorandum.

[13] In the second administrative review of the *Order,* Commerce determined that it would calculate per-unit weighted-average dumping margins and assessment rates for all future reviews. *See Certain Activated Carbon from the People's Republic of China: Final Results and Partial Rescission of Second Antidumping Duty Administrative Review,* 75 FR 70208, 70211 (November 17, 2010).

[14] In a changed circumstances review of the *Order,* Commerce found that Ningxia Huahui Environmental Technology Co., Ltd. is the successor-in-interest to Ningxia Huahui Activated Carbon Co. Ltd. (Ningxia Huahui) and should be assigned the same AD cash deposit rate assigned to Ningxia Huahui for purposes of determining AD liability in this proceeding. *See Certain Activated Carbon from the People's Republic of China: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 86 FR 64184 (November 17, 2021). Therefore, for the final results of this administrative review, we intend to assign the same AD rate to Ningxia Huahui Environmental Technology Co., Ltd. as the rate assigned to Ningxia Huahui for cash deposit and assessment purposes.

[15] Two of the company names for which Commerce initiated this review are different name variations of the same company (*i.e.,* Ningxia Mineral & Chemical Limited, and Ningxia Mineral & Chemical Ltd.), and therefore, were treated as the same company for purposes of this review. *See Initiation Notice,* 86 FR at 31289.

[16] *See* 19 CFR 351.309(d); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020) (''To provide adequate time for release of case briefs via ACCESS, E&C intends to schedule the due date for all rebuttal briefs to be 7 days after case briefs are filed (while these modifications are in effect).'').

[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* 19 CFR 351.310(c).

[19] *See* 19 CFR 351.310(d).

[20] *See* 19 CFR 351.303.

[21] *See* 19 CFR 351.303(f).

shall assess, antidumping duties on all appropriate entries covered by this review.[22] Commerce intends to issue assessment instructions to CBP 35 days after the publication date 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 any individually examined respondent whose (estimated) *ad valorem* weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.50 percent) in the final results of this review, Commerce will calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales and the total quantity of those sales, in accordance with 19 CFR 351.212(b)(1).[23] Commerce will also calculate (estimated) *ad valorem* importer-specific assessment rates with which to assess whether the per-unit assessment rate is *de minimis.*[24] We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific *ad valorem* assessment rate calculated in the final results of this review is not zero or *de minimis.* Where either the respondent's *ad valorem* weighted-average dumping margin is zero or *de minimis,* or an importer-specific *ad valorem* assessment rate is zero or *de minimis,*[25] we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For the respondents that were not selected for individual examination in this administrative review but qualified for a separate rate, the assessment rate will be the margin established for these companies in the final results of this review.

For the final results, if we continue to treat the six companies, identified at Appendix II to this notice, as part of the China-wide entity, we will instruct CBP to apply a per-unit assessment rate of $2.42 per kilogram to all entries of subject merchandise during the POR which were exported by those companies.[26]

For entries that were not reported in the U.S. sales data submitted by companies individually examined during this review, Commerce will instruct CBP to liquidate such entries at the rate for the China-wide entity.[27] Additionally, if Commerce determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's cash deposit rate) will be liquidated at the rate for the China-wide entity.[28]

In accordance with section 751(a)(2)(C) of the Act, the final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated antidumping duties, as applicable.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For each specific company listed in the final results of this review, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this review (except that if the *ad valorem* rate is *de minimis,* then the cash deposit rate will be zero); (2) for previously investigated or reviewed Chinese and non-Chinese exporters not listed above that have separate rates, the cash deposit rate will continue to be the existing exporter-specific cash deposit rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the China-wide entity; and (4) for all non-Chinese exporters of subject merchandise which have not received their own separate rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These cash 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 POR. 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

This administrative review and notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, 19 CFR 351.213, and 19 CFR 351.221(b)(4).

Dated: April 29, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Discussion of the Methodology
V. Recommendation

Appendix II

Companies Preliminarily Not Eligible for a Separate Rate and Treated as Part of the China-Wide Entity

1. Jacobi Carbons AB/Tianjin Jacobi International Trade Co., Ltd./Jacobi Carbons Industry (Tianjin) Co., Ltd./Jacobi Adsorbent Materials
2. Meadwestvaco Trading (Shanghai)
3. Shanxi DMD Corp.
4. Shanxi Tianxi Purification Filter Co., Ltd.
5. Sinoacarbon International Trading Co., Ltd.
6. Tianjin Maijin Industries Co., Ltd.

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[22] *See* 19 CFR 351.212(b)(1).

[23] In these preliminary results, Commerce applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

[24] For calculated (estimated) *ad valorem* importer-specific assessment rates used in determining whether the per-unit assessment rate is *de minimis, see* Memoranda, ''Preliminary Results Margin Calculation for Datong Juqiang Activated Carbon Co., Ltd.''; and ''Antidumping Duty Administrative Review of Certain Activated Carbon from the People's Republic of China: Preliminary Results Calculation Memorandum for Jilin Bright,'' both dated concurrently with this notice, and accompanying Margin Calculation Program Logs and Outputs.

[25] *See* 19 CFR 351.106(c)(2).

[26] *See, e.g., Certain Activated Carbon from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2012–2013,* 79 FR 70163, 70165 (November 25, 2014).

[27] *See NME Practice* for a full discussion.

[28] *Id.*

DEPARTMENT OF COMMERCE

International Trade Administration

Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty

AGENCY: Enforcement and Compliance, International Trade Administration Department of Commerce.

DATES: Applicable May 6, 2022.

FOR FURTHER INFORMATION CONTACT: John Hoffner, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Ave. NW, Washington, DC 20230, telephone: (202) 482–3315.

SUPPLEMENTARY INFORMATION: On January 20, 2022, the Department of Commerce (Commerce), pursuant to section 702(h) of the Trade Agreements Act of 1979, as amended (the Act), published the quarterly update to the annual listing of foreign government subsidies on articles of cheese subject to an in-quota rate of duty covering the period July 1, 2021, through September 30, 2021.[1] In the *Third Quarter 2021 Update,* we requested that any party that has information on foreign government subsidy programs that benefit articles of cheese subject to an in-quota rate of duty submit such information to Commerce.[2] We received no comments, information, or requests for consultation from any party.

Pursuant to section 702(h) of the Act, we hereby provide Commerce's update of subsidies on articles of cheese that were imported during the period October 1, 2021, through December 31, 2021. The appendix to this notice lists the country, the subsidy program or programs, and the gross and net amounts of each subsidy for which information is currently available.

Commerce will incorporate additional programs which are found to constitute subsidies, and additional information on the subsidy programs listed, as the information is developed. Commerce encourages any person having information on foreign government subsidy programs which benefit articles of cheese subject to an in-quota rate of duty to submit such information in writing through the Federal eRulemaking Portal at *http://www.regulations.gov,* Docket No. ITA–2020–0005, ''Quarterly Update to Cheese Subject to an In-Quota Rate of Duty.'' The materials in the docket will not be edited to remove identifying or contact information, and Commerce cautions against including any information in an electronic submission that the submitter does not want publicly disclosed. Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF formats only. All comments should be addressed to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

Notification to Interested Parties

This determination and notice are in accordance with section 702(a) of the Act.

Dated: May 2, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

SUBSIDY PROGRAMS ON CHEESE SUBJECT TO AN IN-QUOTA RATE OF DUTY

Country	Program(s)	Gross[3] subsidy ($/lb)	Net[4] subsidy ($/lb)
27 European Union Member States[5]	European Union Restitution Payments	$0.00	$0.00
Canada	Export Assistance on Certain Types of Cheese	0.44	0.44
Norway	Indirect (Milk) Subsidy	0.00	0.00
	Consumer Subsidy	0.00	0.00
	Total	0.00	0.00
Switzerland	Deficiency Payments	0.00	0.00

[1] *See Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty,* 87 FR 3080 (January 20, 2022) (*Third Quarter 2021 Update*).

[2] *Id.*

[3] Defined in 19 U.S.C. 1677(5).

[4] Defined in 19 U.S.C. 1677(6).

[5] The 27 member states of the European Union are: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden.

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DEPARTMENT OF COMMERCE

International Trade Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Procedures for Importation of Supplies for Use in Emergency Relief Work

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of Information Collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before July 5, 2022.

ADDRESSES: Interested persons are invited to submit written comments by mail to Scot Fullerton, Associate Deputy Assistant Secretary, Department of Commerce, 14th and Constitution Avenue NW, Washington, DC 20230 or by email to *Scot.Fullerton@trade.gov* or *PRAcomments@doc.gov.* Please reference OMB Control Number 0625–0256 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Scot Fullerton, Associate Deputy Assistant Secretary, International Trade Administration, U.S. Department of Commerce, 14th and Constitution Avenue NW, Washington, DC 20230; telephone: 202–482–1386; email: *Scot.Fullerton@trade.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The regulations (19 CFR 358.101 through 358.104) provide procedures for requesting the Secretary of Commerce to permit the importation of supplies, such as food, clothing, medical, surgical, and other supplies, by for-profit and not-for-profit entities for use in emergency relief work free of antidumping and countervailing duties. The regulations formally provide procedures for requesting waivers of duties on supplies for use in emergency relief work.

There are no proposed changes to this information collection.

II. Method of Collection

Three copies of the request must be submitted in writing to the Secretary of Commerce, Attention: Enforcement and Compliance, Central Records Unit, Room B–8024, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

III. Data

OMB Control Number: 0625–0256.
Form Number(s): None.
Type of Review: Regular submission.
Affected Public: Business, including for-profit and non-profit organizations.
Estimated Number of Respondents: 1.
Estimated Time per Response: 15 hours.
Estimated Total Annual Burden Hours: 15 hours.
Estimated Total Annual Cost to Public: Less than $450.
Legal Authority: 19 U.S.C. 1318(a).

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–09729 Filed 5–5–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–044]

1,1,1,2-Tetrafluoroethane (R-134a) From the People's Republic of China: Final Results of the Antidumping Duty Administrative Review; 2020–2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that the sole company subject to this administrative review is part of the China-wide entity because it did not file a separate rate application (SRA). The period of review (POR) is April 1, 2020, through March 31, 2021.

DATES: Applicable May 6, 2022.

FOR FURTHER INFORMATION CONTACT: Kate Sliney, 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) 482–2437.

SUPPLEMENTARY INFORMATION:

Background

On January 4, 2022, Commerce published the *Preliminary Results* of this administrative review.[1] We invited interested parties to comment on the *Preliminary Results.* We received no comments from interested parties on the *Preliminary Results.* Prior to the publication of the *Preliminary Results,* on December 13, 2021, Commerce referred certain business proprietary information received in the context of this administrative review to U.S. Customs and Border Protection (CBP). Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The merchandise covered by the order is 1,1,1,2-Tetrafluoroethane, R-134a, or its chemical equivalent, regardless of form, type, or purity level. The chemical formula for 1,1,1,2-Tetrafluoroethane is CF3-CH2 F, and the Chemical Abstracts Service (CAS) registry number is CAS 811–97–2.[2]

Merchandise subject to the order is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheading 2903.45.1000. Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

Final Results of Administrative Review

Because we received no comments, we made no changes from the *Preliminary Results.* We continue to find that Puremann, Inc., the sole company subject to this review, did not file an SRA and has not demonstrated its eligibility for separate rate status and, therefore, is part of the China-wide entity. In this administrative review, no party requested a review of the China-wide entity, and Commerce did not self-initiate a review of the China-wide entity. Because no review of the China-wide entity is being conducted, the China-wide entity's entries were not subject to the review, and the rate applicable to the China-wide entity was not subject to change as a result of this review. The China-wide entity rate remains 167.02 percent.

Assessment Rates

Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries in accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b). Because we determined that Puremann, Inc. was not eligible for a separate rate and is part of the China-wide entity, we will instruct CBP to apply an *ad valorem* assessment rate of 167.02 percent to all entries of subject merchandise during the POR that were exported by Puremann, Inc.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this

[1] See 1,1,1,2-Tetrafluoroethane (R-134a) from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2020–2021, 87 FR 216 (January 4, 2022) (Preliminary Results).

[2] 1,1,1,2-Tetrafluoroethane is sold under a number of trade names including Klea 134a and Zephex 134a (Mexichem Fluor); Genetron 134a (Honeywell); Freon™ 134a, Suva 134a, Dymel 134a, and Dymel P134a (Chemours); Solkane 134a (Solvay); and Forane 134a (Arkema). Generically, 1,1,1,2-Tetrafluoroethane has been sold as Fluorocarbon 134a, R-134a, HFC-134a, HF A-134a, Refrigerant 134a, and UN3159.

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).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) For previously investigated or reviewed Chinese or non-Chinese exporters that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (2) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the China-wide entity (*i.e.,* 167.02 percent); and (3) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.213(h) and 351.221(b)(5).

Dated: April 29, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–09802 Filed 5–5–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–107]

Wooden Cabinets and Vanities and Components Thereof From the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review, Rescission and Intent To Rescind Administrative Review, in Part; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that the companies subject to this countervailing duty (CVD) administrative review of wooden cabinets and vanities and components thereof (cabinets) from the People's Republic of China (China) received countervailable subsidies during the period of review (POR), August 12, 2019, through December 31, 2020. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable May 6, 2022.

FOR FURTHER INFORMATION CONTACT: Thomas Schauer, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0410.

SUPPLEMENTARY INFORMATION:

Background

On April 21, 2020, Commerce published the CVD order on cabinets from China.[1] On April 1, 2021, Commerce published a notice of opportunity to request an administrative review of the *Order* for the POR.[2] In April 2021, we received timely requests from multiple parties to conduct an administrative review of the *Order.* On June 11, 2021, we published a notice of initiation for this administrative review.[3] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4] 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.*

On December 7, 2021, Commerce extended the deadline for the preliminary results of this review by 120 days to May 2, 2022.

Scope of the Order

The scope of the *Order* covers cabinets from China. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.[5]

Methodology

We are conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found to be countervailable, we determine that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that confers a benefit to the recipient, and that the subsidy is specific.[6] For a full description of the methodology underlying our preliminary conclusions, including our reliance, in part, on

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[1] *See Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Countervailing Duty Order,* 85 FR 22134 (April 21, 2020) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 86 FR 17137 (April 1, 2021).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 31282, 31296 (June 11, 2021); *see also Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 41821, 41825 (August 3, 2021).

[4] *See* Memorandum, ''Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review; 2019–2020,'' dated December 7, 2021.

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Countervailing Duty Order on Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China; 2019–2020,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

adverse facts available pursuant to sections 776(a) and (b) of the Act, *see* the Preliminary Decision Memorandum. A list of topics included in the Preliminary Decision Memorandum is provided in Appendix I to this notice.

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 withdrawal requests with respect to the 52 companies listed in Appendix II. Because the withdrawal requests were timely filed and no other parties requested a review of these companies, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this review of the *Order* for the 52 companies listed in Appendix II.[7]

Intent To Rescind Administrative Review, in Part

It is Commerce's practice to rescind an administrative review of a CVD order, pursuant to 19 CFR 351.213(d)(3), when there are no reviewable entries of subject merchandise during the POR for which liquidation is suspended.[8] Normally, upon completion of an administrative review, the suspended entries are liquidated at the CVD assessment rate calculated for the review period.[9] Therefore, for an administrative review of a company to be conducted, there must be a reviewable, suspended entry that Commerce can instruct U.S. Customs and Border Protection (CBP) to liquidate at the CVD assessment rate calculated for the review period.[10]

According to the CBP import data, the following four companies subject to this review did not have reviewable entries of subject merchandise during the POR for which liquidation is suspended: (1) Guangzhou Nuolande Import and Export Co., Ltd.; (2) Linyi Kaipu Furniture Co., Ltd.; (3) Shandong Longsen Woods Co., Ltd.; and (4) Zhoushan For-strong Wood Co., Ltd. Accordingly, in the absence of reviewable, suspended entries of subject merchandise during the POR, we intend to rescind this administrative review with respect to these four companies, in accordance with 19 CFR 351.213(d)(3).

Preliminary Rate for Non-Selected Companies

There are two companies 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: (1) Jiangsu Xiangsheng Bedtime Furniture Co., Ltd., and (2) Senke Manufacturing Company. For these non-selected companies, we are basing the subsidy rate on the subsidy rate calculated for Dalian Hualing Wood Co., Ltd., the only mandatory respondent with a preliminary subsidy rate that is not zero, *de minimis,* or based entirely on facts available.[11] This methodology to establish the non-selected subsidy rate is consistent with our practice with regard to the all-others rate, pursuant to section 705(c)(5)(A)(i) of the Act.

Preliminary Results of Administrative Review

As a result of this administrative review, we preliminarily find that the following net countervailable subsidy rates exist for the period August 12, 2019, through December 31, 2020:

Company	Subsidy rate—2019 (percent *ad valorem*)	Subsidy rate—2020 (percent *ad valorem*)
Dalian Hualing Wood Co., Ltd	22.29	16.91
Nantong Aershin Cabinet Co., Ltd.[12]	229.40	229.40
Review-Specific Average Rate Applicable to the Following Companies		
Jiangsu Xiangsheng Bedtime Furniture Co., Ltd	22.29	16.91
Senke Manufacturing Company	22.29	16.91

Assessment Rates

Upon issuance of the final results of this 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. For the 52 companies for which this review is rescinded, Commerce will instruct CBP to assess countervailing duties on all appropriate entries at the 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 August 12, 2019, through December 31, 2020, in accordance with 19 CFR 351.212(c)(l)(i).

For the companies remaining in the review, 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).

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 calculated in the final results of this review for the respective companies 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 minimis,* 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.

[7] *See, e.g., Lightweight Thermal Paper from the People's Republic of China: Notice of Rescission of Countervailing Duty Administrative Review; 2015,* 82 FR 14349 (March 20, 2017); and *Circular Welded Carbon Quality Steel Pipe from the People's Republic of China: Rescission of Countervailing Duty Administrative Review; 2017,* 84 FR 14650 (April 11, 2019).

[8] *Id.*

[9] *See* 19 CFR 351.212(b)(2).

[10] *See* 19 CFR 351.213(d)(3).

[11] *See* Preliminary Decision Memorandum at 6.

[12] This company was selected as a mandatory respondent but did not respond to Commerce's initial questionnaire. Accordingly, the rate for this company was based on facts available with an adverse inference pursuant to sections 776(a) and (b) of the Act. For a detailed discussion, *see* Preliminary Decision Memorandum.

For all non-reviewed companies, CBP will continue to collect cash deposits of estimated countervailing duties at the all-others rate (*i.e.,* 20.93 percent) [13] 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.

Disclosure and Public Comment

We intend to disclose the calculations performed for these preliminary results to the parties within five days after public announcement of the preliminary results in accordance with 19 CFR 351.224(b). Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the date for filing case briefs.[14] Parties who submit case or rebuttal briefs in this proceeding 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.[15] Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information.[16]

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, filed electronically via ACCESS. An electronically filed document must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.[17] Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. If a request for a hearing is made, we will inform parties of the scheduled date and time for the hearing.

Unless extended, we intend to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their case briefs, no later than 120 days after the date of publication of this notice in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act.

[13] *See Order,* 85 FR at 22135.

[14] *See* 19 CFR 351.309(d).

[15] *See* 19 CFR 351.309(c)(2) and (d)(2).

[16] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 41363 (July 10, 2020).

[17] *See* 19 CFR 351.310(c).

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4) and 19 CFR 351.221(b)(4).

Dated: May 2, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Rescission of Administrative Review, in Part
V. Intent to Rescind Administrative Review, in Part
VI. Non-Selected Companies Under Review
VII. Diversification of China's Economy
VIII. Subsidies Valuation
IX. Benchmarks and Discount Rates
X. Use of Facts Otherwise Available and Application of Adverse Inferences
XI. Analysis of Programs
XII. Recommendation

Appendix II—List of Companies for Which Requests for Review Were Timely Withdrawn

1. Anhui Swanch Cabinetry Co., Ltd.
2. Anhui Xinyuanda Cupboard Co., Ltd.
3. Dalian Jiaye Wood Products Co., Ltd.
4. Dalian Meisen Woodworking Co., Ltd.
5. Dandong Laroyal Cabinetry Co., Ltd.
6. Foremost Worldwide Co., Ltd.
7. Fujian Dushi Wooden Industry Co., Ltd.
8. Fujian Senyi Kitchen Cabinet Co., Ltd.
9. Fuzhou CBM Import & Export Co., Ltd.
10. Fuzhou Minlian Wood Industry Co., Ltd.
11. Hangzhou Entop Houseware Co., Ltd.
12. Hangzhou Hoca Kitchen & Bath Products Co., Ltd.
13. Hangzhou Home Dee Sanitary Ware Co., Ltd.
14. Hangzhou Royo Import & Export Co., Ltd.
15. Heyond Cabinet Co., Ltd.
16. Honsoar New Building Material Co., Ltd.
17. HS Furniture Industrial Co., Ltd.
18. Jiang Su Rongxin Wood Industry Co., Ltd.
19. Jiang Su Rongxin Cabinets Ltd.
20. Jiangsu Beichen Wood Co., Ltd.
21. Jiangsu Sunwell Cabinetry Co., Ltd.
22. Jiangsu Weisen Houseware Co., Ltd.
23. KM Cabinetry Co., Limited
24. Kunshan Baiyulan Furniture Co., Ltd.
25. Linyi Bomei Furniture Co., Ltd.
26. Linyi Bonn Flooring Manufacturing Co., Ltd.
27. Morewood Cabinetry Co., Ltd.
28. Pizhou Ouyme Import & Export Trade Co., Ltd.
29. Qingdao Shousheng Industry Co., Ltd.
30. Qufu Xinyu Furniture Co., Ltd.
31. Rizhao Foremost Landbridge Wood Industries Co., Ltd.
32. Rizhao Foremost Woodwork Manufacturing Company Ltd.
33. Shandong Huanmei Wood Co., Ltd.
34. Shanghai Beautystar Cabinetry Co., Ltd.
35. Shanghai Zifeng International Trading Co., Ltd.
36. Sheen Lead International Trading (Shanghai) Co., Ltd.
37. Shenzhen Pengchengzhirong Trade Co., Ltd.
38. Shouguang Fushi Wood Co., Ltd.
39. Shouguang Jinxiangyuan Home Furnishing Co., Ltd.
40. Shouguang Sanyang Wood Industry Co., Ltd.
41. Suzhou Siemo Wood Import & Export Co., Ltd.
42. Tech Forest Cabinetry Co., Ltd.
43. The Ancientree Cabinet Co., Ltd.
44. Weifang Fuxing Wood Co., Ltd.
45. Weihai Jarlin Cabinetry Manufacture Co., Ltd.
46. Xiamen Adler Cabinetry Co., Ltd.
47. Xiamen Goldenhome Co., Ltd.
48. Xuzhou Yihe Wood Co., Ltd.
49. Yichun Dongmeng Wood Co., Ltd.
50. Yixing Pengjia Cabinetry Co., Ltd.
51. Zhangzhou OCA Furniture Co., Ltd.
52. Zhongshan KM Cabinetry Co., Ltd.

[FR Doc. 2022–09816 Filed 5–5–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–033]

Large Residential Washers From the People's Republic of China: Final Results of Expedited Sunset Review of Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this expedited sunset review, the Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on large residential washers (LRWs) from the People's Republic of China (China) would be likely to lead to a continuation or recurrence of dumping at the levels identified in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable May 6, 2022.

FOR FURTHER INFORMATION CONTACT: Max Goldman or Brian Smith, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3896 or (202) 482–1766, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 6, 2017, Commerce published the AD order on LRWs from

China in the **Federal Register**.[1] On January 3, 2022, Commerce published the notice of initiation of the first sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On January 18, 2022, Commerce received a timely and complete notice of intent to participate in this sunset review from a domestic interested party, Whirlpool Corporation (Whirlpool),[3] within the deadline specified in 19 CFR 351.218(d)(1)(i). Whirlpool claimed interested party status within the meaning of section 771(9)(C) of the Act as a producer in the United States of the domestic like product.[4]

On February 2, 2022, Whirlpool filed a timely and adequate substantive response, within the deadline specified in 19 CFR 351.218(d)(3)(i).[5] Commerce did not receive substantive responses from any respondent interested party with respect to the *Order* covered by this sunset review. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the *Order.*

Scope of the Order

The merchandise covered by the *Order* is LRWs from China. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.[6]

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review is provided in the Issues and Decision Memorandum. A list of the topics discussed in the Issues and Decision Memorandum is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx*

Final Results of Sunset Review

Pursuant to sections 751(c)(1), 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to a continuation or recurrence of dumping, and that the magnitude of the dumping margins likely to prevail is up to 57.37 percent.[7]

Notification Regarding Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218(e)(1)(ii)(C)(2) and 19 CFR 351.221(c)(5)(ii).

Dated: May 2, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. History of the *Order*
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of Dumping
  2. Magnitude of the Dumping Margins Likely to Prevail
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2022–09812 Filed 5–5–22; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Large Residential Washers from the People's Republic of China: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Order,* 82 FR 9371 (February 6, 2017) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 87 FR 76 (January 3, 2022).

[3] *See* Whirlpool Letter, ''Five-Year (''Sunset'') Review of Antidumping Duty Order on Large Residential Washers from China: Notice of Intent to Participate,'' dated January 18, 2022.

[4] *Id.*

[5] *See* Whirlpool Letter, ''Five-Year (''Sunset'') Review of Antidumping Duty Order on Large Residential Washers from China: Substantive Response,'' dated February 2, 2022 (Substantive Response).

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Sunset Review of the Antidumping Duty Order on Large Residential Washers from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[7] *See Order,* 82 FR at 9373.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–890]

Wooden Bedroom Furniture From the People's Republic of China: Final Results of the Expedited Third Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this expedited sunset review, the Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on wooden bedroom furniture from the People's Republic of China (China) would likely lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable May 6, 2022.

FOR FURTHER INFORMATION CONTACT: Krisha Hill, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4037.

SUPPLEMENTARY INFORMATION:

Background

After publication of the notice of initiation of this sunset review of the AD order on wooden bedroom furniture from China,[1] [2] pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act), domestic interested parties [3] filed with Commerce a timely and complete notice of intent to participate in the sunset review.[4] Also, the domestic interested parties timely filed an adequate substantive response with

[1] *See Initiation of Five-Year (Sunset) Reviews,* 87 FR 76 (January 3, 2022).

[2] *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Wooden Bedroom Furniture from the People's Republic of China,* 70 FR 329 (January 4, 2005) (*Order*).

[3] The domestic interested parties are the American Furniture Manufacturers Committee for Legal Trade (Committee) and Vaughan-Bassett Furniture Company, Inc. The Committee is an *ad hoc* association of the following eight producers of wooden bedroom furniture: (1) Caperton Furnitureworks, LLC dba Gat Creek and Tom Seely Furniture; (2) Carolina Furniture Works, Inc.; (3) Century Furniture, LLC; (4) Johnston-Tombigbee Furniture Mfg. Co.; (5) L. & J.G. Stickley, Inc.; (6) Perdues Inc.; (7) T. Copeland & Sons, Inc.; and (8) Vaughan-Bassett Furniture Company, Inc.

[4] *See* Domestic Interested Parties' Letter, ''Five-Year (''Sunset'') Review of Antidumping Duty Order On Wooden Bedroom Furniture from the People's Republic of China: Notice Of Intent To Participate In Sunset Review,'' dated January 14, 2022.

Commerce.[5] Commerce did not receive a substantive response from any respondent interested party. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(*2*), Commerce conducted an expedited (120-day) sunset review of the *Order*.[6]

Scope of the Order

The product covered by the *Order* is wooden bedroom furniture, subject to certain exceptions. Imports of subject merchandise are classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 9403.50.9042, 9403.50.9045, 9403.50.9080, 9403.90.7005, 9403.90.7080, 9403.50.9041, 9403.60.8081, 9403.20.0018, 9403.90.8041, 7009.92.1000 or 7009.92.5000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written product description in the order remains dispositive. For a complete description of the scope of the *Order,* see the Decision Memorandum.

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including the likelihood of continuation or recurrence of dumping in the event of revocation of the *Order* and the magnitude of the dumping margins likely to prevail if the *Order* were revoked, is provided in the Decision Memorandum. A list of the sections in the Decision Memorandum is in the appendix to this notice. The 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 Decision Memorandum can be accessed on the internet at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 751(c)(1), 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Order* would likely lead to continuation or recurrence of dumping, and that the magnitude of the dumping margins likely to prevail are weighted-average dumping margins up to 198.08 percent.

Administrative Protective Orders

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials, or the conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218 and 19 CFR 351.221(c)(5)(ii).

Dated: May 2, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

Sections in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. History of the Proceeding
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of Dumping
  2. Magnitude of the Margin of Dumping Likely to Prevail
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2022–09811 Filed 5–5–22; 8:45 am]

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[5] *See* Domestic Interested Parties' Letter, ''Five-Year (''Sunset'') Review of Antidumping Duty Order On Wooden Bedroom Furniture from the People's Republic of China: Domestic Industry Substantive Response,'' dated January 31, 2022 (Substantive Response).

[6] For a complete description of the background of this sunset review of the *Order, see* Memorandum, ''Issues and Decision Memorandum for the Expedited Third Sunset Review of the Antidumping Duty Order on Wooden Bedroom Furniture from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Decision Memorandum).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–890]

Wooden Bedroom Furniture From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) continues to determine that the sole respondent under review, Hui Zhou Tian Mei Investment Co., Ltd. (aka Hui Zhou Tian Mei Furniture Co., Ltd.) (Tian Mei), is not eligible for a separate rate and is therefore a part of the China-wide entity. The period of review (POR) is January 1, 2020 through December 31, 2020.

DATES: Applicable May 6, 2022.

FOR FURTHER INFORMATION CONTACT: Krisha Hill, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4037.

SUPPLEMENTARY INFORMATION:

Background

On October 7, 2021, Commerce published in the **Federal Register** the preliminary results of the 2020 administrative review of the antidumping duty (AD) order on wooden bedroom furniture (WBF) from the People's Republic of China (China).[1] We invited interested parties to comment on the *Preliminary Results.* On February 1, 2022, Commerce extended the deadline to issue the final results of this review until April 5, 2022.[2] A full description of case events that occurred since issuance of the *Preliminary Results,* is in the Issues and Decision Memorandum.[3]

Scope of the Order

The product covered by the *Order* is wooden bedroom furniture, subject to certain exceptions.[4] Imports of subject merchandise are classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 9403.50.9042, 9403.50.9045, 9403.50.9080, 9403.90.7005, 9403.90.7080, 9403.50.9041, 9403.60.8081, 9403.20.0018, 9403.90.8041, 7009.92.1000 or 7009.92.5000. Although the HTSUS subheadings are provided for convenience and customs purposes, the

[1] *See Wooden Bedroom Furniture from the People's Republic of China: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review; 2020,* 86 FR 55809 (October 7, 2021) (*Preliminary Results*).

[2] *See* Memorandum, ''Antidumping Duty Administrative Review of Wooden Bedroom Furniture from the People's Republic of China: Extension of Deadline for Final Results of Antidumping Duty Administrative Review,'' dated February 1, 2022.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review: Wooden Bedroom Furniture from the People's Republic of China; 2020,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Wooden Bedroom Furniture from the People's Republic of China,* 70 FR 329 (January 4, 2005) (*Order*).

written description of the scope of the *Order* is dispositive.[5]

Methodology

Commerce conducted this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act). For a discussion of the comment received, *see* the Issues and Decision Memorandum.[6] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Review

Consistent with the *Preliminary Results,* we continue to determine that the sole respondent under review, Tian Mei, did not establish its eligibility for a separate rate and is part of the China-wide entity. No parties commented on this decision.

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. No earlier than 35 days after the date of publication of this notice in the **Federal Register**, Commerce intends to instruct CBP to liquidate any entries of subject merchandise from Tian Mei that entered the United States during the POR at the China-wide rate (*i.e.,* 216.01 percent). 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).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of this notice in the **Federal Register** for all shipments of subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice, as provided by section 751(a)(2)(C) of the Act: (1) For previously investigated or reviewed China and non-China exporters which are not under review in this review, but which received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the exporter's existing cash deposit rate; (2) for all China exporters of subject merchandise that do not have a separate rate, the cash deposit rate will be the China-wide entity rate (*i.e.,* 216.01 percent); and (3) for all non-China exporters of subject merchandise that do not have their own rate, the cash deposit rate will be the rate applicable to the China exporter(s) that supplied that non-China exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties/and or countervailing duties prior to liquidation of the relevant entries during the POR. 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.

Administrative Protective Orders

This notice also serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results of administrative review in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5) and 19 CFR 351.213(h)(1).

Dated: April 5, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Discussion of the Issue
Comment: Whether Commerce Should Extend the Deadline to Issue the Final Results
V. Recommendation

[FR Doc. 2022–09817 Filed 5–5–22; 8:45 am]

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[5] For a complete description of the scope of the *Order, see Wooden Bedroom Furniture from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2018,* 85 FR 7731 (February 11, 2020); *see also* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review: Wooden Bedroom Furniture from the People's Republic of China,'' dated October 2, 2019.

[6] *See* Issues and Decision Memorandum.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–105]

Carbon and Alloy Steel Threaded Rod From the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review and Rescission of Administrative Review in Part; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that the companies subject to this countervailing duty (CVD) administrative review of carbon and alloy steel threaded rod (threaded rod) from the People's Republic of China (China) received countervailable subsidies during the period of review (POR), July 29, 2019, through December 31, 2020. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable May 6, 2022.

FOR FURTHER INFORMATION CONTACT: Thomas Schauer or Allison Hollander, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0410 or (202) 482–2805, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 9, 2020, Commerce published the CVD order on threaded rod from China.[1] On April 1, 2021, Commerce published a notice of

[1] *See Carbon and Alloy Steel Threaded Rod from India and the People's Republic of China: Countervailing Duty Orders,* 85 FR 19927 (April 9, 2020) (*Order*).

opportunity to request an administrative review of the *Order* for the POR.[2] In April 2021 we received timely requests from multiple parties to conduct an administrative review of the *Order.* On June 11, 2021, we published a notice of initiation for this administrative review.[3] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4] 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.*

On December 3, 2021, Commerce extended the deadline for the preliminary results of this review by 120 days to May 2, 2022.[5]

Scope of the Order

The scope of the *Order* covers threaded rod from China. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

We are conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we determine that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that confers a benefit to the recipient, and that the subsidy is specific.[6] For a full description of the methodology underlying our preliminary 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. A list of topics included in the Preliminary Decision Memorandum is provided in Appendix I to this notice.

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 withdrawal requests with respect to the 18 companies listed in Appendix II.[7] Because the withdrawal requests were timely filed and no other parties requested a review of these companies, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this review of the *Order* for the 18 companies listed in Appendix II.[8]

Preliminary Rate for Non-Selected Companies

There are three companies 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: (1) Ningbo Dingtuo Imp. & Exp. Co., Ltd.; (2) Ningbo Dongxin High-Strength Nut Co., Ltd.; and (3) Ningbo Jinding Fastening Piece Co., Ltd. For these non-selected companies, because the rates calculated for the mandatory respondents, Zhejiang Junyue Standard Part Co., Ltd. (Junyue) and Ningbo Zhongjiang High Strength Bolts Co., Ltd. (Zhongjiang Bolts), were above *de minimis* and not based entirely on facts available, we are applying the weighted average of the net countervailable subsidy rates calculated for the mandatory respondents, which we calculated using the publicly-ranged sales data submitted by Junyue and Zhongjiang Bolts.[9] This methodology to establish the non-selected subsidy rate is consistent with our practice with regard to the all others rate pursuant to section 705(c)(5)(A)(i) of the Act.

Preliminary Results of Administrative Review

As a result of this administrative review, we preliminarily find that the following net countervailable subsidy rates exist for the period July 29, 2019, through December 31, 2020:

Company	Subsidy rate—2019 (percent *ad valorem*)	Subsidy rate—2020 (percent *ad valorem*)
Ningbo Zhongjiang High Strength Bolts Co., Ltd[10]	8.36	7.65
Zhejiang Junyue Standard Part Co., Ltd[11]	7.22	7.97
Review-Specific Average Rate Applicable to the Following Companies		
Ningbo Dingtuo Imp. & Exp. Co., Ltd	7.95	7.75
Ningbo Dongxin High-Strength Nut Co., Ltd	7.95	7.75
Ningbo Jinding Fastening Piece Co., Ltd	7.95	7.75

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 86 FR 17137 (April 1, 2021).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 31282, 31293 (June 11, 2021).

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Countervailing Duty Order on Carbon and Alloy Steel Threaded Rod from the People's Republic of China; 2019–2020,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See* Memorandum, ''Carbon and Alloy Steel Threaded Rod from the People's Republic of China: Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review; 2019–2020,'' dated December 3, 2021.

[6] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[7] *See* Vulcan Threaded Products Inc.'s Letter, ''Carbon and Alloy Steel Threaded Rod from the People's Republic of China: Withdrawal of Requests for Administrative Reviews,'' dated August 30, 2021.

[8] *See, e.g., Lightweight Thermal Paper from the People's Republic of China: Notice of Rescission of Countervailing Duty Administrative Review; 2015,* 82 FR 14349 (March 20, 2017); and *Circular Welded Carbon Quality Steel Pipe from the People's Republic of China: Rescission of Countervailing Duty Administrative Review; 2017,* 84 FR 14650 (April 11, 2019).

[9] With two respondents under examination, Commerce normally calculates (A) a weighted-average of the estimated subsidy rates calculated for the examined respondents; (B) a simple average of the estimated subsidy rates calculated for the examined respondents; and (C) a weighted-average of the estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010); *see also* Memorandum, ''Administrative Review of the Countervailing Duty Order on Carbon and Alloy Steel Threaded Rod from the People's Republic of China: Calculation of Rate for Respondents Not Selected for Individual Examination,'' dated concurrently with this notice.

Assessment Rates

Upon issuance of the final results of this administrative review, consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. For the 18 companies for which this review is rescinded, Commerce will instruct CBP to assess countervailing duties on all appropriate entries at the 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 July 29, 2019, through December 31, 2020, in accordance with 19 CFR 351.212(c)(l)(i).

For the companies remaining in the review, 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).

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 calculated in the final results of this review for the respective companies 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 minimis,* 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 companies, CBP will continue to collect cash deposits of estimated countervailing duties at the all-others rate (*i.e.,* 41.17 percent) [12] 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.

Disclosure and Public Comment

We intend to disclose the calculations performed for these preliminary results to parties in this proceeding within five days after public announcement of the preliminary results in accordance with 19 CFR 351.224(b). Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the date for filing case briefs.[13] Parties who submit case or rebuttal briefs in this proceeding 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.[14] Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information.[15]

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, filed electronically via ACCESS. An electronically filed document must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.[16] Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. If a request for a hearing is made, we will inform parties of the scheduled date and time for the hearing.

Unless extended, we intend to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their case briefs, no later than 120 days after the date of publication of this notice in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4) and 351.221(b)(4).

Dated: May 2, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Rescission of Administrative Review, In Part
V. Non-Selected Companies Under Review
VI. Diversification of China's Economy
VII. Subsidies Valuation
VIII. Benchmarks and Discount Rates
IX. Use of Facts Otherwise Available and Application of Adverse Inferences
X. Analysis of Programs
XI. Recommendation

Appendix II

List of Companies for Which Requests for Review Were Timely Withdrawn

1. Cooper & Turner (Ningbo) International Trading Co., Ltd.
2. EC International (Nantong) Co., Ltd.
3. Haiyan Qinshan Rubber Factory
4. IFI & Morgan Ltd.
5. Jiaxing Genteel Import & Export Co., Ltd
6. Nantong Runyou Metal Products Co., Ltd.
7. Ningbo Qunli Fastener Manufacture Co., Ltd.
8. Ningbo Shareway Import & Export, Co., Ltd.
9. Ningbo Xingsheng Oil Pipe Fittings Manufacture Co., Ltd.
10. Ningbo Zhenghai Yongding Fastener Co., Ltd.
11. Ningbo Zhenghai Yongding Fasteners Manufacture Co., Ltd.
12. Ningbo Zhenhai Zhongbiao Standard Parts Factory
13. RMB Fasteners Ltd.
14. Zhejiang Cooper & Turner Fasteners Co., Ltd.
15. Zhejiang Golden Automotive Fastener Co., Ltd
16. Zhejiang Heiter Mfg & Trade Co., Ltd.
17. Zhejiang Huiyou Import & Export Co., Ltd.
18. Zhejiang Morgan Brother Technology Co., Ltd.

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[10] In the original investigation, Commerce found Ningbo Zhongmin Metal Product Co., Ltd., to be cross-owned with Ningbo Zhongjiang High Strength Bolts Co., Ltd. *See Carbon and Alloy Steel Threaded Rod from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Duty Determination,* 84 FR 36578 (July 29, 2019), and accompanying Preliminary Decision Memorandum at 28, unchanged in *Carbon and Alloy Steel Threaded Rod from the People's Republic of China: Final Affirmative Countervailing Duty Determination,* 85 FR 8833, February 18, 2020). As the facts have not changed in this review, we continue to find Ningbo Zhongmin Metal Product Co., Ltd., to be cross-owned with Ningbo Zhongjiang High Strength Bolts Co., Ltd. *See also* Preliminary Decision Memorandum.

[11] As discussed in the Preliminary Decision Memorandum, Commerce preliminarily finds the following companies to be cross-owned with Zhejiang Junyue Standard Part Co., Ltd.: Jiaxing Chengyue Trading Co., Ltd., and Haiyan County Brothers Paper Industry Co., Ltd.

[12] *See Order,* 85 FR at 19928.

[13] *See* 19 CFR 351.309(d).

[14] *See* 19 CFR 351.309(c)(2) and (d)(2).

[15] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 41363 (July 10, 2020).

[16] *See* 19 CFR 351.310(c).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–887]

Carbon and Alloy Steel Threaded Rod From India: Preliminary Results of Antidumping Duty Administrative Review, 2019–2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that carbon and alloy steel threaded rod (steel threaded rod) from India is not being sold in the United States at below normal value. The period of review (POR) is September 25, 2019, through March 31, 2021. Interested parties are invited to comment on these preliminary results.

DATES: Applicable May 6, 2022.

FOR FURTHER INFORMATION CONTACT: Nicolas Mayora, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3053.

SUPPLEMENTARY INFORMATION:

Background

On April 9, 2020, Commerce published in the **Federal Register** an antidumping duty order on steel threaded rod from India.[1] On April 1, 2021, we published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order.*[2] On June 11, 2021, based on timely requests for an administrative review, Commerce initiated the administrative review of 328 companies.[3] Commerce selected Maharaja International (Maharaja) and Mangal Steel Enterprises Limited (Mangal) as the two mandatory respondents for individual examination.[4]

On December 9, 2021, Commerce extended the time limit for completing the preliminary results of this review until April 29, 2022.[5] For a complete description of the events between the initiation of this review and these preliminary results, *see* the Preliminary Decision Memorandum.[6]

Scope of the Order

The merchandise covered by the scope of this *Order* is carbon and alloy steel threaded rod. A complete description of the scope of the *Order* is contained in the Preliminary Decision Memorandum.[7]

Methodology

Commerce is conducting this review in accordance with section 751(a)(2) of the Tariff Act of 1930, as amended (the Act). Commerce has calculated export prices and constructed export prices in accordance with sections 772(a) and 772(b) of the Act, respectively. Normal Value (NV) is calculated in accordance with section 773(e) of the Act. For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum. *See* Appendix I for a complete list of topics discussed in the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is made available to the public *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum is available at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Rate for Non-Examined Companies

The Act and Commerce's regulations do not address the establishment of a rate to be applied to companies not selected for examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market economy investigation, for guidance when calculating the rate for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely {on the basis of facts available}.''

Where the dumping margin for individually examined respondents are all zero, *de minimis,* or based entirely on facts available, section 735(c)(5)(B) of the Act provides that Commerce may use ''any reasonable method to establish the estimated all-others rate for exporters and producers not individually investigated, including averaging the estimated weighted average dumping margins determined for the exporters and producers individually investigated.''

In this review, Commerce preliminarily determines that the estimated weighted-average dumping margins for both Maharaja and Mangal are zero percent. Therefore, in accordance with section 735(c)(5)(B) of the Act, we are preliminarily applying to the 326 companies not selected for individual examination a rate of zero percent, because we calculated rates of zero percent for both mandatory respondents (*see* Appendix II for a full list of these companies).

Preliminary Results of the Review

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist during the period September 25, 2019, through March 31, 2021:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Maharaja International	0.00
Mangal Steel Enterprises Limited	0.00
Non-Examined Companies[8]	0.00

Disclosure and Public Comment

Commerce intends to disclose to interested parties the calculations performed for these preliminary results within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no

[1] *See Carbon and Alloy Steel Threaded Rod from India: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 85 FR 19925 (April 9, 2020) (*Order*).

[2] *See Antidumping and Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 86 FR 17137 (April 1, 2021).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 31282 (June 11, 2021) (*Initiation Notice*); *see also Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 87 FR 21619 (April 12, 2022) that includes Kova Fasteners Pvt., Ltd. Commerce inadvertently omitted this company from the initial *Initiation Notice.*

[4] *See* Memorandum, ''Respondent Selection,'' dated July 16, 2021.

[5] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review; 2019–2021,'' dated December 9, 2021.

[6] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review of Carbon and Alloy Steel Threaded Rod from India; 2019–2021,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[7] *See* Preliminary Decision Memorandum at ''Scope of the *Order.*''

[8] *See* Appendix II for a list of these companies.

later than seven days after the date for filing case briefs.[9] Commerce modified certain of its requirements for servicing documents containing business proprietary information until further notice.[10] Parties who submit case briefs or rebuttal briefs in this proceeding 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.[11] Note that Commerce has temporarily modified certain portions of its requirements for serving documents containing business proprietary information, until further notice.[12]

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 *via* ACCESS within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date. An electronically-filed hearing request must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline.

Commerce intends to issue the final results of this administrative review, including the results of its analysis of issues raised in the case briefs, no later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act, unless otherwise extended.

Assessment Rates

Upon issuance of the final results of this administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[13] If a respondent's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, we will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). We intend to instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is not zero or *de minimis.* Where an importer-specific assessment rate is zero or *de minimis* in the final results of this review, we intend to instruct CBP to liquidate the appropriate entries without regard to antidumping duties in accordance with 19 CFR 351.106(c)(2). If Commerce calculates margins above *de minimis* in the final results of this review, we intend to instruct CBP to take into account the ''provisional measures deposit cap,'' in accordance with 19 CFR 351.212(d). The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review and for future deposits of estimated duties, where applicable.[14]

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by Maharaja or Mangal for which these companies did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate those entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[15] For the companies which were not selected for individual review, we will assign an assessment rate based on the review-specific average rate, calculated as noted in the ''Preliminary Results of Review'' section above.

We intend to issue instructions to CBP no earlier than 35 days after the publication date 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).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication in the **Federal Register** of the notice of final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the companies listed in the final results of this review will be equal to the weighted-average dumping margin established in the final results of this administrative review; (2) for merchandise exported by producers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which they were reviewed; (3) if the exporter is not a firm covered in this review, or the original investigation but the producer is, then the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be 0.00 percent, the all-others rate established in the less-than-fair-value investigation, adjusted for the export-subsidy rate in the companion countervailing duty investigation.[16] The cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice 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 the POR. 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

Commerce is issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: April 28, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background

[9] *See* 19 CFR 351.309(d).

[10] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension Effective Period,* 85 FR 41363 (July 10, 2020) (*Temporary Rule*).

[11] *See* 19 CFR 351.309(c) and (d); *see also* 19 CFR 351.303 (for general filing requirements).

[12] *See Temporary Rule.*

[13] *See* 19 CFR 351.212(b)(1).

[14] *See* section 751(a)(2)(C) of the Act.

[15] For a full description of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[16] *See Order,* 85 FR at 19926.

III. Scope of the *Order*
IV. Rates for Non-Examined Companies
V. Affiliation
VI. Discussion of the Methodology
VII. Currency Conversion
VIII. Recommendation

Appendix II

List of Companies Not Individually Examined

A H Enterprises
A S International
Aadi Shree Fastener Industries
Aanjaney Micro Engy Pvt., Ltd.
Aaran 1 Engineering Pvt., Ltd.
Aask Precision Engineers
Abhi Metals
Accumax Lab Devices Pvt., Ltd.
Acmi Industries
Adhi Automation (India) Pvt., Ltd.
Adma Auto Components Pvt., Ltd.
Adma Fabrications (P) Ltd.
Aesthetic Living Merchants Pvt., Ltd.
Agarwal Fastners Pvt., Ltd.
Ajay Electric And Metal Industries
Akg India Private Ltd.
Ambana Exp.
Amtek Auto Ltd.
Ap Trading
Apa Engineering Pvt., Ltd.
Arcotherm Pvt., Ltd.
Arohi International
Aruna Alloy Steels Pvt., Ltd.
Ashish International
Asma International
Asp Pvt., Ltd.
August Industries
Aura Industries Equipement & Project Pvt. Ltd.
Avtar Exp.
Babu Exp.
Bajaj Auto Ltd.
Balmer Lawrie & Co., Ltd.
Bansal Wire Industries Ltd.
Bee Dee Cycle Industries
Belgaum Ferrocast India Pvt., Ltd.
Beri Udyog Pvt., Ltd.
Best Quality Fastners
Bhansali Inc.
Bhuj Polymers Pvt., Ltd.
C Tech Engineers Pvt. Ltd.
Caliber Enterprises
Canco Fasteners
Caparo Engineering India Pvt., Ltd.
Capital Bolts And Hardwares
Case New Holland Construction Equipment(I) Pvt. Ltd.
Century Distribution System Inc.
Challenger Sweepers Private Ltd.
Chandra Mats Pvt., Ltd.
Charu Enterprises
Chhabra Forgings
Chirag International
Clasquin India Pvt., Ltd.
Cnh Industries (India) Pvt., Ltd.
Collection Exp.
Concept Fasteners
Conex Metals
Continental Hardware Mart
Cosmo International
Cummins India Ltd.
Cummins India Ltd. Pdc Mfg Unit
Damco India Pvt., Ltd.
Danesh Industries
Danta Exim
Dauji Engineering Ltd.
Dcw Ltd.
Deepak Brass Industries
Deepak Fasteners Ltd.
Deneb
Dhara Foods Pvt., Ltd.
Dmw Cnc Solutions India Pvt., Ltd.
Dst Industries
Durable Metalcraft
Eagle Line Fixings&Fixtures (P) Ltd.
Eastman Industries Ltd.
Echjay Forgings Pvt. L
Edicon Pneumatic Tool Co. Pvt. Ltd.
Efficient Automotives Pvt., Ltd.
Eicher Motors Ltd.
Elite Green Pvt., Ltd.
Ellias International
Emmforce Inc.
Emu Lines Pvt., Ltd.
Ess Enn Auto Cnc .P. Ltd.
Everest Engineering Equipment Pvt., Ltd.
Everest Industries Ltd.
Fence Fixings
Fine Products (India)
Fine Thread Form Industries
Fit Right Nuts And Bolts Pvt., Ltd.
Flowserve India Controls Pvt., Ltd.
Ford India Pvt., Ltd.
Ganesh Brass Industries
Ganga Technocast
Ganges Internationale
Ganpati Fastners Pvt., Ltd.
Gayatri Metal Products
Ghanshyamlal Co.
Global Engineering Exports
Gloster Jute Mills Limited
Goel & Goel International
Good Ways Corporation
Goodgood Manufacturers
GPDA Fasteners
Gripwel Fasteners
Gvn Fuels Ltd.
Hamidi Exp.
Haria Trading Co.
Him Overseas
Hind Metal & Industries Pvt., Ltd.
Hindostan Expo
Hiten Fastners Pvt., Ltd.
Hobb International Pvt., Ltd.
Humboldt Wedag India P Ltd.
Husco Hydraulics Pvt., Ltd.
Idea Fastners Pvt., Ltd.
Imco Alloys Pvt., Ltd.
Inder Industries
India Yamaha Motor Pvt., Ltd.
Indo Schottle Auto Parts Pvt., Ltd.
Indra Engineering
Induspro Auto Engineers Pvt., Ltd.
Industrias Gol S.A.U.
Ingersoll Rand India Ltd.
Intex Home Solutions
Intl Tractors Ltd.
Irm Offshore & Marine Engineer Pvt., Ltd.
Ispt India Pvt., Ltd.
J.K. Fenner (India) Ltd.
Jain Grani Marmo Pvt., Ltd.
Jayson International
Jhv Engicon Pvt., Ltd.
Jindal Fasteners
K V Tech India LLP
Kalpana Brass Industries
Kanika Exp.
Kanika Overseas Inc.
Kapil Enterprises
Kapson India
Kapurthala Industrial Corporation
Karamtara Engineering Pvt., Ltd.
Karna International
KBV Industries India Pvt., Ltd.
KEC International Ltd.
Keith Ceramic India Private Ltd.
Kewaunee Labway India Pvt., Ltd.
King Exports
Kmp Freight
Knk Enterprises
Knl Drive Line Parts Pvt., Ltd.
Kohler India Corp. Pvt Ltd.
Kova Fasteners Pvt., Ltd.
Krisam Automation Pvt., Ltd.
KSP Engineering Co.
Kumar Auto Parts Pvt., Ltd.
Kundan Industries Ltd.
Lasercut Metal Technology Private Ltd.
LCL Logistix (I) Pvt., Ltd.
Lg Balakrishnan & Bros Ltd.
Live Rock Bangalore Pvt., Ltd.
M K Fastners
M.D. Industries
M.K.Fasteners
M.M. Intl
Mack Machine Products Pvt., Ltd.
Maini Precision Products Ltd.
Mangalam Alloys Ltd.
Mansons International Pvt., Ltd.
Mark Industries
Marudhar Enterprises
Maxop Engineering Co.
Maya Enterprises
MB Metallic Bellows Pvt., Ltd.
Mechasoft
Meeras International
Mega Engineers
Metaloft Industries Private Ltd.
Metrix Autocomp Pvt., Ltd.
Mohindra Fasteners Ltd.
Movex Cargo Pvt., Ltd.
MSS India Pvt., Ltd. (100%Eou)
Mukund Overseas
Multimech Engineers
Multitech Products Pvt., Ltd.
N. A. Roto Machines & Moulds India
Navketan Engineering Works
Neon Alloys
Nexo Industries Ltd.
Nipha Enterprises LLP
Niranjan Engineering Works
Nishant Steel Industries
Nivic Technocast
Norquest Brands Private Ltd.
Northpole Industries
Ommi Forge Pvt., Ltd.
Omnitech Engineering
Onkar International
Oriental Exp. Corporation
Oriental Rubber Industries
P N International
P R Rolling Mills Pvt., Ltd.
Paani Precision Products Llp
Paloma Turning Co. Pvt., Ltd.
Panesar Engineers
Pankaj Exp.
Paramount Agriparts
Parshva India
Parul Exp.
Perfect Forgings
Perfect Industries (India)
Pheon Auto Tech Pvt., Ltd.
Piping & Energy Products (P) Ltd
Pooja Forge Ltd.
Pooja Precision Screws Pvt., Ltd.
Pr Professional Services
Precision Engineering Industries
Precision Products Marketing Pvt., Ltd.

Prime Steel Products
Protech International
Psl Pipe & Fittings Co.
R F India
R K Fasteners (India)
R. Kay Exp.
Raajratna Metal Industries Ltd.
Raajratna Ventures Ltd.
Rachna Fastners
Randack Fasteners India Pvt., Ltd.
Rar Exim Pvt., Ltd.
Ravi Engineers
Rbm International
Resilent Autocomp Pvt., Ltd.
Ridvan Fasteners India Pvt., Ltd.
Right Tight Fastners Pvt., Ltd.
Rishi International
Rohlig India Pvt., Ltd.
Roots Multiclean Ltd.
Rotzler Services Private Ltd.
S K Brass Works
Sakthi Forgings
Sameer Exports International
Sandip Brass Industries
Sanghvi Metal Coporation
Sarveshwari Engineers
Satyam Engineering Works
Schenker India Pvt., Ltd.
Scorpio Precisions
Shalaka Shafts Private Ltd.
Shiv Om Brass Industries
Shree Exp.
Shree Luxmi Fasteners
Shree Raj Industries
Shreeraj Industries
Shri L.G. Hindustan Handicrafts
Shri Ram Castings
Shri Shirdi Sai Baba Moorti Art
Shrijee Process Engineering
Shrutee Exp. Pvt., Ltd.
Shyam Enterprises
Sigmaflow Production Solutions Priv
Simplex Engineering Co.
Singhania International
Sivaramakrishna Forgings P. Ltd.
Skf India Ltd.
Sks Fasteners Ltd.
Sonesta Corporation
Sri Ranganathar Industries Private Limited
Stelco Ltd.
Sterling Tools Ltd.
Strut Support Systems
Sundram Fasteners Ltd.
Sunil Chirag & Co.
Sunil Industries, Ltd.
Supreme Overseas Exports India Pvt. Ltd.
Surelock Plastics Pvt., Ltd.
Suzlon Energy Ltd.
Suzy Indusries Ltd.
Sv Engineerings
Swadesh Engineering Industries
Swamiji Transmission Pvt., Ltd.
Swati Enterprise
Techbolt Industries Private Ltd.
Technical Products
Technocraft Industries (India) Ltd.
Tega Industries Ltd.
Teryair Equipment Pvt., Ltd.
Texas Technology
Tijiya Engineering Pvt., Ltd.
Tijiya Exp. Pvt., Ltd.
Torqbolt Inc.
Total Transport Systems Pvt., Ltd.
Trans Tool Pvt., Ltd.
Tristar International
Triton Foodworks Pvt., Ltd.
Trueform Exp. Pvt.L
Turbo Tools Pvt., Ltd.
Teyamaha Motor Asia Pte., Ltd.
Umaa Engineers
Unexo Life Sciences Private Ltd.
Universal Precision Screws
Unlimited Inc.
UT Worldwide (India) Pvt., Ltd.
V.K Fasteners Pvt., Ltd.
V.R.Logistics Pvt., Ltd.
V.S.Industries
Vatsalya Metal Industries
Vega Industries
Velvin Paper Products
Venu Engineering Services (P) Ltd.
Versatile Instruments & Controls
Vestas Wind Technology India Private Ltd.
Vibracoustic Noida Pvt., Ltd.
Victaulic Piping Products India Pvt., Ltd.
Vidhi Industries
Vidushi Wires Pvt., Ltd.
Vijay Engineering Works
Viraj Profiles Ltd.
Vollan Shipping Pvt., Ltd.
Vph International
Waveerk Enterprises
White Mountain Fixings India
Wintage Engineers & Consultants
Wire Rings
Xcel Exports
Yerik International
Yogendra International
Youyun Logistics & Technology Pvt. Ltd.
Zenith Precision Pvt., Ltd.

[FR Doc. 2022–09801 Filed 5–5–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Specified Fishing Agreements for U.S. Territorial Catch, Effort, and Allocation Limits

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 January 20th, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: NOAA National Marine Fisheries Service (NMFS).

Title: Specified Fishing Agreements for U.S. Territorial Catch, Effort, and Allocation Limits.

OMB Control Number: 0648–0689.

Form Number(s): None.

Type of Request: Regular (extension of a current collection of information).

Number of Respondents: 3.

Average Hours per Response: 30 hours per agreement; 15 hours per appeal.

Total Annual Burden Hours: 90.

Needs and Uses: The Fishery Ecosystem Plan for Pacific Pelagic Fisheries of the Western Pacific Region (FEP) and regulations at 50 CFR 665.819 allow the Western Pacific Fishery Management Council (Council) to recommend and NMFS to implement catch or fishing effort limits for pelagic fisheries in the Territory of American Samoa, the Territory of Guam, and the Commonwealth of the Northern Mariana Islands (CNMI) (hereinafter, ''territory'' or ''territories''). The regulations further allow NMFS to authorize the government of each territory to allocate a portion of its catch or fishing effort limit to U.S. fishing vessels through specified fishing agreements between the vessels and the respective territories. Payments made by the vessels under these agreements support fisheries development in the territories.

Specified fishing agreements include the identity of fishing vessels subject to the agreement, the amount (weight) of fish or fishing effort to which the agreement applies, and any amount paid under the agreement. Additionally, an authorized official of the U.S. territory and each vessel owner or their designated representative must sign the agreements. There is no specified form for an agreement.

NMFS uses the information in the agreements to determine vessel eligibility, and ensure the amount of fish or fishing effort allocated under the agreement is consistent with the FEP, the Magnuson-Stevens Fishery Conservation and Management Act, other applicable laws, and the conservation needs of the fish stock.

The request also includes a change to the collection's title for improved clarity, from ''Amendment 7 to the Fishery Ecosystem Plan for Pelagic Fisheries of the Western Pacific Region—U.S. Territorial Catch and Fishing Effort Limits'' to ''Specified Fishing Agreements for U.S. Territorial Catch, Effort, and Allocation Limits.''

Affected Public: Individuals or households; business or other for-profit organizations; State or Territorial governments.

Frequency: Annual.

Respondent's Obligation: Required to Obtain or Retain Benefits.

Legal Authority: Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*; 50 CFR 665.819).

This information collection request may be viewed at *reginfo.gov*. Follow the instructions to view 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 0648–0689.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–09830 Filed 5–5–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB866]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Geophysical Surveys of the Guerrero Gap in the Eastern Tropical Pacific

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

ACTION: Notice; issuance of an incidental harassment authorization (IHA).

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, NMFS has issued an IHA to the Lamont-Doherty Earth Observatory (L–DEO) to incidentally harass marine mammals during geophysical surveys of the Guerrero Gap off the coast of Mexico in the Eastern Tropical Pacific.

DATES: This authorization is effective from May 2, 2022 through May 1, 2023.

FOR FURTHER INFORMATION CONTACT: Amy Fowler, 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/permit/incidental-take-authorizations-under-marine-mammal-protection-act.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The 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 August 21, 2021, NMFS received a request from L–DEO for an IHA to take marine mammals incidental to geophysical surveys of the Guerrero Gap off the coast of Mexico in the Eastern Tropical Pacific (ETP). The application was deemed adequate and complete on December 14, 2021. L–DEO's request is for take of a small number of 30 species of marine mammals by Level B harassment and, for two of those species, by Level A harassment. NMFS published a notice of proposed IHA for public review and comment on January 12, 2022 (87 FR 1992). Neither L–DEO nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Planned Activity

Researchers from L–DEO, University of Texas Institute of Geophysics (UTIG), and Northern Arizona University (NAU), with funding from the National Science Foundation (NSF), and in collaboration with researchers from the National Autonomous University of Mexico (Universidad Nacional Autonoma de Mexico or UNAM) and Kyoto University, plan to conduct high-energy seismic surveys from the research vessel (R/V) *Marcus G. Langseth* (*Langseth*) in and around the Guerrero Gap off western Mexico, in the ETP in the mid- to late-spring of 2022. The study uses two-dimensional (2–D) seismic surveying to quantify incoming plate hydration and examine the role of fluids on megathrust slip behavior in and around the Guerrero Gap of the Middle America Trench. L–DEO plans to conduct two different methods of seismic acquisition, multi-channel seismic (MCS) using a hydrophone streamer and refraction surveys using ocean bottom seismometers (OBSs). A total of 3,600 kilometers (km) of transect lines would be surveyed (2,230 km of 2–D MCS reflection data and 1,370 km of OBS refraction data). Approximately 62 percent of the total survey effort would be MCS surveys, with the remaining 38 percent using OBSs. The planned surveys use a 36-airgun towed array with a total discharge volume of ~6600 cubic inches (in^3) as an acoustic source, acquiring return signals using both a towed streamer as well as OBSs. The total survey duration will be approximately 48 days, including approximately 20 days of seismic survey operations, 3 days of transit to and from the survey area, 19 days for equipment deployment/recovery, and 6 days of contingency time for poor weather, etc.

The majority of the 2–D seismic surveys would occur within the Exclusive Economic Zone (EEZ) of Mexico, including territorial seas, and a small portion would occur in International Waters. Approximately 6 percent of the total survey effort would occur in Mexican territorial waters. Note that the MMPA does not apply in Mexican territorial waters. L–DEO is subject only to Mexican law in conducting that portion of the survey. However, NMFS has calculated the expected level of incidental take in the entire activity area (including Mexican territorial waters) as part of the analysis supporting our determination under the MMPA that the activity will have a negligible impact on the affected species or stocks (see Estimated Take and

Negligible Impact Analysis and Determination).

A detailed description of the planned geophysical surveys is provided in the **Federal Register** notice for the proposed IHA (87 FR 1992; January 12, 2022). Since that time, no changes have been made to the planned survey activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specific activity.

Comments and Responses

A notice of NMFS's proposal to issue an IHA to L–DEO was published in the **Federal Register** on January 12, 2022 (87 FR 1992). That notice described, in detail, L–DEO'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, NMFS received comment letters from the Center for Biological Diversity (CBD), Whales of Guerrero, and the Sociedad Mexicana de Mastozoología Marina, A.C. (SOMEMMA). The Sociedad Mexicana de Mastozoología Marina's comment letter was written in support of and reiterated the recommendations in the Whales of Guerrero letter, and we therefore address their comments together.

Comment 1: Whales of Guerrero and SOMEMMA highlighted the status of the endangered Central America Distinct Population Segment (DPS) of humpback whales. Whales of Guerrero noted that in addition to transiting through the survey area along their migratory route, humpback whales from the Central America DPS have been observed calving, nursing, resting, and breeding in the planned survey area between November and May. Citing their own research surveys, Whales of Guerrero recommended that seismic surveys not occur in the region between November 1 and May 1 to ensure minimal impact on the Central America DPS humpback whales.

Response: As required under the MMPA, NMFS preliminarily determined that the mitigation measures in the proposed IHA set forth the means of effecting the least practicable impact on the species and its habitat. ''Minimal impact''—which was not defined by the commenter—is not the standard that must be met through the prescription of mitigation requirements. However, in consideration of the data and maps provided by Whales of Guerrero in their comment letter, showing humpback whale presence concentrated in nearshore waters, and on review of its survey plans, L–DEO agreed that limiting surveys of nearshore tracklines to between May 1 and October 31 would be practicable. NMFS here defines ''nearshore'' tracklines as those tracklines planned to occur in areas where humpback whale sightings (as provided by Whales of Guerrero in their comment letter) have been recorded during the migratory period (*i.e.,* until May 1), or where the associated estimated Level B harassment area would overlap areas where humpback whale sightings have been recorded. This definition includes tracklines within approximately 33.4 km of shore (*i.e.,* the maximum reported distance from shore of humpback sightings in the area). For example, this definition includes the 264-km MCS and OBS trackline running parallel to shore off Guerrero, as well as all connector lines and portions of tracklines landward of that trackline (see Figure 1 of L–DEO's IHA application). NMFS has included this requirement in the final IHA.

Comment 2: Whales of Guerrero and SOMEMMA noted that at least 16 additional species of marine mammals occur in the survey area, including endangered species and species with limited data on abundance and status. Whales of Guerrero included a table of sightings of these species over the course of their research activities between 2014 and 2021. Whales of Guerrero states that they have launched a 3-year, 6-site land-based field survey to identify important and vulnerable nursing and resting sites for humpback whales in Guerrero and are seeking funds to undertake year-round environmental DNA (eDNA) collections to determine cetacean usage of Guerrero's waters, coupled with concurrent boat-based year-round surveys to refine current understanding of marine mammal species present in Guerrero. Until these studies have been completed, Whales of Guerrero states that it would be ''irresponsible'' to approve seismic surveys in the region and that in-depth, year-round research is required to determine species presence and habitat usage before seismic surveys can safely occur in the region.

Response: All species referenced by Whales of Guerrero were included in the table of marine mammals that could occur in the region (Table 1) in the notice of proposed IHA (87 FR 1992; January 12, 2022) and in Table 1 of this notice. The abundance and status of all species in Table 1, as well as the potential effects of L–DEO's activities on these species, have been considered in our determinations. Whales of Guerrero did not provide any additional information on these species that would change our determinations. Additionally, we note that NMFS does not have the authority to approve the seismic surveys, only the take of marine mammals incidental to the seismic surveys. NMFS must grant incidental take authorizations if it can find, based on the best scientific information available, 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). While Whales of Guerrero referenced ongoing studies, these studies have not yet been completed and are not available for NMFS's consideration. The available information for all species referenced by Whales of Guerrero thus supports our required findings for authorizing the taking of marine mammals incidental to L–DEO's planned surveys.

Comment 3: Whales of Guerrero and SOMEMMA stated that Guerrero lacks the infrastructure to support response to potential marine mammal strandings and mortality events. Whales of Guerrero further states that there is no year-round monitoring or stranding response team in place and the remote locations and difficulty in accessing much of the coastline would make it unlikely that live stranding events could be documented and responded to appropriately. Both organizations noted that scientists and stranding experts from SOMEMMA are planning a stranding network capacity-building workshop for Guerrero-based officials, scientists, and local stakeholders in summer of 2022. Whales of Guerrero recommended seismic surveys in the region not be approved until a region-wide stranding and monitoring support network is established.

Response: As stated above, NMFS does not have the authority to approve the seismic surveys, only the take of marine mammals incidental to the surveys. We note that L–DEO has conducted seismic surveys around the world for decades, including in areas without dedicated stranding networks, and no mass strandings have been reported. As discussed in the notice of proposed IHA (87 FR 1992; January 12, 2022), stranding is not expected to result from L–DEO's surveys. In a review of possible stranding associations with seismic surveys, Castellote and Llorens (2016) noted one stranding event, involving two Cuvier's beaked whales, that was contemporaneous with and reasonably associated spatially with a seismic survey conducted by L–DEO. However, the event was not considered a ''true atypical mass stranding'' and the L–DEO

survey was not determined to be a cause of the stranding event. While we agree with the authors of that review in that lack of evidence should not be considered conclusive, it is clear that there is very little evidence that seismic surveys should be considered as posing a significant risk of acute harm to beaked whales or other mid-frequency cetaceans. Using the best available information, which does not suggest that stranding is a likely outcome of the planned surveys, NMFS has made the necessary findings and is authorizing the incidental take requested by L–DEO.

Comment 4: Whales of Guerrero and SOMEMMA noted that Guerrero is an authorized whale watch state in Mexico, with 56 boats and 200 crew members participating in the whale watch industry. Whales of Guerrero stated that the whale watch industry and larger community depend on marine mammal ecotourism, and would be impacted, should the population of humpback whales, which calve, breed, and nurse in the region be harmed. The whale watch guide network requested that seismic surveys do not occur during whale migration season, as threats to whales and dolphins are a threat to their livelihood.

Response: Again, NMFS does not have the authority to authorize seismic surveys and will not require L–DEO to change their planned survey timing to accommodate the whale watch industry. However, since L–DEO is required to limit its surveys of the ''nearshore'' tracklines (see definition above) between May 1 and October 31, when migrating humpbacks are expected to have transited through the area. NMFS has determined that L–DEO's planned surveys would have a negligible impact on all species, including the humpback whales that are of particular interest to the whale watch companies.

Comment 5: Whales of Guerrero and SOMEMMA expressed concern that the surveys would harm the reputation of the region as environmentally protective, which would be financially damaging to the area. Both organizations requested L–DEO discuss the ''potentially harmful'' surveys with regional governmental officials and scientific organizations which are invested in a healthy marine ecology prior to conducting survey work in Guerrero.

Response: This comment is outside the scope of our action. L–DEO conducted all necessary consultations with the Mexican government to obtain approval to operate in the area.

Comment 6: The CBD stated that the proposed IHA does not include the best available science regarding humpback whales. The CBD stated that the proposed IHA says that both the threatened Mexico DPS and endangered Central America DPS may occur in the proposed survey area, while the CBD said that humpback whales that winter along the Pacific coast of southern Mexico off the states of Oaxaca and Guerrero are likely to be part of the Central America DPS, not the Mexico DPS.

Response: The CBD is correct that the notice of proposed IHA (87 FR 1992; January 12, 2022) stated that humpback whales from both the Central America DPS and Mexico DPS may occur in the survey area. The notice further states that due to the expected timing of the surveys (spring), most humpbacks from the Mexico DPS will have begun their migration north toward the feeding grounds off of the U.S. west coast and are likely to be outside of the survey area. Humpbacks from the Central America DPS will likely be migrating northward through the survey area at the time of the proposed survey. The notice stated that we assume that most humpback whales taken by the proposed survey activities will be from the Central America DPS. NMFS has used the best available science in assessing the likelihood of each DPS occurring in the survey area during the planned surveys, and CBD does not offer new or contradictory information.

Comment 7: The CBD stated that NMFS overestimated the abundance of the humpback whale population that may be exposed to the surveys. The CBD referenced Wade (2021) which estimated the abundance of the Central America DPS of humpback whales to be 755 individuals, while Table 1 in the notice of proposed IHA gives an abundance estimate of the Central North Pacific stock of humpback whales as 10,103 individuals. The CBD asserts that the Central North Pacific stock of humpback whales is the wrong stock for the area.

Response: As noted by the CBD in previous comment letters (*e.g.,* 86 FR 29090; May 28, 2021), the designated stocks of humpback whales under the MMPA do not neatly align with the ESA-designated DPSs. Some humpback whales from the Mexico and Central America DPSs may be part of the Central North Pacific stock, and some may be part of the California/Oregon/Washington stock, which has an estimated abundance of 4,973 individuals (Carretta *et al.,* 2021). The abundance of humpback whales used to assess the relative proportion of the population taken, which informs our small numbers determination, is the estimated population of humpbacks in the Pacific waters of Mexico (2,566 individuals; Gerrodette and Palacios, 1996). NMFS has authorized a total of only 8 takes of humpback whales, which is considered small numbers relative to any of the aforementioned abundance estimates for each population.

Comment 8: The CBD asserts that NMFS failed to adequately assess the impacts of the surveys on the Central America DPS of humpback whales. The CBD states that the surveys may disrupt breeding activity, which would have a potential individual effect (*i.e.,* lowering the individual's reproductive fitness), and a population-level impact by decreasing the population's ability to grow and recover, referring to a paper cited by NMFS in the notice of proposed IHA (Cerchio *et al.,* 2014). The CBD recommended NMFS restrict the authorization to the summer months to minimize harm to humpback whales.

Response: The paper referenced by the CBD (Cerchio *et al.,* 2014) describes observations of humpback whales off the coast of Angola reducing their singing activity when exposed to noise from seismic surveys. However, the authors of that paper state that it is impossible to determine from the study whether the decrease in humpback whale singing would translate into detrimental effects on individuals or the population. The CBD does not provide any additional evidence to support its assertion that the effects of L–DEO's proposed activity would have population-level impacts, or to justify its assertion that the recommended temporal restriction is warranted under the MMPA. NMFS does not expect any impacts to the fitness of individual breeding humpback whales or the population as a whole, regardless of the prescribed mitigation. However, as described above, Whales of Guerrero informed NMFS that humpback whales have been observed breeding, calving, and nursing in the region throughout the spring. Based on the information provided by Whales of Guerrero, which showed that humpback whale occurrence in the survey area is generally concentrated in the nearshore waters, and confirmation on the measure's practicability, NMFS is adding a requirement to the IHA to limit L–DEO's survey of the ''nearshore'' tracklines until after May 1, at which point all breeding humpback whales are expected to have left the area, through October 31, before breeding humpback whales are expected to return to the area. Therefore, any potential for impacts to the fitness of individual breeding humpback whales or the

population as a whole is further reduced.

Comment 9: The CBD urged NMFS to use density estimates for waters in the area of the survey specifically, rather than in the greater Eastern Tropical Pacific.

Response: The CBD did not provide any sources for site-specific density estimates of any species. Therefore, NMFS' utilization of the density estimates for the greater Eastern Tropical Pacific to estimate take as the best available science remains valid.

Comment 10: The CBD stated that no one-time, one-year IHA renewal should be issued without an opportunity for public comment published in the **Federal Register** prior to issuance because the timing of the survey could result in much more severe impacts to Central America humpback whales if it interrupts more of their breeding season.

Response: As described in the notice of proposed IHA (87 FR 1992; January 12, 2022), on a case-by-case basis, NMFS may issue a 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 Activity section of the notice of proposed IHA is planned or (2) the activities as described in the Description of Proposed Activity section of the notice of proposed IHA 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 section of this notice, provided specific conditions are met. All proposed Renewal IHAs are posted for public comment in the **Federal Register**. Additionally, all parties that commented on the initial proposed IHA are directly contacted to provide opportunity to submit additional comments. If L–DEO requests an IHA Renewal, NMFS will comply with all procedural requirements, including the 15-day public comment period and notification to the CBD. Any Renewal IHA issued to L–DEO would include the same mitigation requirements as the initial IHA, including the timing restrictions described in the Mitigation section of this notice.

Changes From the Proposed IHA to Final IHA

No changes have been made to the survey equipment, tracklines, or objectives. The only change from the proposed to final IHA is the addition of a requirement to limit surveys of ''nearshore'' tracklines (see definition in the Comments and Responses section and in the Mitigation section of this notice) between May 1 and October 31.

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. Additional information regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SARs; *https://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's website (*https://www.fisheries.noaa.gov/find-species*).

Table 1 lists all species or stocks for which take is expected and authorized for this action, 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. For taxonomy, we follow Committee on Taxonomy (2021). 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's SARs). While no 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's 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 managed stocks in this region are assessed in NMFS's U.S. Pacific SARs. All values presented in Table 1 are the most recent available at the time of publication and are available in the 2020 SARs (Carretta *et al.,* 2021) and draft 2021 SARs (available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports*). Where available, abundance and status information is also presented for marine mammals in the Pacific waters of Mexico and/or the greater ETP region. Table 1 denotes the status of species and stocks under the U.S. MMPA and ESA. We note also that the Guadalupe fur seal is classified as ''En peligro de extinción'' (in danger of extinction) under the Norma Oficial Mexicana NOM–059–SEMARNAT–2010 and all other marine mammal species listed in Table 1, with the exception of Longman's beaked whales and Deraniyagala's beaked whales, are listed as ''Sujetas a protección especial'' (subject to special protection).

TABLE 1—MARINE MAMMALS THAT COULD OCCUR IN THE SURVEY AREA

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]	ETP abundance [4]	Mexico Pacific abundance [5]
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)								
Family Balaenopteridae (rorquals):								
Humpback Whale	*Megaptera novaeangliae.*	Central N Pacific	-, -, Y	10,103 (0.3, 7,890, 2006).	83	26	2,566	
Minke whale	*Balaenoptera acutorostrata.*	N/A	-, -, N	N/A	N/A	N/A	115	
Bryde's whale	*Balaenoptera edeni*	Eastern Tropical Pacific.	-, -, N	Unknown (Unknown, Unknown, N/A).	Undetermined	Unknown	10,411	649
Sei whale	*Balaenoptera borealis*	Eastern N Pacific	E, D, Y	519 (0.4, 374, 2014)	0.75	≥0.2	0	

TABLE 1—MARINE MAMMALS THAT COULD OCCUR IN THE SURVEY AREA—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]	ETP abundance [4]	Mexico Pacific abundance [5]
Fin whale	*Balaenoptera physalus.*	N/A	E, D, Y	N/A	N/A	N/A	574	145
Blue whale	*Balaenoptera musculus.*	Eastern N Pacific	E, D, Y	1,898 (0.085, 1,767, 2018).	4.1	≥19.4	1,415	773
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)								
Family Physeteridae:								
Sperm whale	*Physeter macrocephalus.*	N/A	E, D, Y	N/A	N/A	N/A	4,145	2,810
Family Kogiidae:								
Dwarf Sperm Whale.	*Kogia sima*	N/A	N/A	N/A	N/A	N/A	[6] 11,200	
Family Ziphiidae (beaked whales):								
Cuvier's Beaked Whale.	*Ziphius cavirostris*	N/A	-, -, N	N/A	N/A	N/A	[7] 20,000	[8] 68,828
Longman's beaked whale.	*Indopacetus pacificus*	N/A	-, -, N	N/A	N/A	N/A	1,007	
Blainville's beaked whale.	*Mesoplodon densirostris.*	N/A	-, -, N	N/A	N/A	N/A	[9] 25,300	[8] 68,828
Ginkgo-toothed beaked whale.	*M. ginkgodens*	N/A	-, -, N	N/A	N/A	N/A	[9] 25,300	[8] 68,828
Deraniyagala's beaked whale.	*M. hotaula*	N/A	-, -, N	N/A	N/A	N/A	[9] 25,300	[8] 68,828
Pygmy beaked whale.	*M. peruvianus*	N/A	-, -, N	N/A	N/A	N/A	[9] 25,300	[8] 68,828
Family Delphinidae:								
Risso's dolphin	*Grampus griseus*	N/A	-, -, N	N/A	N/A	N/A	110,457	24,084
Rough-toothed dolphin.	*Steno bredanensis*	N/A	-, -, N	N/A	N/A	N/A	107,663	37,511
Common bottlenose dolphin.	*Tursiops truncatus*	N/A	-, -, N	N/A	N/A	N/A	335,834	61,536
Pantropical spotted dolphin.	*Stenella attenuata*	N/A [10]	-, D, N	N/A	N/A	N/A	[11] 1,297,091	146,296
Spinner dolphin	*Stenella longirostris*	N/A [10]	-, D, N	N/A	N/A	N/A	[11] 2,075,871	186,906
Striped dolphin	*Stenella coeruleoalba*	N/A	-, -, N	N/A	N/A	N/A	964,362	128,867
Short-beaked common dolphin.	*Delphinus delphis*	N/A	-, -, N	N/A	N/A	N/A	3,127,203	283,196
Fraser's dolphin	*Lagenodelphis hosei*	N/A	-, -, N	N/A	N/A	N/A	[7] 289,300	
Short-finned pilot whale.	*Globicephala macrorhynchus.*	N/A	-, -, N	N/A	N/A	N/A	[12] 589,315	3,348
Killer whale	*Orcinus orca*	N/A	-, -, N	N/A	N/A	N/A	[7] 8,500	852
False killer whale	*Pseudorca crassidens*	N/A	-, -, N	N/A	N/A	N/A	[7] 39,800	
Pygmy killer whale	*Feresa attenuata*	N/A	-, -, N	N/A	N/A	N/A	[7] 38,900	
Melon-headed whale.	*Peponocephala electra.*	N/A	-, -, N	N/A	N/A	N/A	[7] 45,400	
Order Carnivora—Superfamily Pinnipedia								
Family Otariidae (eared seals and sea lions):								
Guadalupe fur seal.	*Arctocephalus townsendi.*	Mexico	T, D, Y	34,187 (N/A, 31,019, 2013).	1,062	≥3.8		
California sea lion	*Zalophus californianus*	U.S	-, -, N	257,606 (N/A,233,515, 2014).	14,011	>320	105,000	

[1] 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.

[2] NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports*. CV is coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable.

[3] 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.

[4] From NMFS (2015b) unless otherwise noted.

[5] Pacific Mexico excluding the Gulf of California (from Gerrodette and Palacios (1996) unless otherwise noted).

[6] Estimate for ETP is mostly for *K. sima* but may also include some *K. breviceps* (Wade and Gerrodette 1993).

[7] Wade and Gerrodette 1993.

[8] Abundance for all ziphiids.

[9] This estimate for the ETP includes all species of the genus *Mesoplodon*.

[10] Several stocks of these species, while not classified as such in the U.S. SARs, are considered depleted due to historical interactions with tuna fisheries in the area. Please see the notice of proposed IHA (87 FR 1992; January 12, 2022) for a discussion of these stocks.

As indicated above, all 30 species (with six managed stocks) in Table 1 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur, and we have authorized it. As the planned survey lines are outside of the U.S. EEZ, they do not directly overlap with the defined ranges for most U.S. managed stocks (Carretta *et al.,* 2021). For some species (*e.g.,* Bryde's whale, Guadalupe fur seal; see Table 1), animals encountered during the surveys could be from a defined stock under the MMPA but most marine mammals in the survey area do not belong to any defined stock.

A detailed description of the species likely to be affected by the geophysical surveys, 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 L–DEO's IHA application and summarized in the **Federal Register** notice for the proposed IHA (87 FR 1992; January 12, 2022). Additional information provided by Whales of Guerrero regarding seasonal presence of humpback whales is summarized in the Comments and Responses section above, and their full comment letter is available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-research-and-other-activities.* Since publication of the notice of proposed IHA, we are not aware of any changes in ESA or MMPA status of these species or stocks; therefore, detailed descriptions are not provided here. Please refer to that **Federal Register** notice and the IHA application for these descriptions. Please also refer to NMFS' website (*www.nmfs.noaa.gov/pr/species/mammals/*) 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. Current data indicate that 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) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. 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. 30 marine mammal species (28 cetacean and two pinniped (both otariid) species) have the reasonable potential to co-occur with the planned survey activities. Please refer to Table 1. Of the cetacean species that may be present, six are classified as low-frequency cetaceans (*i.e.,* all mysticete species), 20 are classified as mid-frequency cetaceans (*i.e.,* all delphinid and ziphiid species and the sperm whale), and two are classified as high-frequency cetaceans (*i.e., Kogia* spp.).

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

The effects of underwater noise from L–DEO's geophysical survey activities have the potential to result in behavioral harassment of marine mammals in the vicinity of the survey area. The notice of proposed IHA (87 FR 1992; January 12, 2022) included a discussion of the effects of anthropogenic noise on marine mammals and the potential effects of underwater noise from L–DEO's geophysical survey activities on marine mammals and their habitat. That information and analysis is incorporated by reference into this final IHA determination and is not repeated here; please refer to the notice of proposed IHA (87 FR 1992; January 12, 2022). The referenced information includes a summary and discussion of the ways that the specified activity may impact marine mammals and their habitat. Consistent with the analysis in our prior **Federal Register** notices for similar L–DEO surveys and after independently evaluating the analysis in L–DEO's application, we determine that the survey is likely to result in the takes described in the Estimated Take section of this document and that other forms of take are not expected to occur.

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 Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals are likely to impact marine mammal species or stocks.

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 determination.

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 are primarily by Level B harassment, as use of seismic airguns 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) for mysticetes and high frequency cetaceans (*i.e., Kogia* spp.). The required mitigation and monitoring measures are expected to minimize the severity of such taking to the extent practicable. As described previously, no serious injury or mortality is anticipated or authorized for this activity. Below we describe how the take is estimated.

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 basic factors can contribute to a basic calculation to provide an initial prediction of 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 take estimate.

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 permanent threshold shift (PTS) of some degree (equated to Level A harassment).

Level B Harassment for non-explosive sources—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 (*e.g.,* frequency, predictability, duty cycle), the environment (*e.g.,* bathymetry), and the receiving animals (hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall *et al.,* 2007, Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS predicts that marine mammals are likely to be behaviorally harassed in a manner we consider Level B harassment when exposed to underwater anthropogenic noise above received levels of 120 dB re 1 microPascal (μPa) root mean square (rms) for continuous (*e.g.,* vibratory pile-driving, drilling) and above 160 dB re 1 μPa (rms) for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources.

L–DEO's activity includes the use of impulsive seismic sources, and therefore the 160 dB re 1 μPa (rms) threshold is applicable.

Level A harassment for non-explosive sources—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). L–DEO's planned seismic survey includes the use of impulsive (seismic airguns) 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 *https://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 acoustic thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	*Cell 2:* $L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	*Cell 3:* $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	*Cell 4:* $L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	*Cell 5:* $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	*Cell 6:* $L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	*Cell 7:* $L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	*Cell 8:* $L_{E,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	*Cell 9:* $L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	*Cell 10:* $L_{E,OW,24h}$: 219 dB.

* Dual metric acoustic 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 should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 μPa, and cumulative sound exposure level (L_E) has a reference value of 1μPa^{2}s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript ''flat'' is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. 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 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 acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds, which include source levels and transmission loss coefficient.

The planned 2–D survey would acquire data using the 36-airgun array with a total discharge of 6,600 in^3 at a maximum tow depth of 12 m. L–DEO model results are used to determine the 160-dBrms radius for the 36-airgun array in deep water (>1,000 m) down to a maximum water depth of 2,000 m. Received sound levels were predicted by L–DEO's model (Diebold *et al.,* 2010) which uses ray tracing for the direct wave traveling from the array to the receiver and its associated source ghost (reflection at the air-water interface in the vicinity of the array), in a constant-velocity half-space (infinite homogeneous ocean layer, unbounded by a seafloor). In addition, propagation measurements of pulses from the 36-airgun array at a tow depth of 6 m have been reported in deep water (approximately 1600 m), intermediate water depth on the slope (approximately 600–1100 m), and shallow water (approximately 50 m) in the Gulf of Mexico in 2007–2008 (Tolstoy *et al.* 2009; Diebold *et al.* 2010).

For deep and intermediate-water cases, the field measurements cannot be used readily to derive Level A and Level B harassment isopleths, as at those sites the calibration hydrophone was located at a roughly constant depth of 350–500 m, which may not intersect all the SPL isopleths at their widest point from the sea surface down to the maximum relevant water depth for marine mammals of ~2,000 m. At short ranges, where the direct arrivals dominate and the effects of seafloor interactions are minimal, the data recorded at the deep and slope sites are suitable for comparison with modeled levels at the depth of the calibration hydrophone. At longer ranges, the comparison with the model—constructed from the maximum SPL through the entire water column at varying distances from the airgun array—is the most relevant.

In deep and intermediate-water depths, comparisons at short ranges between sound levels for direct arrivals recorded by the calibration hydrophone and model results for the same array tow depth are in good agreement (Fig. 12 and 14 in Appendix H of NSF–USGS, 2011). Consequently, isopleths falling within this domain can be predicted reliably by the L–DEO model, although they may be imperfectly sampled by measurements recorded at a single depth. At greater distances, the calibration data show that seafloor-reflected and sub-seafloor-refracted arrivals dominate, whereas the direct arrivals become weak and/or incoherent. Aside from local topography effects, the region around the critical distance is where the observed levels rise closest to the model curve. However, the observed sound levels are found to fall almost entirely below the model curve. Thus, analysis of the Gulf of Mexico calibration measurements demonstrates that although simple, the L–DEO model is a robust tool for conservatively estimating isopleths.

For deep water (>1,000 m), L–DEO used the deep-water radii obtained from model results down to a maximum water depth of 2000 m. The radii for intermediate water depths (100–1,000 m) were derived from the deep-water ones by applying a correction factor (multiplication) of 1.5, such that observed levels at very near offsets fall below the corrected mitigation curve (See Fig. 16 in Appendix H of NSF–USGS, 2011).

L–DEO's modeling methodology is described in greater detail in their IHA application. The estimated distances to the Level B harassment isopleths for the array are shown in Table 4. Please note that no survey effort will occur in waters <100 m deep. The estimated isopleth distance specific to shallow water depths are provided for reference only.

TABLE 4—PREDICTED RADIAL DISTANCES TO ISOPLETHS CORRESPONDING TO LEVEL B HARASSMENT THRESHOLD

Source and volume	Tow depth (m)	Water depth (m)	Level B harassment zone (m)
36 airgun array; 6,600 in^3	12	>1,000	[1] 6,733
		100–1,000	[2] 10,100
		<100 [3]	[4] 25,494

[1] Distance based on L–DEO model results.
[2] Distance is based on L–DEO model results with a 1.5 × correction factor between deep and intermediate water depths.
[3] No survey effort will occur in waters <100 m deep.
[4] Distance is based on empirically derived measurements in the Gulf of Mexico with scaling applied to account for differences in tow depth.

Predicted distances to Level A harassment isopleths, which vary based on marine mammal hearing groups, were calculated based on modeling performed by L–DEO using the NUCLEUS source modeling software program and the NMFS User Spreadsheet, described below. The acoustic thresholds for impulsive sounds (*e.g.,* airguns) contained in the Technical Guidance were presented as dual metric acoustic thresholds using both SEL_{cum} and peak sound pressure metrics (NMFS 2018). As dual metrics, NMFS considers onset of PTS (Level A harassment) to have occurred when either one of the two metrics is exceeded (*i.e.,* metric resulting in the largest isopleth). The SEL_{cum} metric considers both level and duration of exposure, as well as auditory weighting functions by marine mammal hearing group. In recognition of the fact that the requirement to calculate Level A

harassment ensonified areas could be more technically challenging to predict due to the duration component and the use of weighting functions in the new SEL_{cum} thresholds, NMFS developed an optional User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to facilitate the estimation of take numbers.

The values for SEL_{cum} and peak SPL for the *Langseth* airgun arrays were derived from calculating the modified far-field signature. The far-field signature is often used as a theoretical representation of the source level. To compute the far-field signature, the source level is estimated at a large distance below the array (*e.g.,* 9 km), and this level is back projected mathematically to a notional distance of 1 m from the array's geometrical center. However, when the source is an array of multiple airguns separated in space, the source level from the theoretical far-field signature is not necessarily the best measurement of the source level that is physically achieved at the source (Tolstoy *et al.,* 2009). Near the source (at short ranges, distances <1 km), the pulses of sound pressure from each individual airgun in the source array do not stack constructively, as they do for the theoretical far-field signature. The pulses from the different airguns spread out in time such that the source levels observed or modeled are the result of the summation of pulses from a few airguns, not the full array (Tolstoy *et al.,* 2009). At larger distances, away from the source array center, sound pressure of all the airguns in the array stack coherently, but not within one time sample, resulting in smaller source levels (a few dB) than the source level derived from the far-field signature. Because the far-field signature does not take into account the large array effect near the source and is calculated as a point source, the modified far-field signature is a more appropriate measure of the sound source level for distributed sound sources, such as airgun arrays. L–DEO used the acoustic modeling methodology as used for estimating Level B harassment distances with a small grid step of 1 m in both the inline and depth directions. The propagation modeling takes into account all airgun interactions at short distances from the source, including interactions between subarrays, which are modeled using the NUCLEUS software to estimate the notional signature and MATLAB software to calculate the pressure signal at each mesh point of a grid.

In order to more realistically incorporate the Technical Guidance's weighting functions over the seismic array's full acoustic band, unweighted spectrum data for the *Langseth's* airgun array (modeled in 1 Hz bands) was used to make adjustments (dB) to the unweighted spectrum levels, by frequency, according to the weighting functions for each relevant marine mammal hearing group. These adjusted/weighted spectrum levels were then converted to pressures (μPa) in order to integrate them over the entire broadband spectrum, resulting in broadband weighted source levels by hearing group that could be directly incorporated within the User Spreadsheet (*i.e.,* to override the Spreadsheet's more simple weighting factor adjustment). Using the User Spreadsheet's ''safe distance'' methodology for mobile sources (described by Sivle *et al.,* 2014) with the hearing group-specific weighted source levels, and inputs assuming spherical spreading propagation and information specific to the planned survey (*i.e.,* the 2.2 m/s source velocity and (worst-case) 50-m shot interval, equivalent to a repetition rate of 23.1 seconds), potential radial distances to auditory injury zones were then calculated for SEL_{cum} thresholds.

Inputs to the User Spreadsheets in the form of estimated source levels are shown in Appendix A of L–DEO's application. User Spreadsheets used by L–DEO to estimate distances to Level A harassment isopleths for the airgun arrays are also provided in Appendix A of the application. Outputs from the User Spreadsheets in the form of estimated distances to Level A harassment isopleths for the survey are shown in Table 5. As described above, NMFS considers onset of PTS (Level A harassment) to have occurred when either one of the dual metrics (SEL_{cum} and Peak SPL_{flat}) is exceeded (*i.e.,* metric resulting in the largest isopleth). L–DEO plans to conduct two different methods of seismic acquisition, MCS using a hydrophone streamer (approximately 62 percent of the total survey effort) and refraction surveys using OBSs (approximately 38 percent of the total survey effort). The airguns would fire at a shot interval of 50 m (repetition rate of 23 seconds) during MCS surveys and at a 400-m interval (repetition rate of 155 seconds) during refraction surveys to OBSs. The distances presented in Table 5 were calculated using the MCS survey inputs as using the 50-m shot interval provides more conservative distances than the 400-m shot interval.

TABLE 5—MODELED RADIAL DISTANCES (m) TO ISOPLETHS CORRESPONDING TO LEVEL A HARASSMENT THRESHOLDS

Source (volume)	Threshold	Level A harassment zone (m)			
		LF cetaceans	MF cetaceans	HF cetaceans	Otariids
36-airgun array (6,600 in³)	SEL_{cum}	320.2	0	1.0	0
	Peak	8.9	13.9	268.3	10.6

Note that because of some of the assumptions included in the methods used (*e.g.,* stationary receiver with no vertical or horizontal movement in response to the acoustic source), isopleths produced may be overestimates to some degree, which will ultimately result in some degree of overestimation of Level A harassment. However, these tools offer the best way to predict appropriate isopleths when more sophisticated modeling methods are not available, and NMFS continues to develop ways to quantitatively refine these tools and will qualitatively address the output where appropriate. For mobile sources, such as the planned seismic survey, the User Spreadsheet predicts the closest distance at which a stationary animal would not incur PTS if the sound source traveled by the animal in a straight line at a constant speed.

Auditory injury is unlikely to occur for mid-frequency cetaceans and otariid pinnipeds, given very small modeled zones of injury for those species (all estimated zones less than 15 m for mid-frequency cetaceans and otariid pinnipeds), in context of distributed source dynamics. The source level of the array is a theoretical definition assuming a point source and measurement in the far-field of the source (MacGillivray, 2006). As

described by Caldwell and Dragoset (2000), an array is not a point source, but one that spans a small area. In the far-field, individual elements in arrays will effectively work as one source because individual pressure peaks will have coalesced into one relatively broad pulse. The array can then be considered a ''point source.'' For distances within the near-field, *i.e.,* approximately 2–3 times the array dimensions, pressure peaks from individual elements do not arrive simultaneously because the observation point is not equidistant from each element. The effect is destructive interference of the outputs of each element, so that peak pressures in the near-field will be significantly lower than the output of the largest individual element. Here, the relevant peak isopleth distances would in all cases be expected to be within the near-field of the array where the definition of source level breaks down. Therefore, actual locations within this distance of the array center where the sound level exceeds the relevant peak SPL thresholds would not necessarily exist. In general, Caldwell and Dragoset (2000) suggest that the near-field for airgun arrays is considered to extend out to approximately 250 m.

In order to provide quantitative support for this theoretical argument, we calculated expected maximum distances at which the near-field would transition to the far-field (Table 5). For a specific array one can estimate the distance at which the near-field transitions to the far-field by:

$$D = \frac{L^2}{4\lambda}$$

with the condition that $D >> \lambda$, and where D is the distance, L is the longest dimension of the array, and λ is the wavelength of the signal (Lurton, 2002). Given that λ can be defined by:

$$\lambda = \frac{v}{f}$$

where f is the frequency of the sound signal and v is the speed of the sound in the medium of interest, one can rewrite the equation for D as:

$$D = \frac{fL^2}{4v}$$

and calculate D directly given a particular frequency and known speed of sound (here assumed to be 1,500 meters per second in water, although this varies with environmental conditions).

To determine the closest distance to the arrays at which the source level predictions in Table 5 are valid (*i.e.,* maximum extent of the near-field), we calculated D based on an assumed frequency of 1 kHz. A frequency of 1 kHz is commonly used in near-field/far-field calculations for airgun arrays (Zykov and Carr, 2014; MacGillivray, 2006; NSF and USGS, 2011), and based on representative airgun spectrum data and field measurements of an airgun array used on the *Langseth,* nearly all (greater than 95 percent) of the energy from airgun arrays is below 1 kHz (Tolstoy *et al.,* 2009). Thus, using 1 kHz as the upper cut-off for calculating the maximum extent of the near-field should reasonably represent the near-field extent in field conditions.

If the largest distance to the peak sound pressure level threshold was equal to or less than the longest dimension of the array (*i.e.,* under the array), or within the near-field, then received levels that meet or exceed the threshold in most cases are not expected to occur. This is because within the near-field and within the dimensions of the array, the source levels specified in Appendix A of L–DEO's application are overestimated and not applicable. In fact, until one reaches a distance of approximately three or four times the near-field distance the average intensity of sound at any given distance from the array is still less than that based on calculations that assume a directional point source (Lurton, 2002). The 6,600-in^3 airgun array planned for use during the planned survey has an approximate diagonal of 28.8 m, resulting in a near-field distance of 138.7 m at 1 kHz (NSF and USGS, 2011). Field measurements of this array indicate that the source behaves like multiple discrete sources, rather than a directional point source, beginning at approximately 400 m (deep site) to 1 km (shallow site) from the center of the array (Tolstoy *et al.,* 2009), distances that are actually greater than four times the calculated 140-m near-field distance. Within these distances, the recorded received levels were always lower than would be predicted based on calculations that assume a directional point source, and increasingly so as one moves closer towards the array (Tolstoy *et al.,* 2009). Given this, relying on the calculated distance (138.7 m) as the distance at which we expect to be in the near-field is a conservative approach since even beyond this distance the acoustic modeling still overestimates the actual received level. Within the near-field, in order to explicitly evaluate the likelihood of exceeding any particular acoustic threshold, one would need to consider the exact position of the animal, its relationship to individual array elements, and how the individual acoustic sources propagate and their acoustic fields interact. Given that within the near-field and dimensions of the array source levels would be below those assumed here, we believe exceedance of the peak pressure threshold would only be possible under highly unlikely circumstances.

In consideration of the received sound levels in the near-field as described above, we expect the potential for Level A harassment of mid-frequency cetaceans, otariid pinnipeds, and phocid pinnipeds to be de minimis, even before the likely moderating effects of aversion and/or other compensatory behaviors (*e.g.,* Nachtigall *et al.,* 2018) are considered. We do not believe that Level A harassment is a likely outcome for any mid-frequency cetacean, otariid pinniped, or phocid pinniped and have not authorized any Level A harassment for these species.

Marine Mammal Occurrence

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations.

L–DEO used habitat-based stratified marine mammal densities for summer for the ETP when available (Barlow *et al.,* 2009), and densities for the ETP from NMFS (2015b) for all other species (Table 6). Barlow *et al.* (2009) used data from 16 NMFS Southwest Fisheries Science Center (SWFSC) ship-based cetacean and ecosystem assessment surveys between 1986 and 2006 to develop habitat models to predict density for 15 cetacean species in the ETP. Model predictions were then used in standard line-transect formulae to estimate density for each transect segment for each survey year. Predicted densities for each year were smoothed with geospatial methods to obtain a continuous grid of density estimates for the surveyed area in the ETP. These annual grids were then averaged to obtain a composite grid that represents our best estimates of cetacean density over the past 20 years in the ETP. The models developed by Barlow *et al.* (2009) have been incorporated into a web-based GIS software system developed by Duke University's Strategic Environmental Research and Development Program. The habitat-based density models consist of 100 km x 100 km grid cells. Densities in the grid cells that overlapped the survey area were averaged for each of the three water depth categories (shallow, intermediate, deep).

The NMFS SWFSC also developed density estimates for species in the ETP that may be affected by their own

fisheries research activities (NMFS 2015b). These estimates were derived from abundance estimates using ship-based surveys of marine mammals in the ETP, as reported by Gerrodette *et al.* (2008). While the SWFSC developed volumetric density estimates (animals/km^3) to account for typical dive depth of each species (0–200 m and >200 m), L–DEO used the area density (animals/km^2) to represent expected density across all water depth strata.

For the sei whale, for which NMFS (2015b) reported a density of zero, L–DEO used the spring density for Baja from U.S. Navy (2017b). No regional density estimates are available for Guadalupe fur seals in the ETP; therefore, NMFS (2015b) used the density of Guadalupe fur seals in the California Current Ecosystem (CCE) as a proxy. However, as the survey area is south of the typical range of Guadalupe fur seals (Ortiz *et al.,* 2019), the density from the CCE is likely an overestimate. In the survey area, Guadalupe fur seals are extremely unlikely to occur in waters over the continental shelf under 2,000 m (T. Norris, pers. comm.). NMFS has therefore assumed that the density of Guadalupe fur seals in water depths under 2,000 m is zero animals per square km, and have retained the CCE density estimate for waters over 2,000 m deep (Table 6).

TABLE 6—ESTIMATED DENSITIES OF MARINE MAMMALS IN THE SURVEY AREA

Species	Density (#/km^2) in survey area		
	Shallow water (<100 m)	Intermediate water (100–1,000 m)	Deep water (>1,000 m)
Humpback whale	[1] 0.00013	[1] 0.00013	[1] 0.00013
Minke whale	[1] 0.00001	[1] 0.00001	[1] 0.00001
Bryde's whale	[2] 0.000486	[2] 0.000489	[2] 0.000451
Fin whale	[1] 0.00003	[1] 0.00003	[1] 0.00003
Sei whale	[3] 0.00005	[3] 0.00005	[3] 0.00005
Blue whale	[2] 0.00010	[2] 0.00009	[2] 0.00008
Sperm whale	[1] 0.00019	[1] 0.00019	[1] 0.00019
Cuvier's beaked whale	[2] 0.00105	[2] 0.00106	[2] 0.00107
Longman's beaked whale	[1] 0.00004	[1] 0.00004	[1] 0.00004
Mesoplodon spp.[4]	[2] 0.00032	[2] 0.00033	[2] 0.00036
Risso's dolphin	[1] 0.00517	[1] 0.00517	[1] 0.00517
Rough-toothed dolphin	[2] 0.00880	[2] 0.00891	[2] 0.00945
Common bottlenose dolphin	[2] 0.04809	[2] 0.04502	[2] 0.03557
Pantropical spotted dolphin	[1] 0.12263	[1] 0.12263	[1] 0.12263
Spinner dolphin (whitebelly)	[2] 0.00148	[2] 0.00155	[2] 0.00193
Spinner dolphin (eastern)	[2] 0.13182	[2] 0.12989	[2] 0.12791
Striped dolphin	[2] 0.02800	[2] 0.02890	[2] 0.03516
Short-beaked common dolphin	[2] 0.04934	[2] 0.04881	[2] 0.04435
Fraser's dolphin	[1] 0.01355	[1] 0.01355	[1] 0.01355
Short-finned pilot whale[5]	[2] 0.00346	[2] 0.00344	[2] 0.00382
Killer whale	[1] 0.0004	[1] 0.0004	[1] 0.0004
False killer whale	[1] 0.00186	[1] 0.00186	[1] 0.00186
Pygmy killer whale	[1] 0.00183	[1] 0.00183	[1] 0.00183
Melon-headed whale	[1] 0.00213	[1] 0.00213	[1] 0.00213
Kogia spp.	[1] 0.00053	[1] 0.00053	[1] 0.00053
Guadalupe fur seal	0	[1] [6] 0.00741	[1] 0.00741
California sea lion	[1] 0.16262	[1] 0.16262	[7] 0

[1] Density in greater ETP (NMFS 2015b).
[2] Density in planned survey area (Barlow *et al.,* 2009).
[3] Density for Baja (U.S. Navy 2017b).
[4] Density for Mesoplodon species guild (Blainville's beaked whale, Gingko-toothed beaked whale, Deraniyagala's beaked whale, and pygmy beaked whale).
[5] Density for *Globicephala* species guild.
[6] Density is assumed to be zero in waters <2,000 m.
[7] Density is assumed to be zero in deep water (>1,000 m).

Take Calculation and Estimation

Here we describe how the information provided above is brought together to produce a quantitative take estimate.

In order to estimate the number of marine mammals predicted to be exposed to sound levels that would result in Level A or Level B harassment, radial distances from the airgun array to predicted isopleths corresponding to the Level A harassment and Level B harassment thresholds are calculated, as described above. Those radial distances are then used to calculate the area(s) around the airgun array predicted to be ensonified to sound levels that exceed the Level A and Level B harassment thresholds. L–DEO identified specific seismic survey trackline(s) that could be surveyed on one day of research; in this case, a representative 182-km MCS line and a 222-km long OBS line were chosen. The distances to the 160-dB Level B harassment threshold and PTS (Level A harassment) thresholds (based on L–DEO model results) were used to draw a buffer around every transect line in GIS to determine the daily ensonified area in each depth category. The ensonified areas were then multiplied by the number of survey days (7 days for OBS survey effort; 13 days for MCS survey effort) increased by 25 percent. As noted previously, L–DEO has added 25 percent in the form of operational days, which is equivalent to adding 25 percent to the planned line kilometers to be surveyed. This accounts for the possibility that additional operational days are required, but likely results in an overestimate of actual exposures. For additional details regarding calculations of ensonified area, please see Appendix D of L–DEO's application. L–DEO's estimated incidents of exposure above Level A and Level B harassment criteria are presented in Table 7.

As previously noted, NMFS does not have authority under the MMPA within the territorial seas of foreign nations (from 0–12 nmi (22.2 km) from shore), as the MMPA does not apply in those waters, and therefore does not authorize incidental take that may occur as a result of activities occurring within territorial waters. However, NMFS has still calculated the estimated level of incidental take in the entire activity area (including Mexican territorial waters) as part of the analysis supporting our determination under the MMPA that the activity will have a negligible impact on the affected species. The total estimated take in U.S. and Mexican waters is presented in Table 8 (see Negligible Impact Analysis and Determination).

L–DEO generally assumed that their estimates of marine mammal exposures above harassment thresholds to equate to take and requested authorization of those takes. Those estimates in turn form the basis for our take authorization numbers. For the species for which NMFS does not expect there to be a reasonable potential for take by Level A harassment to occur, *i.e.,* mid-frequency cetaceans and all pinnipeds, we have added L–DEO's estimated exposures above Level A harassment thresholds (and requests for take by Level A harassment) to their estimated exposures above the Level B harassment threshold to produce a total number of incidents of take by Level B harassment that is authorized. Estimated exposures and authorized take numbers are shown in Table 7.

TABLE 7—ESTIMATED AND AUTHORIZED TAKE BY LEVEL A AND LEVEL B HARASSMENT, AND PERCENTAGE OF POPULATION

Species	Estimated takes by Level B harassment	Estimated takes by Level A harassment	Authorized takes by Level B harassment	Authorized takes by Level A harassment	Total authorized take	Regional population size	Percent of population
Humpback whale	8	0	8	0	8	[a] 2,566	0.31
Minke whale	1	0	[b] 2	0	[b] 2	115	1.74
Bryde's whale	27	1	27	1	28	[a] 649	4.31
Fin whale	2	0	2	0	2	[a] 145	1.38
Sei whale	3	0	3	0	3	[c] 29,600	0.01
Blue whale	5	0	5	0	5	773	0.65
Sperm whale	12	0	12	0	12	2,810	0.43
Cuvier's beaked whale	69	0	69	0	69	[c] 20,000	0.35
Longman's beaked whale	3	0	3	0	3	[c] 1,007	0.30
Mesoplodon spp.	23	0	23	0	23	[c] 25,300	0.09
Risso's dolphin	327	1	328	0	328	[a] 24,084	1.36
Rough-toothed dolphin	596	1	597	0	597	[a] 37,511	1.59
Common bottlenose dolphin	2,268	6	2,274	0	2,274	[a] 61,536	3.70
Pantropical spotted dolphin	7,973	15	7,988	0	7,988	[a] 146,296	5.46
Spinner dolphin (whitebelly)	121	0	121	0	121	[a] 186,906	0.06
Spinner dolphin (eastern)	8,173	16	8,189	0	8,189	[a] 186,906	4.38
Striped dolphin	2,209	3	2,212	0	2,212	[a] 128,867	1.72
Short-beaked common dolphin	2,812	6	2,818	0	2,818	[a] 283,196	1.00
Fraser's dolphin	856	2	858	0	858	[c] 289,300	0.30
Short-finned pilot whale	244	0	244	0	244	[a] 3,348	7.29
Killer whale	25	0	25	0	25	[a] 852	2.93
False killer whale	118	0	118	0	118	[c] 39,600	0.30
Pygmy killer whale	116	0	116	0	116	[c] 38,900	0.30
Melon-headed whale	135	0	135	0	135	[c] 45,400	0.30
Kogia spp	33	1	33	1	34	[c d] 11,200	0.30
Guadalupe fur seal	415	1	416	0	416	[c] 34,187	1.22
California sea lion	349	16	365	0	365	[c] 105,000	0.35

[a] Estimated population in Pacific waters of Mexico (Gerrodette and Palacios (1996)).
[b] Authorized take increased to maximum group size.
[c] Population in ETP or wider Pacific (NMFS 2015b).
[d] Population of *Kogia* species guild.

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, we carefully consider 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, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

In order to satisfy the MMPA's least practicable adverse impact standard, NMFS has evaluated a suite of basic mitigation protocols for seismic surveys that are required regardless of the status of a stock. Additional or enhanced protections may be required for species whose stocks are in particularly poor health and/or are subject to some significant additional stressor that lessens that stock's ability to weather the effects of the specified activities without worsening its status. We reviewed seismic mitigation protocols required or recommended elsewhere (*e.g.,* HESS, 1999; DOC, 2013; IBAMA, 2018; Kyhn *et al.,* 2011; JNCC, 2017; DEWHA, 2008; BOEM, 2016; DFO, 2008; GHFS, 2015; MMOA, 2016; Nowacek *et al.,* 2013; Nowacek and Southall, 2016), recommendations received during public comment periods for previous actions, and the available scientific literature. We also considered recommendations given in a number of review articles (*e.g.,* Weir and Dolman, 2007; Compton *et al.,* 2008; Parsons *et al.,* 2009; Wright and Cosentino, 2015; Stone, 2015b). This exhaustive review and consideration of public comments regarding previous, similar activities has led to development of the protocols included here.

Vessel-Based Visual Mitigation Monitoring

Visual monitoring requires the use of trained observers (herein referred to as visual protected species observers (PSOs)) to scan the ocean surface for the presence of marine mammals. The area to be scanned visually includes primarily the exclusion zone (EZ), within which observation of certain marine mammals requires shutdown of the acoustic source, but also a buffer zone and, to the extent possible depending on conditions, the surrounding waters. The buffer zone means an area beyond the EZ to be monitored for the presence of marine mammals that may enter the EZ. During pre-start clearance monitoring (*i.e.,* before ramp-up begins), the buffer zone also acts as an extension of the EZ in that observations of marine mammals within the buffer zone would also prevent airgun operations from beginning (*i.e.,* ramp-up). The buffer zone encompasses the area at and below the sea surface from the edge of the 0–500 m EZ, out to a radius of 1,000 m from the edges of the airgun array (500–1,000 m). This 1,000-m zone (EZ plus buffer) represents the pre-start clearance zone. Visual monitoring of the EZ and adjacent waters is intended to establish and, when visual conditions allow, maintain zones around the sound source that are clear of marine mammals, thereby reducing or eliminating the potential for injury and minimizing the potential for more severe behavioral reactions for animals occurring closer to the vessel. Visual monitoring of the buffer zone is intended to (1) provide additional protection to marine mammals that may be in the vicinity of the vessel during pre-start clearance, and (2) during airgun use, aid in establishing and maintaining the EZ by alerting the visual observer and crew of marine mammals that are outside of, but may approach and enter, the EZ.

L–DEO must use dedicated, trained, NMFS-approved PSOs. The PSOs must have no tasks other than to conduct observational effort, record observational data, and communicate with and instruct relevant vessel crew with regard to the presence of marine mammals and mitigation requirements. PSO resumes shall be provided to NMFS for approval.

At least one of the visual and two of the acoustic PSOs (discussed below) aboard the vessel must have a minimum of 90 days at-sea experience working in those roles, respectively, with no more than 18 months elapsed since the conclusion of the at-sea experience. One visual PSO with such experience must be designated as the lead for the entire protected species observation team. The lead PSO must serve as primary point of contact for the vessel operator and ensure all PSO requirements per the IHA are met. To the maximum extent practicable, the experienced PSOs must be scheduled to be on duty with those PSOs with appropriate training but who have not yet gained relevant experience.

During survey operations (*e.g.,* any day on which use of the acoustic source is planned to occur, and whenever the acoustic source is in the water, whether activated or not), a minimum of two visual PSOs must be on duty and conducting visual observations at all times during daylight hours (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset). Visual monitoring of the pre-start clearance zone must begin no less than 30 minutes prior to ramp-up, and monitoring must continue until one hour after use of the acoustic source ceases or until 30 minutes past sunset. Visual PSOs must 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 and in a consistent, systematic, and diligent manner.

PSOs must establish and monitor the exclusion and buffer zones. These zones must be based upon the radial distance from the edges of the acoustic source (rather than being based on the center of the array or around the vessel itself). During use of the acoustic source (*i.e.,* anytime airguns are active, including ramp-up), detections of marine mammals within the buffer zone (but outside the EZ) must be communicated to the operator to prepare for the potential shutdown of the acoustic source. Visual PSOs must immediately communicate all observations to the on duty acoustic PSO(s), including any determination by the PSO regarding species identification, distance, and bearing and the degree of confidence in the determination. Any observations of marine mammals by crew members must be relayed to the PSO team. During good conditions (*e.g.,* daylight hours; Beaufort sea state (BSS) 3 or less), visual PSOs must conduct observations when the acoustic source is not operating for comparison of sighting rates and behavior with and without use of the acoustic source and between acquisition periods, to the maximum extent practicable.

Visual PSOs may be on watch for a maximum of 4 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. Combined observational duties (visual and acoustic but not at same time) may not exceed 12 hours per 24-hour period for any individual PSO.

Passive Acoustic Monitoring

Acoustic monitoring means the use of trained personnel (sometimes referred to as passive acoustic monitoring (PAM) operators, herein referred to as acoustic PSOs) to operate PAM equipment to acoustically detect the presence of marine mammals. Acoustic monitoring involves acoustically detecting marine mammals regardless of distance from the source, as localization of animals may not always be possible. Acoustic monitoring is intended to further support visual monitoring (during

daylight hours) in maintaining an EZ around the sound source that is clear of marine mammals. In cases where visual monitoring is not effective (*e.g.,* due to weather, nighttime), acoustic monitoring may be used to allow certain activities to occur, as further detailed below.

PAM must take place in addition to the visual monitoring program. Visual monitoring typically is not effective during periods of poor visibility or at night, and even with good visibility, is unable to detect marine mammals when they are below the surface or beyond visual range. Acoustic monitoring can be used in addition to visual observations to improve detection, identification, and localization of cetaceans. The acoustic monitoring would serve to alert visual PSOs (if on duty) when vocalizing cetaceans are detected. It is only useful when marine mammals vocalize, but it can be effective either by day or by night, and does not depend on good visibility. It must be monitored in real time so that the visual observers can be advised when cetaceans are detected.

The R/V *Langseth* must use a towed PAM system, which must be monitored by at a minimum one on duty acoustic PSO beginning at least 30 minutes prior to ramp-up and at all times during use of the acoustic source. Acoustic PSOs may be on watch for a maximum of 4 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. Combined observational duties (acoustic and visual but not at same time) may not exceed 12 hours per 24-hour period for any individual PSO.

Survey activity may continue for 30 minutes when the PAM system malfunctions or is damaged, while the PAM operator diagnoses the issue. If the diagnosis indicates that the PAM system must be repaired to solve the problem, operations may continue for an additional 5 hours without acoustic monitoring during daylight hours only under the following conditions:

- Sea state is less than or equal to BSS 4;
- No marine mammals (excluding delphinids) detected solely by PAM in the applicable EZ in the previous 2 hours;
- NMFS is notified via email as soon as practicable with the time and location in which operations began occurring without an active PAM system; and
- Operations with an active acoustic source, but without an operating PAM system, do not exceed a cumulative total of 5 hours in any 24-hour period.

Establishment of Exclusion and Pre-Start Clearance Zones

An EZ is a defined area within which occurrence of a marine mammal triggers mitigation action intended to reduce the potential for certain outcomes, *e.g.,* auditory injury, disruption of critical behaviors. The PSOs must establish a minimum EZ with a 500-m radius. The 500-m EZ must be based on radial distance from the edge of the airgun array (rather than being based on the center of the array or around the vessel itself). With certain exceptions (described below), if a marine mammal appears within or enters this zone, the acoustic source must be shut down.

The pre-start clearance zone is defined as the area that must be clear of marine mammals prior to beginning ramp-up of the acoustic source, and includes the EZ plus the buffer zone. Detections of marine mammals within the pre-start clearance zone must prevent airgun operations from beginning (*i.e.,* ramp-up).

The 500-m EZ is intended to be precautionary in the sense that it would be expected to contain sound exceeding the injury criteria for all cetacean hearing groups, (based on the dual criteria of SEL_{cum} and peak SPL), while also providing a consistent, reasonably observable zone within which PSOs would typically be able to conduct effective observational effort. Additionally, a 500-m EZ is expected to minimize the likelihood that marine mammals will be exposed to levels likely to result in more severe behavioral responses. Although significantly greater distances may be observed from an elevated platform under good conditions, we believe that 500 m is likely regularly attainable for PSOs using the naked eye during typical conditions. The pre-start clearance zone simply represents the addition of a buffer to the EZ, doubling the EZ size during pre-clearance.

An extended EZ of 1,500 m must be enforced for all beaked whales and *Kogia* species. No buffer of this extended EZ is required.

Pre-Start Clearance and Ramp-Up

Ramp-up (sometimes referred to as ''soft start'') means the gradual and systematic increase of emitted sound levels from an airgun array. Ramp-up begins by first activating a single airgun of the smallest volume, followed by doubling the number of active elements in stages until the full complement of an array's airguns are active. Each stage should be approximately the same duration, and the total duration must not be less than approximately 20 minutes. The intent of pre-start clearance observation (30 minutes) is to ensure no protected species are observed within the pre-clearance zone (or extended EZ, for beaked whales and *Kogia* spp.) prior to the beginning of ramp-up. During pre-start clearance period is the only time observations of marine mammals in the buffer zone would prevent operations (*i.e.,* the beginning of ramp-up). The intent of ramp-up is to warn marine mammals of pending seismic survey operations and to allow sufficient time for those animals to leave the immediate vicinity. A ramp-up procedure, involving a step-wise increase in the number of airguns firing and total array volume until all operational airguns are activated and the full volume is achieved, is required at all times as part of the activation of the acoustic source. 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 must not be less than 60 minutes prior to the planned ramp-up in order to allow the PSOs time to monitor the pre-start clearance zone (and extended EZ) for 30 minutes prior to the initiation of ramp-up (pre-start clearance);
- Ramp-ups must be scheduled so as to minimize the time spent with the source activated prior to reaching the designated run-in;
- One of the PSOs 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;
- Ramp-up may not be initiated if any marine mammal is within the applicable exclusion or buffer zone. If a marine mammal is observed within the pre-start clearance zone (or extended EZ, for beaked whales and *Kogia* species) 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 (15 minutes for small odontocetes and pinnipeds, and 30 minutes for all mysticetes and all other odontocetes, including sperm whales, beaked whales, and large delphinids, such as killer whales);
- Ramp-up must begin by activating a single airgun of the smallest volume in the array and shall continue in stages by doubling the number of active elements at the commencement of each stage, with each stage of approximately the same duration. Duration must not be less than 20 minutes. The operator must

provide information to the PSO documenting that appropriate procedures were followed;

- PSOs must monitor the pre-start clearance zone (and extended EZ) during ramp-up, and ramp-up must cease and the source must be shut down upon detection of a marine mammal within the applicable zone. Once ramp-up has begun, detections of marine mammals within the buffer zone do not require shutdown, but such observation must be communicated to the operator to prepare for the potential shutdown;
- Ramp-up may occur at times of poor visibility, including nighttime, if appropriate acoustic monitoring has occurred with no detections in the 30 minutes prior to beginning ramp-up. Acoustic source activation may only occur at times of poor visibility 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 that described for shutdown (*e.g.,* mechanical difficulty), it may be activated again without ramp-up if PSOs have maintained constant visual and/or acoustic observation and no visual or acoustic detections of marine mammals have occurred within the applicable EZ. For any longer shutdown, pre-start clearance observation and ramp-up are required. For any shutdown at night or in periods of poor visibility (*e.g.,* BSS 4 or greater), ramp-up is required, but if the shutdown period was brief and constant observation was maintained, pre-start clearance watch of 30 minutes is not required; and
- Testing of the acoustic source involving all elements requires ramp-up. Testing limited to individual source elements or strings does not require ramp-up but does require pre-start clearance of 30 min.

Shutdown

The shutdown of an airgun array requires the immediate de-activation of all individual airgun elements of the array. Any PSO on duty will have the authority to delay the start of survey operations or to call for shutdown of the acoustic source if a marine mammal is detected within the applicable EZ. The operator must also establish and maintain clear lines of communication directly between PSOs on duty and crew controlling the acoustic source to ensure that shutdown commands are conveyed swiftly while allowing PSOs to maintain watch. When both visual and acoustic PSOs are on duty, all detections must be immediately communicated to the remainder of the on-duty PSO team for potential verification of visual observations by the acoustic PSO or of acoustic detections by visual PSOs. When the airgun array is active (*i.e.,* anytime one or more airguns is active, including during ramp-up) and (1) a marine mammal appears within or enters the applicable EZ and/or (2) a marine mammal (other than delphinids, see below) is detected acoustically and localized within the applicable EZ, the acoustic source must be shut down. When shutdown is called for by a PSO, the acoustic source must be immediately deactivated and any dispute resolved only following deactivation. Additionally, shutdown must occur whenever PAM alone (without visual sighting), confirms presence of marine mammal(s) in the EZ. If the acoustic PSO cannot confirm presence within the EZ, visual PSOs must be notified but shutdown is not required.

Following a shutdown, airgun activity must not resume until the marine mammal has cleared the EZ. The animal is considered to have cleared the EZ if it is visually observed to have departed the EZ (*i.e.,* animal is not required to fully exit the buffer zone where applicable), or it has not been seen within the EZ for 15 minutes for small odontocetes and pinnipeds, or 30 minutes for all mysticetes and all other odontocetes, including sperm whales, beaked whales, *Kogia* species, and large delphinids, such as killer whales.

The shutdown requirement is waived for small dolphins if an individual is detected within the EZ. As defined here, the small dolphin group is intended to encompass those members of the Family Delphinidae most likely to voluntarily approach the source vessel for purposes of interacting with the vessel and/or airgun array (*e.g.,* bow riding). This exception to the shutdown requirement applies solely to specific genera of small dolphins (*Delphinus, Lagenodelphis, Lissodelphis, Stenella, Steno, and Tursiops*).

We include this small dolphin exception because shutdown requirements for small dolphins under all circumstances represent practicability concerns without likely commensurate benefits for the animals in question. Small dolphins are generally the most commonly observed marine mammals in the specific geographic region and would typically be the only marine mammals likely to intentionally approach the vessel. As described above, auditory injury is extremely unlikely to occur for mid-frequency cetaceans (*e.g.,* delphinids), as this group is relatively insensitive to sound produced at the predominant frequencies in an airgun pulse while also having a relatively high threshold for the onset of auditory injury (*i.e.,* permanent threshold shift).

A large body of anecdotal evidence indicates that small dolphins commonly approach vessels and/or towed arrays during active sound production for purposes of bow riding, with no apparent effect observed in those delphinoids (*e.g.,* Barkaszi *et al.,* 2012, Barkaszi and Kelly, 2018). The potential for increased shutdowns resulting from such a measure would require the *Langseth* to revisit the missed track line to reacquire data, resulting in an overall increase in the total sound energy input to the marine environment and an increase in the total duration over which the survey is active in a given area. Although other mid-frequency hearing specialists (*e.g.,* large delphinids) are no more likely to incur auditory injury than are small dolphins, they are much less likely to approach vessels. Therefore, retaining a shutdown requirement for large delphinids would not have similar impacts in terms of either practicability for the applicant or corollary increase in sound energy output and time on the water. We do anticipate some benefit for a shutdown requirement for large delphinids in that it simplifies somewhat the total range of decision-making for PSOs and may preclude any potential for physiological effects other than to the auditory system as well as some more severe behavioral reactions for any such animals in close proximity to the *Langseth.*

Visual PSOs must use best professional judgment in making the decision to call for a shutdown if there is uncertainty regarding identification (*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 EZ).

L–DEO must implement shutdown if a marine mammal species for which take was not authorized, or a species for which authorization was granted but the takes have been met, approaches the Level A or Level B harassment zones. L–DEO must also implement shutdown if any large whale (defined as a sperm whale or any mysticete species) with a calf (defined as an animal less than two-thirds the body size of an adult observed to be in close association with an adult) and/or an aggregation of six or more large whales are observed at any distance.

Vessel Strike Avoidance

Vessel operators and crews must maintain a vigilant watch for all protected species and slow down, stop their vessel, or alter course, as

appropriate and regardless of vessel size, to avoid striking any marine mammal. A visual observer aboard the vessel must monitor a vessel strike avoidance zone 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 marine mammals from other phenomena and (2) broadly to identify a marine mammal as a whale or other marine mammal.

Vessel speeds must be reduced 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 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). If marine mammals are sighted within the relevant separation distance, the vessel must reduce speed and shift the engine to neutral, not engaging the engines until animals are clear of the area. This does not apply to any vessel towing gear or any vessel that is navigationally constrained.

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.

Operational Restrictions

L–DEO has agreed to limit surveys of all ''nearshore'' tracklines (*i.e.,* tracklines occurring in, or which are anticipated to result in ensonification above the Level B harassment threshold of, areas where humpback whale sightings have been recorded during the migratory period, *e.g.,* the 264-km MCS and OBS trackline nearest and parallel to the shoreline, and all lines landward of that trackline) to between May 1 and October 31. Offshore tracklines may be surveyed outside that date range. This is included as a requirement of the IHA.

We have carefully evaluated the suite of mitigation measures described here and considered a range of other measures in the context of ensuring that we prescribe the means of effecting the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. Based on our evaluation of the required measures, as well as other measures considered by NMFS described above, 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.

Mitigation Measures in Mexican Waters

As stated previously, NMFS cannot authorize the incidental take of marine mammals in the territorial seas of foreign nations, as the MMPA does not apply in those waters. L–DEO is required to adhere to the mitigation measures described above while operating within the Mexican EEZ and International Waters. The requirements do not apply within Mexican territorial waters. Mexico may prescribe mitigation measures that would apply to survey operations within the Mexican EEZ and territorial waters but NMFS is currently unaware of any specific potential requirements. While operating within the Mexican EEZ but outside Mexican territorial waters, if mitigation requirements prescribed by NMFS differ from the requirements established under Mexican law, L–DEO must adhere to the most protective measure. For operations in Mexican territorial waters, L–DEO would implement measures required under Mexican law (if any). No new information is available on mitigation measures required under Mexican law.

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 in the survey area. 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).
- Mitigation and monitoring effectiveness.

Vessel-Based Visual Monitoring

As described above, PSO observations must take place during daytime airgun operations. During seismic survey operations, at least five visual PSOs must be based aboard the *Langseth.* Two visual PSOs must be on duty at all time during daytime hours. Monitoring must be conducted in accordance with the following requirements:

- The operator must provide PSOs with bigeye binoculars (*e.g.,* 25 x 150; 2.7 view angle; individual ocular focus; height control) of appropriate quality (*i.e.,* Fujinon or equivalent) solely for PSO use. These must be pedestal-mounted on the deck at the most appropriate vantage point that provides for optimal sea surface observation, PSO safety, and safe operation of the vessel; and
- The operator must work with the selected third-party observer 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.

PSOs must have the following requirements and qualifications:

- PSOs must be independent, dedicated, trained visual and acoustic PSOs and must be employed by a third-party observer provider;
- PSOs must have no tasks other than to conduct observational effort (visual or acoustic), collect data, and communicate with and instruct relevant vessel crew with regard to the presence of protected species and mitigation requirements (including brief alerts regarding maritime hazards);
- PSOs must have successfully completed an approved PSO training course appropriate for their designated task (visual or acoustic). Acoustic PSOs are required to complete specialized training for operating PAM systems and are encouraged to have familiarity with the vessel with which they will be working;
- PSOs can act as acoustic or visual observers (but not at the same time) as long as they demonstrate that their training and experience are sufficient to perform the task at hand;
- NMFS must review and approve PSO resumes accompanied by a relevant training course information packet that includes the name and qualifications (*i.e.,* experience, training completed, or educational background) of the instructor(s), the course outline or syllabus, and course reference material as well as a document stating successful completion of the course;
- 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; and
- 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. Requests shall be granted or denied (with justification) by NMFS within 1 week of receipt of submitted information. 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 protected species surveys; or (3) previous work experience as a PSO; the PSO must demonstrate good standing and consistently good performance of PSO duties.

For data collection purposes, PSOs must use standardized data collection forms, whether hard copy or electronic. PSOs must record detailed information about any implementation of mitigation requirements, including the distance of animals 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 must record a description of the circumstances. At a minimum, the following information must be recorded:

- Vessel names (source vessel and other vessels associated with survey) and call signs;
- PSO names and affiliations;
- Dates of departures and returns to port with port name;
- Date and participants of PSO briefings;
- Dates and times (Greenwich Mean Time) of survey effort and times corresponding with PSO effort;
- Vessel location (latitude/longitude) when survey effort began and ended and vessel location at beginning and end of visual PSO duty shifts;
- Vessel heading and speed at beginning and end of visual PSO duty shifts and upon any line change;
- Environmental conditions while on visual survey (at beginning and end of PSO shift and whenever conditions changed significantly), including BSS and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon;
- Factors that may have contributed to impaired observations during each PSO shift change or as needed as environmental conditions changed (*e.g.,* vessel traffic, equipment malfunctions); and
- Survey activity information, such as acoustic source power output while in operation, number and volume of airguns operating in the array, tow depth of the array, and any other notes of significance (*i.e.,* pre-start clearance, ramp-up, shutdown, testing, shooting, ramp-up completion, end of operations, streamers, etc.).

The following information must be recorded upon visual observation of any protected species:

- Watch status (sighting made by PSO on/off effort, opportunistic, crew, alternate vessel/platform);
- PSO who sighted the animal;
- Time of sighting;
- Vessel location at time of sighting;
- Water depth;
- Direction of vessel's travel (compass direction);
- Direction of animal's travel relative to the vessel;
- Pace of the animal;
- Estimated distance to the animal and its heading relative to vessel at initial sighting;
- Identification of the animal (*e.g.,* genus/species, lowest possible taxonomic level, or unidentified) and the composition of the group if there is a mix of species;
- Estimated number of animals (high/low/best);
- Estimated number of animals by cohort (adults, yearlings, juveniles, calves, group composition, etc.);
- 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);
- Detailed behavior observations (*e.g.,* number of blows/breaths, number of surfaces, breaching, spyhopping, diving, feeding, traveling; as explicit and detailed as possible; note any observed changes in behavior);
- Animal's closest point of approach (CPA) and/or closest distance from any element of the acoustic source;
- Platform activity at time of sighting (*e.g.,* deploying, recovering, testing, shooting, data acquisition, other); and
- 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 marine mammal is detected while using the PAM system, the following information must be recorded:

- An acoustic encounter identification number, and whether the detection was linked with a visual sighting;
- Date and time when first and last heard;
- Types and nature of sounds heard (*e.g.,* clicks, whistles, creaks, burst pulses, continuous, sporadic, strength of signal); and
- Any additional information recorded such as water depth of the hydrophone array, bearing of the animal to the vessel (if determinable), species or taxonomic group (if determinable), spectrogram screenshot, and any other notable information.

Reporting

A report must be submitted to NMFS within 90 days after the end of the cruise. The report must summarize the dates and locations of seismic survey operations, and all marine mammal sightings (dates, times, locations, activities, associated seismic survey activities), and provide full documentation of methods, results, and interpretation pertaining to all monitoring.

The draft report must also include geo-referenced time-stamped vessel tracklines for all time periods during which airguns were operating. Tracklines must include points recording any change in airgun status (*e.g.,* when the airguns began operating, when they were turned off, or when they changed from full array to single gun or vice versa). GIS files must be provided in ESRI shapefile format and include the UTC date and time, latitude in decimal degrees, and longitude in decimal degrees. All coordinates must be referenced to the WGS84 geographic coordinate system. In addition to the report, all raw observational data must be made available to NMFS. The report must summarize the data collected as described above and in the IHA. A final report must be submitted within 30 days following resolution of any comments on the draft report.

Reporting Injured or Dead Marine Mammals

Discovery of injured or dead marine mammals—In the event that personnel involved in survey activities covered by the authorization discover an injured or dead marine mammal, the L–DEO must report the incident to the Office of Protected Resources (OPR), NMFS and to the NMFS West Coast Regional Stranding Coordinator as soon as feasible. The report must include the following information:

- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal was discovered.

Vessel strike—In the event of a ship strike of a marine mammal by any vessel involved in the activities covered by the authorization, L–DEO must report the incident to OPR, NMFS and to the NMFS West Coast Regional Stranding Coordinator as soon as feasible. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Vessel's speed during and leading up to the incident;
- Vessel's course/heading and what operations were being conducted (if applicable);
- Status of all sound sources in use;
- Description of avoidance measures/requirements that were in place at the time of the strike and what additional measure were taken, if any, to avoid strike;
- Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, visibility) immediately preceding the strike;
- Species identification (if known) or description of the animal(s) involved;
- Estimated size and length of the animal that was struck;
- Description of the behavior of the animal immediately preceding and following the strike;
- If available, description of the presence and behavior of any other marine mammals present immediately preceding the strike;
- 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
- To the extent practicable, photographs or video footage of the animal(s).

Actions To Minimize Additional Harm to Live-Stranded (or Milling) Marine Mammals

In the event of a live stranding (or near-shore atypical milling) event within 50 km of the survey operations, where the NMFS stranding network is engaged in herding or other interventions to return animals to the water, the Director of OPR, NMFS (or designee) will advise L–DEO of the need to implement shutdown for all active acoustic sources operating within 50 km of the stranding. Procedures related to shutdowns for live stranding or milling marine mammals include the following:

- If at any time, the marine mammal(s) die or are euthanized, or if herding/intervention efforts are stopped, the Director of OPR, NMFS (or designee) will advise L–DEO that the shutdown around the animals' location is no longer needed.
- Otherwise, shutdown procedures will remain in effect until the Director of OPR, NMFS (or designee) determines and advises L–DEO that all live animals involved have left the area (either of their own volition or following an intervention).
- If further observations of the marine mammals indicate the potential for re-stranding, additional coordination with L–DEO will be required to determine what measures are necessary to minimize that likelihood (*e.g.,* extending the shutdown or moving operations farther away) and to implement those measures as appropriate.

Additional Information Requests—If NMFS determines that the circumstances of any marine mammal stranding found in the vicinity of the activity suggest investigation of the association with survey activities is warranted, and an investigation into the stranding is being pursued, NMFS will submit a written request to L–DEO indicating that the following initial available information must be provided as soon as possible, but no later than 7 business days after the request for information:

- Status of all sound source use in the 48 hours preceding the estimated time of stranding and within 50 km of the discovery/notification of the stranding by NMFS; and
- If available, description of the behavior of any marine mammal(s) observed preceding (*i.e.,* within 48 hours and 50 km) and immediately after the discovery of the stranding.

In the event that the investigation is still inconclusive, the investigation of the association of the survey activities is still warranted, and the investigation is still being pursued, NMFS may provide additional information requests, in writing, regarding the nature and location of survey operations prior to the time period above.

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 responses (*e.g.,* intensity,

duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), 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's 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 environmental 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, our analysis applies to all species listed in Table 1, given that NMFS expects the anticipated effects of the planned geophysical survey to be 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, NMFS has identified species-specific factors to inform the analysis.

As described above, we have authorized only the takes estimated to occur outside of Mexican territorial waters (Table 7); however, for the purposes of our negligible impact analysis and determination, we consider the total number of takes that are anticipated to occur as a result of the entire survey (including the portion of the survey that would occur within the Mexican territorial waters (approximately 6 percent of the survey) (Table 8).

TABLE 8—TOTAL ESTIMATED TAKE INCLUDING MEXICAN TERRITORIAL WATERS

Species	Level B harassment (excluding Mexican territorial waters)	Level A harassment (excluding Mexican territorial waters)	Level B harassment (Mexican territorial waters)	Level A harassment (Mexican territorial waters)	Total Level B harassment	Total Level A harassment
Humpback whale	8	0	1	0	9	0
Minke whale	2	0	0	0	2	0
Bryde's whale	27	1	2	0	29	1
Fin whale	2	0	0	0	2	0
Sei whale	3	0	0	0	3	0
Blue whale	5	0	0	0	5	0
Sperm whale	12	0	1	0	13	0
Cuvier's beaked whale	69	0	69	0	138	0
Longman's beaked whale	3	0	0	0	3	0
Mesoplodon spp	23	0	1	0	24	0
Risso's dolphin	328	0	22	0	350	0
Rough-toothed dolphin	597	0	38	0	635	0
Common bottlenose dolphin	2,274	0	196	0	2,470	0
Pantropical spotted dolphin	7,988	0	519	0	8,507	0
Spinner dolphin (whitebelly)	121	0	7	0	128	0
Spinner dolphin (eastern)	8,189	0	557	0	8,746	0
Striped dolphin	2,212	0	122	0	2,334	0
Short-beaked common dolphin	2,818	0	209	0	3,027	0
Fraser's dolphin	858	0	58	0	916	0
Short-finned pilot whale	244	0	15	0	259	0
Killer whale	25	0	2	0	27	0
False killer whale	118	0	8	0	126	0
Pygmy killer whale	116	0	8	0	124	0
Melon-headed whale	135	0	9	0	144	0
Kogia spp	33	1	2	0	35	1
Guadalupe fur seal	416	0	1	0	417	0
California sea lion	365	0	693	0	1,058	0

NMFS does not anticipate that takes by serious injury or mortality would occur as a result of L–DEO's planned survey, even in the absence of mitigation, and no such takes are authorized. Non-auditory physical effects, stranding, and vessel strike are also not expected to occur.

We have authorized a limited number of instances of Level A harassment of two species (Bryde's whale and dwarf sperm whales, which are members of the low- and high-frequency cetacean hearing groups, respectively) in the form of PTS, and Level B harassment only of the remaining marine mammal species. We believe that any PTS incurred in marine mammals as a result of the planned activity would be in the form of only a small degree of PTS, not total deafness, because of the constant movement of both the R/V *Langseth* and of the marine mammals in the project areas, as well as the fact that the vessel is not expected to remain in any one area in which individual marine mammals would be expected to concentrate for an extended period of time. Additionally, L–DEO must shut down the airgun array if marine mammals approach within 500 m (with the exception of specific genera of dolphins, see Mitigation), further reducing the expected duration and intensity of sound, and therefore the likelihood of marine mammals incurring PTS. Since the duration of exposure to loud sounds will be relatively short, it would be unlikely to affect the fitness of any individuals. Also, as described above, we expect that marine mammals would likely move away from a sound source that represents an aversive stimulus, especially at levels that would be expected to result in PTS, given sufficient notice of the R/V *Langseth's* approach due to the vessel's relatively low speed when conducting seismic surveys. Accordingly, we expect that the majority of takes would be in the form of short-term Level B behavioral harassment in the form of temporary avoidance of the area or decreased foraging (if such activity were

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). L–DEO will only survey ''nearshore'' tracklines between May 1 and October 31, at which point no breeding humpback whales are expected to be in survey area. We therefore expect no impacts on the fitness of individual humpback whales or on recruitment of survival for the population as a whole.

Marine mammal habitat may be impacted by elevated sound levels, but these impacts would be temporary. Prey species are mobile and are broadly distributed throughout the project areas; therefore, marine mammals that may be temporarily displaced during survey activities are expected to be able to resume foraging once they have moved away from areas with disturbing levels of underwater noise. Because of the relatively short duration (up to 25 days) and temporary nature of the disturbance, the availability of similar habitat and resources in the surrounding area, the impacts to marine mammals and the food sources that they utilize are not expected to cause significant or long-term consequences for individual marine mammals or their populations.

Yazvenko *et al.* (2007) reported no apparent changes in the frequency of feeding activity in Western gray whales exposed to airgun sounds in their feeding grounds near Sakhalin Island. Goldbogen *et al.* (2013) found blue whales feeding on highly concentrated prey in shallow depths were less likely to respond and cease foraging than whales feeding on deep, dispersed prey when exposed to simulated sonar sources, suggesting that the benefits of feeding for humpbacks foraging on high-density prey may outweigh perceived harm from the acoustic stimulus, such as the seismic survey (Southall *et al.,* 2016). Additionally, L–DEO must shut down the airgun array upon observation of an aggregation of six or more large whales, which would reduce impacts to cooperatively foraging animals. For all habitats, no physical impacts to habitat are anticipated from seismic activities. While SPLs of sufficient strength have been known to cause injury to fish and fish and invertebrate mortality, in feeding habitats, the most likely impact to prey species from survey activities would be temporary avoidance of the affected area and any injury or mortality of prey species would be localized around the survey and not of a degree that would adversely impact marine mammal foraging. The duration of fish avoidance of a given area after survey effort stops is unknown, but a rapid return to normal recruitment, distribution and behavior is expected. Given the short operational seismic time near or traversing specific habitat areas, as well as the ability of cetaceans and prey species to move away from acoustic sources, NMFS expects that there would be, at worst, minimal impacts to animals and habitat within these areas. The planned survey tracklines do not overlap with any designated critical habitat for ESA-listed species or areas of known importance for any species.

Negligible Impact Conclusions

The planned survey is of short duration (up to 25 days of seismic operations), and the acoustic ''footprint'' of the survey is small relative to the ranges of the marine mammals that would potentially be affected. Sound levels would increase in the marine environment in a relatively small area surrounding the vessel compared to the range of the marine mammals within the survey area. Short-term exposures to survey operations are not likely to significantly disrupt marine mammal behavior, and the potential for longer-term avoidance of important areas is limited.

The required mitigation measures are expected to reduce the number of takes by Level A harassment (in the form of PTS) by allowing for detection of marine mammals in the vicinity of the vessel by visual and acoustic observers. The required mitigation measures are also expected to minimize the severity of any potential behavioral disturbance (Level B harassment) via shutdowns of the airgun array. Based on previous monitoring reports for substantially similar activities that have been previously authorized by NMFS (available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-research-and-other-activities*), we expect that the mitigation will be effective in preventing, at least to some extent, potential PTS in marine mammals that may otherwise occur in the absence of the required mitigation (although all authorized PTS has been accounted for in this analysis).

NMFS concludes that exposures to marine mammal species and stocks due to L–DEO's seismic survey activities would result in only short-term (temporary and short in duration) effects to individuals exposed, over relatively small areas of the affected animals' ranges. Animals may temporarily avoid the immediate area, but are not expected to permanently abandon the area. Major shifts in habitat use, distribution, or foraging success are not expected. Due to the timing of the survey, no impacts to breeding humpback whales are anticipated and NMFS does not anticipate the authorized take to impact annual rates of recruitment or survival for humpback whales or any other species.

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 the species or stock through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated or authorized, even absent mitigation;
- The planned activity is temporary and of relatively short duration (up to 25 days);
- The anticipated impacts of the activity on marine mammals would primarily be temporary behavioral changes due to avoidance of the area around the survey vessel;
- The number of instances of potential PTS that may occur are expected to be very small in number. Instances of potential PTS that are incurred in marine mammals are expected to be of a low level, due to constant movement of the vessel and of the marine mammals in the area, and the nature of the survey design (not concentrated in areas of high marine mammal concentration);
- The availability of alternate areas of similar habitat value for marine mammals to temporarily vacate the survey area during the survey to avoid exposure to sounds from the activity;
- The potential adverse effects on fish or invertebrate species that serve as prey species for marine mammals from the survey would be temporary and spatially limited, and impacts to marine mammal foraging would be minimal; and
- The required mitigation measures, including visual and acoustic monitoring and shutdowns are expected to minimize potential impacts to marine mammals (both amount and severity).

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 required mitigation and monitoring 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 amount of authorized take is below one third of the estimated population abundance of all species (Gerrodette and Palacios 1996; NMFS 2015b). In fact, take of individuals is less than 8 percent of the abundance of any affected population.

Based on the analysis contained herein of the planned activity (including the required 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 would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

National Environmental Policy Act

In compliance with Executive Order (E.O.) 12114, the NSF prepared an Environmental Analysis to consider the direct, indirect and cumulative effects to the human environment resulting from this marine geophysical survey in the Eastern Tropical Pacific. The NSF's Environmental Analysis tiers to the 2011 Final Programmatic Environmental Impact Statement/Overseas Environmental Impact Statement for marine-related research funded by the NSF, which was prepared under E.O. 12114 and the National Environmental Policy Act (NEPA).

NMFS determined that the form and substance of the Environmental Analysis satisfies all the requirements of an Environmental Assessment under NEPA, as implemented by the regulations published by the Council on Environmental Quality (CEQ; 40 CFR parts 1500–1508) and includes adequate information analyzing the effects on the human environment of issuing the IHA. The NSF's draft Environmental Analysis was made available to the public for review and comment. In compliance with NEPA and CEQ regulations, as well as NOAA Administrative Order 216–6A, NMFS has reviewed the NSF's Environmental Analysis, determined it to be sufficient, and adopted that Environmental Analysis. The NSF's Environmental Analysis and NMFS' Determination are available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-research-and-other-activities.*

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.

The NMFS OPR ESA Interagency Cooperation Division issued a Biological Opinion under section 7 of the ESA, on the issuance of an IHA to L–DEO under section 101(a)(5)(D) of the MMPA by the NMFS OPR Permits and Conservation Division and the NSF's funding of L–DEO's survey. The Biological Opinion concluded that the action is not likely to jeopardize the continued existence of ESA-listed blue whales, fin whales, sei whales, sperm whales, Mexico DPS humpback whales, Central America DPS humpback whales, and Guadalupe fur seals.

Authorization

As a result of these determinations, NMFS has issued an IHA to L–DEO for conducting geophysical surveys of the Guerrero Gap in the Eastern Tropical Pacific in spring 2022, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: May 2, 2022.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–09792 Filed 5–5–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Southeast Region Vessel Monitoring System (VMS) and Related Requirements

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 January 12, 2022, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic & Atmospheric Administration (NOAA), Commerce.

Title: Southeast Region Vessel Monitoring System and Related Requirements.

OMB Control Number: 0648–0544.

Form Number(s): None.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 901.

Average Hours per Response: Annual VMS maintenance, 2 hours; Installation/Activation of VMS unit, 5 hours; Installation and activation checklist, 20 minutes; power-down exemption request, 5 minutes; and trip declaration, 1 minute.

Total Annual Burden Hours: 2,628.

Needs and Uses: The NMFS, Office of Law Enforcement, Southeast Enforcement Division is submitting this request for an extension of a currently approved information collection.

The Magnuson-Stevens Fishery Conservation and Management Act authorizes the Gulf of Mexico Fishery Management Council (Gulf Council) and South Atlantic Fishery Management Council (South Atlantic Council) to prepare and amend fishery management plans for any fishery in Federal waters under their respective jurisdictions. NMFS and the Gulf Council manage the reef fish fishery in the Gulf of Mexico (Gulf) under the Fishery Management

Plan (FMP) for the Reef Fish Resources of the Gulf of Mexico. NMFS and the South Atlantic Council manage the fishery for rock shrimp in the South Atlantic under the FMP for the Shrimp Fishery in the South Atlantic Region. The vessel monitoring system (VMS) regulations for the Gulf reef fish fishery and the South Atlantic rock shrimp fishery may be found at 50 CFR 622.28 and 622.205, respectively.

The FMPs and the implementing regulations contain several specific management areas where fishing is restricted or prohibited to protect habitat or spawning aggregations, or to control fishing pressure. Unlike size, bag, and trip limits, where the catch can be monitored on shore when a vessel returns to port, area restrictions require at-sea enforcement. However, at-sea enforcement of offshore areas is difficult due to the distance from shore and the limited number of patrol vessels, resulting in a need to improve enforceability of area fishing restrictions through remote sensing methods. In addition, all fishing gears are subject to some area fishing restrictions. Because of the sizes of these areas and the distances from shore, the effectiveness of enforcement through over flights and at-sea interception is limited. An electronic VMS allows a more effective means to monitor vessels for intrusions into restricted areas.

The VMS provides effort data and significantly aids in enforcement of areas closed to fishing. All position reports are treated in accordance with NMFS existing guidelines for confidential data. As a condition of authorized fishing for or possession of Gulf reef fish or South Atlantic rock shrimp in or from Federal waters, vessel owners or operators subject to VMS requirements must allow NMFS, the United States Coast Guard, and their authorized officers and designees, access to the vessel's position data obtained from the VMS.

The information collected on the ''Vessel Monitoring System Installation and Activation Certification for the Reef Fish Fishery of the Gulf of Mexico'' form provides NMFS assurance that vessels are compliant with the requirements to install and activate an approved VMS unit. Information collected on the ''Vessel Monitoring System Mobile Transceiver Unit (MTU) Power-Down Exemption Request for Vessels in the Gulf of Mexico Reef Fish Fishery'' form provides information that allows NMFS to exempt a vessel from their the VMS reporting requirement under specific criteria.

Affected Public: Business or other for-profit organizations.

Frequency: VMS unit installation, once; installation and activation checklist, once; power down exemption request, variable but on average less than once per year; trip declaration, variable but an average of 9 annually per vessel; and annual maintenance once per year.

Respondent's Obligation: Submission of the Installation and Activation certification is and mandatory. Transmission of fishing activity report is mandatory. Submission of a Power down Exemption Authorization request is required to obtain or retain benefits.

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

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 0648–0544.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–09820 Filed 5–5–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Fisheries Certificate of Origin

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 January 24, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic and Atmospheric Administration (NOAA), Commerce.

Title: Fisheries Certificate of Origin.

OMB Control Number: 0648–0335.

Form Number(s): NOAA Form 370.

Type of Request: Regular submission, extension of a current information collection.

Number of Respondents: 540.

Average Hours per Response: 25 minutes.

Total Annual Burden Hours: 5,833.

Needs and Uses: This request is for an extension of a current information collection sponsored by NMFS' Office of International Affairs, Trade, and Commerce. The information required by the International Dolphin Conservation Program Act, amendment to the Marine Mammal Protection Act, is needed to: (1) Document the dolphin-safe status of frozen and/or processed tuna import shipments; (2) verify that import shipments of fish were not harvested by large-scale, high seas driftnets; and (3) verify that tuna was not harvested by an embargoed nation or one that is otherwise prohibited from exporting tuna to the United States.

Collected information includes the U.S. Customs and Border Protection Entry Identification, date of entry, and contact details on the exporting and importing companies. Collected information also includes harvest characteristics such as fishing vessel name, fishing trip dates, vessel flag, vessel gear type, and ocean area of harvest, as well as the declaration of the dolphin-safe status of the shipment, and if applicable, the attachment of required certifications. Forms are submitted by importers and processors. NMFS uses this information to verify the dolphin-safe status of tuna shipments.

Affected Public: Business or other for-profit organizations.

Frequency: Per applicable tuna importation.

Respondent's Obligation: Mandatory.

Legal Authority: Marine Mammal Protection Act (16 U.S.C. 1361 *et seq.*) and the Dolphin Protection Consumer Information Act (16 U.S.C. 1385).

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 0648–0335.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–09829 Filed 5–5–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB897]

Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits

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

ACTION: Notice; request for comments.

SUMMARY: The Assistant Regional Administrator for Sustainable Fisheries, Greater Atlantic Region, NMFS, has made a preliminary determination that an Exempted Fishing Permit application contains all of the required information and warrants further consideration. The Exempted Fishing Permit would allow commercial fishing vessels to fish outside fishery regulations in support of research conducted by the applicant. Regulations under the Magnuson-Stevens Fishery Conservation and Management Act require publication of this notification to provide interested parties the opportunity to comment on applications for proposed Exempted Fishing Permits.

DATES: Comments must be received on or before May 23, 2022.

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

- *Email: nmfs.gar.efp@noaa.gov.* Include in the subject line ''*NEFSC Study Fleet EFP*''.

FOR FURTHER INFORMATION CONTACT: Louis Forristall, Fishery Management Specialist, (339) 674–7646.

SUPPLEMENTARY INFORMATION: The applicant submitted a complete application for an Exempted Fishing Permit (EFP) to conduct commercial fishing activities that the regulations would otherwise restrict. This EFP would exempt the participating vessels from the following Federal regulations:

TABLE 1—REQUESTED EXEMPTIONS

Citation	Regulation	Need for exemption
648.83	Multispecies Minimum Fish Sizes	Allow possession of haddock, yellowtail flounder, winter flounder, and American plaice below minimum size on Common pool and sector vessels for biological sampling purposes.
684.86(a)	Haddock Possession Restriction	Allow possession of haddock for biological sampling.
648.86(d)	Small-Mesh Multispecies Possession Restriction.	Exempt vessels from small-mesh possession restrictions for biological sampling.
648.86(g)	Yellowtail Flounder Possession Restriction	Exempt common pool vessels from yellowtail possession restrictions and limitations.
648.86(j)	Georges Bank Winter Flounder Possession Restriction.	Exempt common pool vessels from winter flounder restrictions.
648.86(l)	Ocean Pout, Windowpane Flounder, and Atlantic Wolffish Possession Restriction.	Exempt vessels from wolffish possession prohibitions.

TABLE 2—PROJECT SUMMARY

Project title	Study fleet program
Applicant	NESFC Cooperative Research Branch.
Project objectives	Allow fishermen and Center staff to collect biological data and biological samples relevant to stock assessments and fish biology.
Application date	February 7, 2022.
Project period	May 1, 2022.
Project location	April 30, 2023.
Number of vessels	19.
Number of trips	40.
Trip duration (days)	3.
Total number of days	72.
Gear type(s)	Otter trawl, scallop dredge, midwater otter trawl, paired trawl.
Number of tows or sets	5.
Duration of tows or sets	2 hours.

Project Narrative

The Northeast Fisheries Science Center's Cooperative Research Branch is requesting an EFP to allow participants in their Study Fleet Program to collect biological information on discarded catch. The Center established the Study Fleet Program in 2002 to more fully characterize commercial fishing operations and provide sampling opportunities to augment NOAA's National Marine Fisheries Service's data collection programs. As part of the program, the Center contracts commercial fishing vessels to collect biological data and fish specimens for the Center to use in research relevant to stock assessments and fish biology.

Under the EFP, Study Fleet participants would be allowed to

temporarily possess catch that is below minimum size restrictions and above possession limits for the purposes of biological sampling. When directed by the Center, participating vessels would be authorized to retain and land specific amounts of fish exceeding possession limits and/or below minimum fish sizes, for research purposes only. The captain or crew would deliver these fish to Center staff or local Port Agents upon landing. In these limited circumstances, the Study Fleet Program would give participating vessels a formal biological sampling request prior to landing. This would ensure that the landed fish do not exceed any collection needs of the Study Fleet Program, as detailed below.

During EFP trips, crew would sort, weigh, measure, and collect biological data from fish prior to discarding. During sampling, some discarded fish would remain on deck slightly longer than they would under normal sorting procedures. Exemptions from minimum fish sizes and possession restrictions would allow vessels to temporarily retain catch for at-sea sampling.

Vessels would be required to comply with all other applicable regulations specified at 50 CFR part 648 and would not be exempt from any inseason quota closures. All catch would be attributed to the appropriate commercial fishing quota. For a vessel fishing on a groundfish sector trip, all catch of groundfish stocks allocated to sectors would be deducted from the vessel's sector's annual catch entitlement (ACE). Once the ACE for a stock has been reached in a sector, participating vessels would no longer be allowed to fish in that stock area unless the sector acquires additional ACE for the stock in question. For participating common pool vessels, all groundfish catch would be counted toward the appropriate trimester total allowable catch (TAC). Common pool vessels would be exempt from the possession and trip limits, but would still be subject to trimester TAC closures.

Vessels fishing under this EFP would be required to report via their Vessel Monitoring System (VMS) or the web- or app-based Interactive Voice Response (IVR) system to identify trips that would be landing species below minimum size limits and/or in excess of possession limits. Vessels not landing fish for the Center, but temporarily possessing fish for at-sea sampling, would not be required to report via the IVR system or VMS.

If approved, the applicant may request minor modifications and extensions to the EFP throughout the year. EFP modifications and extensions may be granted without further notice if they are deemed essential to facilitate completion of the proposed research and have minimal impacts that do not change the scope or impact of the initially approved EFP request. Any fishing activity conducted outside the scope of the exempted fishing activity would be prohibited.

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

Dated: May 3, 2022.

Jennifer M. Wallace,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–09805 Filed 5–5–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Florida Fishing and Boating Survey

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of Information Collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before July 5, 2022.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *NOAA.PRA@noaa.gov.* Please reference OMB Control Number 0648- in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed David W. Carter, Economist, Southeast Fisheries Science Center, NMFS, 75 Virginia Beach Drive, Miami FL 33149, Tel: (305) 361–4467 or *david.w.carter@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for an extension of a currently approved information collection and is sponsored by NOAA's Southeast Fisheries Science Center (SEFSC).

The objective of the data collection effort under OMB Control Number 0648-0769 is to understand how anglers respond to changes in trip costs and/or fishing regulations in the Gulf of Mexico. This will improve the analysis of the economic effects of proposed changes in fishing regulations and changes in economic factors that affect the cost of fishing such as fuel prices. The survey will be used to develop predictive models that forecast how fishing effort changes when either trip costs change or when fishing regulations (season length or bag limits) change. The survey will ask about the number of trips anglers take under current costs and regulations and anticipated number of trips when costs and/or regulations change.

The population to be surveyed consists of those anglers who fish in the Gulf of Mexico from Florida, including those who possess a license to fish, and those who are not required to have a license (*e.g.,* seniors). The sample will be drawn from the list of licensed Florida anglers and/or Florida private boat owners using the state of Florida's boat registration list. With the boat registration list, the sample can be targeted to anglers who fish for offshore species, when desired, and will capture those who fish from a boat but may not be required to have a fishing license (*e.g.* seniors). Anglers and/or boat owners will be either emailed an invitation to the online survey or mailed a postcard that directs them to a website to complete the survey. A limited number of anglers who do not respond to the online survey may receive a paper survey in the mail.

II. Method of Collection

Surveys will be conducted using two modes: Internet and mail.

III. Data

OMB Control Number: 0648- 0769.

Form Number(s): None.

Type of Review: Regular submission, extension of a current information collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 1800.

Estimated Time Per Response: Survey, 3 minutes; Non-response survey, 3 minutes.

Estimated Total Annual Burden Hours: 90 hours.

Estimated Total Annual Cost to Public: $0 in record keeping and reporting costs.

Respondent's Obligation: Voluntary.

Legal Authority: Magnuson-Stevens Fishery Conservation and Management Act.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–09819 Filed 5–5–22; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to the Procurement List.

SUMMARY: The Committee is proposing to add service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before: May 29, 2022.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the service(s) listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following service(s) are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Service(s)

Service Type: Custodial Service
Mandatory for: OPM, Theodore Roosevelt Building, Washington, DC
Designated Source of Supply: Melwood Horticultural Training Center, Inc., Upper Marlboro, MD
Contracting Activity: OFFICE OF PERSONNEL MANAGEMENT, OPM PHILADELPHIA REGION CONTRACTING

Service Type: Facility Support Services
Mandatory for: U.S. Navy, DFAS Command Building, Bratenahl, Ohio
Designated Source of Supply: VGS, Inc., Cleveland, OH
Contracting Activity: DEPT OF THE NAVY, NAVAL FAC ENGINEERING CMD MID LANT

Service Type: Labeling and Packaging Vials
Mandatory for: NOAA, National Marine Fisheries Service, Seattle, WA
Designated Source of Supply: AtWork!, Bellevue, WA
Contracting Activity: NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION, DEPT OF COMMERCE NOAA

Michael R. Jurkowski,

Deputy Director, Business & PL Operations.

[FR Doc. 2022–09795 Filed 5–5–22; 8:45 am]

BILLING CODE 6353–01–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2022–0026]

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) is requesting to establish the Office of Management and Budget's (OMB's) approval for an existing information collection, titled ''Section 1022 Monitoring Collections.''

DATES: Written comments are encouraged and must be received on or before July 5, 2022 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–2022–0026 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. Please note that due to circumstances associated with the COVID–19 pandemic, the Bureau discourages the submission of comments by mail, hand delivery, or courier. 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: Documentation prepared in support of this information collection request is available at *www.regulations.gov.* 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: Section 1022 Monitoring Collections.

OMB Control Number: 3170–00XX.

Type of Review: New information collection.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 50,000.

Estimated Total Annual Burden Hours: 10,000.

Abstract: Public Law 111–203, section 1022(c)(4)(B)(ii) authorizes the Director of the Bureau to ''require covered persons and service providers participating in consumer financial services markets to file with the Bureau, under oath or otherwise, in such form and within such reasonable period of time as the Bureau may prescribe by rule or order, annual or special reports, or answers in writing to specific questions, furnishing information described in paragraph (4), as necessary for the Bureau to fulfill the monitoring, assessment, and reporting responsibilities imposed by Congress.'' Further, section 1022(c)(5) authorizes the Director ''in order to assess whether a non-depository is a covered person, as defined in section 5481 of this title, the Bureau may require such non-depository to file with the Bureau, under oath or otherwise, in such form and within such reasonable period of time as the Bureau may prescribe by rule or order, annual or special reports, or answers in writing to specific questions.''

Potential questions and other required types of information which persons could be required to provide will be approved for use under this information collection. Individual questions contained in this information collection may or may not be used at the Director's discretion.

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 approval. All comments will become a matter of public record.

Anthony May,

Paperwork Reduction Act Officer, Consumer Financial Protection Bureau.

[FR Doc. 2022–09712 Filed 5–5–22; 8:45 am]

BILLING CODE 4810–AM–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Sunshine Act Meetings

The Board of Directors of the Corporation for National and Community Service (operating as AmeriCorps) gives notice of the following meeting:

TIME AND DATE: Friday, May 13, 2022, 12:00 p.m.–2:00 p.m. (ET).

PLACE: Virtual, by Zoom and telephone.

- To register for the meeting, please use this link: *https://americorps.zoomgov.com/webinar/register/WN_hGYcFXb-TuqS8Kyfxbqfcg.*
- To participate by phone, call (833) 568–8864 (Toll Free).

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

I. Election of a Chair
II. Board Member Introductory Remarks
III. Discussion on AmeriCorps 2022–2026 Strategic Plan and Strategic Learning and Evidence Plan
IV. CEO Report
V. Spotlight and Panel on American Rescue Plan Implementation
VI. Public Comment
VII. Chair's Closing Remarks and Adjournment

Members of the public who would like to comment on the business of the Board may do so in writing or virtually. Submit written comments to *board@cns.gov* with the subject line: ''Comments for May 13, 2022 AmeriCorps Board Meeting'' no later than 5:00 p.m. (ET) May 9, 2022. Individuals who would like to comment during the meeting will be given instructions for signing up when they join the meeting. Comments are requested to be limited to two minutes.

AmeriCorps provides reasonable accommodation to individuals with disabilities, where needed.

CONTACT PERSON FOR MORE INFORMATION: Henry Hicks, by telephone: (202) 606–6864 or by email: *hhicks@cns.gov.*

Dated: May 4, 2022.

Fernando Laguarda,

General Counsel.

[FR Doc. 2022–09904 Filed 5–4–22; 4:15 pm]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Renewal of Department of Defense Federal Advisory Committees—Defense Science Board

AGENCY: Department of Defense (DoD).

ACTION: Renewal of federal advisory committee.

SUMMARY: The DoD is publishing this notice to announce that it is renewing the Defense Science Board (DSB).

FOR FURTHER INFORMATION CONTACT: Jim Freeman, DoD Advisory Committee Management Officer, 703–692–5952.

SUPPLEMENTARY INFORMATION: The DSB is being renewed in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C., appendix) and 41 CFR 102–3.50(d). The charter and contact information for the DSB's Designated Federal Officer (DFO) are found at *https://www.facadatabase.gov/FACA/apex/FACAPublicAgencyNavigation.*

The DSB provides the Secretary of Defense and Deputy Secretary of Defense with independent advice on matters supporting the DoD's scientific and technical enterprise. The DSB shall focus on matters concerning science, technology, manufacturing, acquisition process, and other topics of special interest to the Department in response to specific tasks from the Secretary of Defense, the Deputy Secretary of Defense (''the DoD Appointing Authority''), or the Under Secretary of Defense for Research and Engineering (USD(R&E)). The DSB is composed of no more than 40 members who are eminent authorities in the fields of science, technology, manufacturing, acquisition process, and other matters of special interest to the DoD.

Individual members are appointed according to DoD policy and procedures, and serve a term of service of one-to-four years with annual renewals. One member will be appointed as Chair of the DSB. No member, unless approved according to DoD policy and procedures, may serve more than two consecutive terms of service on the DSB, or serve on more than two DoD Federal advisory committees at one time.

DSB members who are not full-time or permanent part-time Federal civilian officers or employees, or active duty members of the Uniformed Services, are appointed as experts or consultants, pursuant to 5 U.S.C. 3109, to serve as special government employee members. DSB members who are full-time or permanent part-time Federal civilian officers or employees, or active duty

members of the Uniformed Services are appointed pursuant to 41 CFR 102–3.130(a), to serve as regular government employee members.

All DSB members are appointed to provide advice based on their best judgment without representing any particular point of view and in a manner that is free from conflict of interest. Except for reimbursement of official DSB-related travel and per diem, members serve without compensation.

The public or interested organizations may submit written statements about the DSB's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the DSB. All written statements shall be submitted to the DFO for the DSB, and this individual will ensure that the written statements are provided to the membership for their consideration.

Dated: May 3, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–09778 Filed 5–5–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0061]

Agency Information Collection Activities; Comment Request; Campus Equity in Athletics Disclosure Act (EADA) Survey

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before July 5, 2022.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2022–SCC–0061. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.*

Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave SW, LBJ, Room 6W208D, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Sophia McArdle, (202) 453–6318.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Campus Equity in Athletics Disclosure Act (EADA) Survey.

OMB Control Number: 1840–0827.

Type of Review: Extension without change of a currently approved collection.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 2,073.

Total Estimated Number of Annual Burden Hours: 11,401.

Abstract: The collection of information is necessary under section 485 of the Higher Education Act of 1965, as amended, with the goal of increasing transparency surrounding college athletics for students, prospective students, parents, employees and the general public. The survey is a collection tool to compile the annual data on college athletics. The data is collected from the individual institutions by ED and is made available to the public through the Equity in Athletics Data Analysis Cutting Tool as well as the College Navigator.

Dated: May 2, 2022.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–09699 Filed 5–5–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[EERE–2013–BT–NOC–0005]

Appliance Standards and Rulemaking Federal Advisory Committee

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a virtual open meeting of the Appliance Standards and Rulemaking Federal Advisory Committee (ASRAC). The Federal Advisory Committee Act requires that agencies publish notice of an advisory committee meeting in the **Federal Register**.

DATES: June 9, 2022; from 12 p.m.–5 p.m.

ADDRESSES: Meeting will be held virtually via Webex. See *Public Participation* section of this notice for webinar registration information, participant instructions, and information about the capabilities available to webinar participants, or visit the committee's website at: *https://www.energy.gov/eere/buildings/appliance-standards-and-rulemaking-federal-advisory-committee.*

FOR FURTHER INFORMATION CONTACT: Mr. John Cymbalsky, ASRAC Designated Federal Officer, U.S. Department of Energy, Building Technologies Program, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1692. Email: *asrac@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of Committee: The Committee provides advice and recommendations related to the development of minimum efficiency standards for residential appliances and commercial equipment; the development of product test procedures; the certification and enforcement of standards; the labeling for various residential products and commercial equipment; and specific issues of concern to DOE as requested by the Secretary of Energy, the Assistant Secretary for Energy Efficiency and Renewable Energy (EERE), and the Building Technologies Office (BTO) Director.

Tentative Agenda: DOE plans to hold this meeting virtually via webinar to gather advice and recommendations to the Department on the development of standards and test procedures for residential appliances and commercial equipment with the primary focus being the discussion and prioritization of topic areas that ASRAC can assist the Appliance and Equipment Standards Program with, particularly relating to rulemakings that could be subject to negotiation through ASRAC. (The final agenda will be available for public viewing at *https://www.regulations.gov/docket?D=EERE-2013-BT-NOC-0005.*)

Public Participation: The meeting is open to the public. Individuals and representatives of organizations who would like to offer comments and suggestions may do so during the meeting. Approximately 30 minutes will be reserved for public comments. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website: *https://www.energy.gov/eere/buildings/appliance-standards-and-rulemaking-federal-advisory-committee.*

The webinar will held using the Webex software platform and participants are responsible for ensuring their systems are compatible with the webinar software. If you plan to attend the webinar, please notify the ASRAC staff at *asrac@ee.doe.gov.*

Please note that foreign nationals participating in the webinar are subject to advance security screening procedures which require advance notice prior to attendance at the webinar. If a foreign national wishes to participate in the webinar, please inform DOE 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.

Conduct of Webinar: ASRAC's Designated Federal Officer will preside over the webinar and may also use a professional facilitator to aid discussion. The webinar 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).

Meeting Minutes: A transcript of the webinar will be included in the ASRAC docket: *https://www.regulations.gov/docket?D=EERE-2013-BT-NOC-0005.*

Signed in Washington, DC, on May 3, 2022.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2022–09781 Filed 5–5–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collection Proposed Extension

AGENCY: U.S. Energy Information Administration (EIA), Department of Energy (DOE).

ACTION: Notice and request for comments.

SUMMARY: EIA invites public comment on the proposed three-year extension, with changes, to the Petroleum Supply Reporting System (PSRS), as required by the Paperwork Reduction Act of 1995. The PSRS consists of six weekly surveys that make up the Weekly Petroleum Supply Reporting System (WPSRS), eight monthly surveys that make up the Monthly Petroleum Supply Reporting System (MPSRS), and one annual survey. EIA uses WPSRS surveys to collect data from a sample of operators on input, production, imports, and inventory levels of crude oil, hydrocarbon gas liquids, petroleum products, and biofuels. EIA uses MPSRS surveys to collect data from all in-scope operators on input, production, imports, biofuel feedstocks consumed, refinery capacity, biofuel plant production capacity, fuels consumed in plant operations, and annual storage capacity of crude oil, hydrocarbon gas liquids petroleum products, and biofuels. EIA uses annual Form EIA–820 to collect data on refinery capacity, refinery fuels and feedstocks consumed, and the quantity of crude oil received by method of transportation.

DATES: EIA must receive all comments on this proposed information collection no later than July 5, 2022. If you anticipate any difficulties in submitting your comments by the deadline, contact the person listed in the **ADDRESSES** section of this notice as soon as possible.

ADDRESSES: Submit comments electronically to *PetroleumSupplyForms@eia.gov* or mail comments to Michael Conner, Petroleum and Biofuel Supply Statistics Team, EI–23, U.S. Energy Information Administration, Forrestal Building, 1000 Independence Ave. SW, Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: If you need additional information, contact Michael Conner, U.S. Energy Information Administration, telephone (202) 586–1795, or by email at *PetroleumSupplyForms@eia.gov.* The forms and instructions are available on EIA's website at *www.eia.gov/survey/.*

SUPPLEMENTARY INFORMATION: Comments are invited on whether or not: (a) The proposed collection of information is necessary for the proper performance of agency functions, including whether the information will have a practical utility; (b) EIA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used, is accurate; (c) EIA can improve the quality, utility, and clarity of the information it will collect; and (d) EIA can minimize the burden of the collection of information on respondents, such as automated collection techniques or other forms of information technology.

This information collection request contains:

(1) *OMB No.:* 1905–0165;

(2) *Information Collection Request Title:* Petroleum Supply Reporting System (PSRS);

(3) *Type of Request:* Three-year extension with changes;

(4) *Purpose:* The surveys included in the PSRS collect information, that is largely unavailable from other sources, on production, input, inventory levels, imports, inter-regional movements, and fuels and feedstocks consumed for plant operation, for crude oil, hydrocarbon gas liquids, petroleum products, and biofuels. PSRS surveys also collect storage capacities for crude oil, hydrocarbon gas liquids, petroleum products, and biofuels, refinery capacities, biofuel production capacities, and biofuel feedstocks consumed.

EIA requires data from PSRS surveys to meet requirements of energy data users for credible, reliable, and timely energy information. EIA uses PSRS survey data in statistical reports including, but not limited to, the Weekly Petroleum Status Report (WPSR), Petroleum Supply Monthly

(PSM), and the Monthly Energy Review (MER). EIA uses PSRS survey data to support analysis and projection work with results reported in the Short Term Energy Outlook (STEO), Annual Energy Outlook (AEO), and other reports. EIA makes reports available at *https://www.eia.gov/*. EIA also uses PSRS data to complete monthly and annual reports of U.S. petroleum and biofuel supplies to the International Energy Agency to support U.S. participation as an IEA member county. In some cases, agencies outside of EIA publish data sourced from PSRS surveys in their own reports. For example Bioenergy Statistics reported by the U.S. Department of Agriculture.

Data from PSRS surveys provide data to inform policy and business decisions, the data promote efficient markets by providing transparency to petroleum and biofuel supplies. Use of PSRS data by academic researchers, educators, news media, and the general public promotes understanding of energy and its interaction with the economy and the environment.

(4a) *Proposed Changes to Information Collection:*

Form EIA–800 Weekly Refinery Report

• Change survey instructions to require reporting production of propane and propylene fractionated from still gas whether fractionation takes place at the refinery or at a facility downstream of the refinery. This change is needed to more completely account for the quantity of propane and propylene supplied, particularly as petrochemical feedstock. The current practice of reporting still gas shipped from refineries as still gas (not reported weekly on Form EIA–800) when the still gas will ultimately be fractionated into product components overstates supply of still gas (implying use as plant fuel) and understates supply of propane and propylene.

• Change the ''Who Must Submit'' part of survey instructions to include reporting by non-refinery operators of distillation, reforming, cracking, coking, hydrotreating, and similar processes. This change is needed in order for EIA to capture complete data on operations of process units commonly associated with oil refineries but operated at non-refinery facilities such as natural gas liquids fractionation plants.

• Discontinue collecting propane production, propane stocks, and total natural gas liquids (NGL) stocks at NGL fractionators. NGL fractionators that hold stocks will report on the new Form EIA–806 *Weekly Natural Gas Liquids Report.* Rename Form EIA–800 from *Weekly Refinery and Fractionator Report* to *Weekly Refinery Report.*

Form EIA–805 Weekly Bulk Terminal Report

• Add a product line for bulk terminal operators to report stocks of propane that meet at least the minimum specifications to be classified as consumer-grade propane (product code 626). The added product detail for consumer-grade propane will add transparency to propane supplies by showing separate stock levels of consumer-grade propane readily available for consumption and propane held as a component of product mixes where the propane requires processing through a fractionator or other unit before being consumed as propane. At present, EIA stock levels for propane do not differentiate between consumer-grade and higher grades of propane that are ready for use and propane contained as a component of a product mix.

Form EIA–806 Weekly Natural Gas Liquids Report

EIA proposes to add Form EIA–806 *Weekly Natural Gas Liquids Report* to the WPSRS. Form EIA–806 will be the weekly counterpart to Form EIA–816 *Monthly Natural Gas Liquids Report.* When implemented, EIA will use data from Form EIA–806 to report weekly total production of natural gas liquids (NGL), propane production from natural gas processing, and propane and NGL stocks held by operators of natural gas processing plants and NGL fractionators.

Current EIA weekly reporting practice is to use Form EIA–800 to collect production of propane from natural gas processing equal to barrels of propane fractionated from mixed NGL by operators of NGL fractionators. Operators of NGL fractionators also report ending stocks of total NGL and propane on Form EIA–800. EIA intends to replace current reporting by NGL fractionators on NGL fractionators on Form EIA–800 with reports submitted by operators of natural gas processing plants that produce and/or hold stocks, and operators of NGL fractionation plants that hold stocks.

With Form EIA–806, EIA proposes to collect the total quantity of natural gas liquids produced weekly by operators of natural gas processing plants. Weekly total NGL production is unavailable from current data collected on Form EIA–800. In addition, collecting weekly data from operators of natural gas processing plants allows EIA to improve consistency of weekly and monthly regional propane production by reporting weekly propane production in the region of the producing natural gas processing plant as is done in monthly data, rather than in the region where a fractionator operator separated propane from mixed NGL.

EIA proposes to collect total NGL stocks held by operators of natural gas processing plants and NGL fractionators. EIA will use plant-level NGL product composition data reported on Form EIA–816 to allocate total production and stocks reported weekly on Form EIA–806 to propane and other NGL products. EIA will allocate total NGL production and stocks reported weekly on Form EIA–806 to propane and other NGL current composition data, since this data is likely to be unavailable to plant operators in time to report weekly (*i.e.,* weekly reports due to EIA by 5:00 p.m. eastern time on Monday with data for the week ended at 7:00 a.m. eastern time the previous Friday).

Form EIA–810 Monthly Refinery Report

• Change the ''Who Must Submit'' part of survey instructions to include reporting by non-refinery operators of distillation, reforming, cracking, coking, hydrotreating, and similar processes. This change is needed in order for EIA to capture complete data on operations of process units commonly associated with oil refineries but operated at non-refinery facilities such as natural gas liquids fractionation plants.

• Change the label for product code 207 from the current ''Other renewable fuels and intermediate products'' to ''Other Biofuels and Biointermediates'' not elsewhere specified or indicated. This change is to make the Form EIA–810 product label consistent with terminology used in EIA, other government agencies, and the biofuel industry.

• Change survey instructions to require reporting production of natural gas liquids (ethane, propane, normal butane, and isobutane) and refinery olefins (ethylene, propylene, normal butylene, isobutylene) on a product basis when the products are fractionated from still gas whether fractionation takes place at the refinery or at a facility downstream of the refinery. This change is needed to more completely account for quantities supplied of natural gas liquids and refinery olefins on a product basis, particularly for use as petrochemical feedstock. The current practice of reporting still gas shipped from refineries as still gas when the still gas will ultimately be fractionated into product components overstates supply of still gas (implying use as plant fuel)

and understates supply of natural gas liquids and refinery olefin products.

Form EIA–815 Monthly Bulk Terminal Report

• Change the label for product code 207 from the current ''Other renewable fuels and intermediate products'' to ''Other Biofuels and Biointermediates'' not elsewhere specified or indicated. This change is to make the Form EIA–815 product label consistent with terminology used in EIA, other government agencies, and the biofuel industry.

• Add a product line for bulk terminal operators to report stocks of propane that meet at least the minimum specifications to be classified as consumer-grade propane (product code 626). The added product detail for consumer-grade propane will add transparency to propane supplies by showing separate stock levels of consumer-grade propane readily available for consumption and propane held as a component of product mixes where the propane requires processing through a fractionator or other unit before being consumed as propane. At present, EIA stock levels for propane do not differentiate between consumer-grade and higher grades of propane that are ready for use and propane contained as a component of a product mix.

Form EIA–816 Monthly Natural Gas Liquids Report

Add a separate product line for operators of natural gas processing plants to report plant condensate (product code 210) as a product separate from natural gasoline (product code 220). Plant condensate and natural gasoline are separate products of natural gas processing plants with different uses, but the current Form EIA–816 combines the two products under the natural gasoline label. Natural gasoline is normally used either for blending into gasoline, as petrochemical feedstock, or exported. Plant condensate is usually either blended into crude oil or exported. Reporting plant condensate as a product separate from natural gasoline will provide greater transparency to supplies of both NGL and crude oil. This change will also make reporting on Form EIA–816 consistent, in terms of the products reported, with Form EIA–64A *Annual Report of the Origin of Natural Gas Liquids.*

Form EIA–817 Monthly Tanker and Barge Movements Report

Change the label for product code 207 from the current ''Other renewable fuels and intermediate products'' to ''Other Biofuels and Biointermediates'' not elsewhere specified or indicated. This change is to make the Form EIA–817 product label consistent with terminology used in EIA, other government agencies, and the biofuel industry.

Form EIA–819 Monthly Report of Biofuels, Fuel Oxygenates, Isooctane, and Isooctene

• Change the label for product code 183 in part 8 of Form EIA–819 from the current ''Other renewable fuels and intermediate products'' to ''Other Biofuels and Biointermediates'' not elsewhere specified or indicated. This change is to make the Form EIA–819 product label consistent with terminology used in EIA, other government agencies, and the biofuel industry.

(5) *Annual Estimated Number of Respondents:* 4,744 total respondents;

EIA–800 consists of 100 respondents
EIA–802 consists of 46 respondents
EIA–803 consists of 90 respondents
EIA–804 consists of 102 respondents
EIA–805 consists of 764 respondents
EIA–806 consists of 200 respondents
EIA–809 consists of 147 respondents
EIA–810 consists of 133 respondents
EIA–812 consists of 104 respondents
EIA–813 consists of 235 respondents
EIA–814 consists of 294 respondents
EIA–815 consists of 1,484 respondents
EIA–816 consists of 489 respondents
EIA–817 consists of 36 respondents
EIA–819 consists of 287 respondents
EIA–820 consists of 133 respondents
Pretest methodology consists of 100 respondents

(6) *Annual Estimated Number of Total Responses:* 112,325 total responses;

(7) *Annual Estimated Number of Burden Hours:* 203,414 total annual burden hours;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* 203,414 annual hours * $83.38/hour = $16,960,659.

EIA estimates that respondents will have no additional costs associated with the surveys other than the burden hours and the maintenance of the information during the normal course of business.

Statutory Authority: 15 U.S.C. 772(b) and 42 U.S.C. 7101 *et seq.*

Signed in Washington, DC, on May 2nd, 2022.

Samson A. Adeshiyan,

Director, Office of Statistical Methods and Research, U.S. Energy Information Administration.

[FR Doc. 2022–09752 Filed 5–5–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC22–61–000.
Applicants: LSP-Whitewater Limited Partnership, Wisconsin Public Service Corporation, Wisconsin Electric Power Company.
Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of LSP-Whitewater Limited Partnership, et al.
Filed Date: 4/29/22.
Accession Number: 20220429–5689.
Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: EC22–62–000.
Applicants: E. BarreCo Corp LLC.
Description: Application for Authorization Under Section 203 of the Federal Power Act of E. BarreCo Corp LLC.
Filed Date: 4/29/22.
Accession Number: 20220429–5701.
Comment Date: 5 p.m. ET 5/20/22.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG22–107–000.
Applicants: Thunder Wolf Energy Center, LLC.
Description: Thunder Wolf Energy Center, LLC submits Notification of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 4/29/22.
Accession Number: 20220429–5430.
Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: EG22–108–000.
Applicants: Neptune Energy Center, LLC.
Description: Neptune Energy Center, LLC submits Notification of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 4/29/22.
Accession Number: 20220429–5433.
Comment Date: 5 p.m. ET 5/20/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1852–065; ER10–2641–041.
Applicants: Dodge Flat Solar, LLC, NextEra Energy Marketing, LLC, Mountain View Solar, LLC, NEPM II, LLC, Gexa Energy L.L.C., Florida Power & Light Company.
Description: Notice of Change in Status of Florida Power & Light Company, et al.
Filed Date: 4/29/22.

Accession Number: 20220429–5691.
Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: ER10–1852–066; ER10–1951–045; ER11–4462–067; ER14–21–013; ER17–838–042; ER21–2118–005.
Applicants: Dodge Flat Solar, LLC, NextEra Energy Marketing, LLC, Mountain View Solar, LLC, NEPM II, LLC, Gexa Energy L.L.C., Florida Power & Light Company.
Description: Notice of Change in Status of Dodge Flat Solar, LLC, et al.
Filed Date: 4/29/22.
Accession Number: 20220429–5698.
Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: ER10–1910–023; ER10–1911–023.
Applicants: Duquesne Power, LLC, Duquesne Light Company.
Description: Supplement to March 24, 2022 Notice of Change in Status of Duquesne Light Company et al.
Filed Date: 4/29/22.
Accession Number: 20220429–5699.
Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: ER10–2835–010.
Applicants: Google Energy LLC.
Description: Triennial Market Power Analysis for Southwest Power Pool Inc. Region of Google Energy LLC.
Filed Date: 4/29/22.
Accession Number: 20220429–5695.
Comment Date: 5 p.m. ET 6/28/22.

Docket Numbers: ER13–146–003; ER13–140–003; ER15–2455–002.
Applicants: Koch Energy Services, LLC, Georgia-Pacific Consumer Operations LLC, Port Hudson, Georgia-Pacific Toledo LLC.
Description: Notice of Non-Material Change in Status of Georgia-Pacific Toledo LLC, et al.
Filed Date: 4/29/22.
Accession Number: 20220429–5696.
Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: ER15–1447–007.
Applicants: Mid-Georgia Cogen L.P.
Description: Notice of Change in Status of Mid-Georgia Cogen L.P.
Filed Date: 4/29/22.
Accession Number: 20220429–5693.
Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: ER17–2059–010.
Applicants: Puget Sound Energy, Inc.
Description: Notice of Non-Material Change in Status of Puget Sound Energy, Inc.
Filed Date: 4/29/22.
Accession Number: 20220429–5658.
Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: ER21–2429–001.
Applicants: Tulare Solar Center, LLC.
Description: Notice of Change in Status of Tulare Solar Center, LLC, et al.
Filed Date: 4/28/22.
Accession Number: 20220428–5519.
Comment Date: 5 p.m. ET 5/19/22.

Docket Numbers: ER22–1592–000.
Applicants: Starion Energy Inc.
Description: Notice of Cancellation of Market Based Rate Tariff of Starion Energy Inc.
Filed Date: 4/27/22.
Accession Number: 20220427–5399.
Comment Date: 5 p.m. ET 5/18/22.

Docket Numbers: ER22–1778–000.
Applicants: Midway-Sunset Cogeneration Company.
Description: § 205(d) Rate Filing: Midway Sunset Cogeneration Turbine A Filing to be effective 5/1/2022.
Filed Date: 4/29/22.
Accession Number: 20220429–5323.
Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: ER22–1779–000.
Applicants: Marion County Solar Project, LLC.
Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 6/29/2022.
Filed Date: 4/29/22.
Accession Number: 20220429–5327.
Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: ER22–1780–000.
Applicants: Entergy Arkansas, LLC, Entergy Louisiana, LLC, Entergy Mississippi, LLC, Entergy New Orleans, LLC, Entergy Texas, Inc.
Description: Annual Informational Filing regarding Prepaid Pension Cost and Accrued Pension Cost of Entergy Arkansas, LLC, et al.
Filed Date: 4/29/22.
Accession Number: 20220429–5633.
Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: ER22–1781–000.
Applicants: Entergy Arkansas, LLC, Entergy Louisiana, LLC, Entergy Mississippi, LLC, Entergy New Orleans, LLC, Entergy Texas, Inc.
Description: Post-Retirement Benefits Other than Pensions for 2021 Calendar Year of Entergy Arkansas, LLC, et al.
Filed Date: 4/29/22.
Accession Number: 20220429–5634.
Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: ER22–1782–000.
Applicants: System Energy Resources, Inc.
Description: Annual Informational Filing regarding Prepaid Pension Cost and Accrued Pension Cost of System Energy Resources, Inc.
Filed Date: 4/29/22.
Accession Number: 20220429–5681.
Comment Date: 5 p.m. ET 5/20/22.

Docket Numbers: ER22–1783–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original NSA, Service Agreement No. 6452; Queue No. AC1–034 to be effective 3/31/2022.
Filed Date: 5/2/22.
Accession Number: 20220502–5049.
Comment Date: 5 p.m. ET 5/23/22.

Docket Numbers: ER22–1784–000.
Applicants: Midcontinent Independent System Operator, Inc., Ameren Illinois Company.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2022–05–02_SA 2880 Att A-Proj Spec No. 8 WVPA-Kappa to be effective 7/2/2022.
Filed Date: 5/2/22.
Accession Number: 20220502–5145.
Comment Date: 5 p.m. ET 5/23/22.

Docket Numbers: ER22–1785–000.
Applicants: Golden Spread Electric Cooperative, Inc.
Description: § 205(d) Rate Filing: Amended and Restated WPC Filing to be effective 7/1/2022.
Filed Date: 5/2/22.
Accession Number: 20220502–5247.
Comment Date: 5 p.m. ET 5/23/22.

Take notice that the Commission received the following electric securities filings:
Docket Numbers: ES22–44–000; ES22–45–000.
Applicants: Kentucky Power Company, AEP Kentucky Transmission Company, Inc., Kentucky Power Company, AEP Kentucky Transmission Company, Inc.
Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Kentucky Power Company, et al.
Filed Date: 4/29/22.
Accession Number: 20220429–5671.
Comment Date: 5 p.m. ET 5/20/22.

Take notice that the Commission received the following public utility holding company filings:
Docket Numbers: PH22–11–000.
Applicants: BillerudKorsnäs AB, BillerudKorsnäs Inc.
Description: BillerudKorsnäs AB et al., submits FERC 65–B Notice of Change in Fact to Waiver Notification.
Filed Date: 5/2/22.
Accession Number: 20220502–5226.
Comment Date: 5 p.m. ET 5/23/22.

Docket Numbers: PH22–12–000.
Applicants: Billerud Americas Corporation.
Description: Billerud Americas Corporation submits FERC–65A Notice of Change in Fact to Waiver Notification.
Filed Date: 5/2/22.
Accession Number: 20220502–5227.
Comment Date: 5 p.m. ET 5/23/22.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF22–609–000.
Applicants: UE–00602CO, LLC.
Description: Form 556 of UE–00602CO, LLC.
Filed Date: 4/29/22.
Accession Number: 20220429–5360.
Comment Date: 5 p.m. ET 5/20/22.

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: May 2, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–09770 Filed 5–5–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–1777–000]

Madison Fields Solar Project, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Madison Fields Solar Project, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 23, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: May 2, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–09772 Filed 5–5–22; 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: RP22–881–000.
Applicants: Texas Eastern Transmission, LP.
Description: Compliance filing: TETLP OFO April 2022 Penalty Disbursement Report to be effective N/A.
Filed Date: 4/29/22.
Accession Number: 20220429–5147.
Comment Date: 5 p.m. ET 5/11/22.

Docket Numbers: RP22–882–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Southern 49811 to Spotlight 55299) to be effective 5/1/2022.
Filed Date: 4/29/22.
Accession Number: 20220429–5170.
Comment Date: 5 p.m. ET 5/11/22.

Docket Numbers: RP22–883–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (FPL 41619 to Eco-Energy 55311) to be effective 5/1/2022.
Filed Date: 4/29/22.
Accession Number: 20220429–5171.
Comment Date: 5 p.m. ET 5/11/22.

Docket Numbers: RP22–884–000.
Applicants: Gulfstream Natural Gas System, L.L.C.
Description: § 4(d) Rate Filing: 2022 GNGS TUP/SBA Annual Filing to be effective 6/1/2022.
Filed Date: 4/29/22.
Accession Number: 20220429–5176.
Comment Date: 5 p.m. ET 5/11/22.

Docket Numbers: RP22–885–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Osaka 46428 to Uniper 55304, Sequent 55312) to be effective 5/1/2022.
Filed Date: 4/29/22.
Accession Number: 20220429–5177.
Comment Date: 5 p.m. ET 5/11/22.

Docket Numbers: RP22–886–000.
Applicants: Southern Star Central Gas Pipeline, Inc.
Description: § 4(d) Rate Filing: Vol. 2–Neg and Conforming Rate Agreements—Tenaska PLS to be effective 5/1/2022.
Filed Date: 4/29/22.
Accession Number: 20220429–5230.
Comment Date: 5 p.m. ET 5/11/22.

Docket Numbers: RP22–887–000.
Applicants: Enable Mississippi River Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Filing (Non-Conforming)—US Steel 5.1.2022 to be effective 5/1/2022.
Filed Date: 4/29/22.
Accession Number: 20220429–5247.

Comment Date: 5 p.m. ET 5/11/22.

Docket Numbers: RP22–889–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Leidy South—IT—Fuel Balancing—Seneca to be effective 5/1/2022.

Filed Date: 4/29/22.

Accession Number: 20220429–5264.

Comment Date: 5 p.m. ET 5/11/22.

Docket Numbers: RP22–890–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate Agreement (Eco Energy #617531–FT1EPNG) to be effective 5/1/2022.

Filed Date: 4/29/22.

Accession Number: 20220429–5289.

Comment Date: 5 p.m. ET 5/11/22.

Docket Numbers: RP22–891–000.

Applicants: Discovery Gas Transmission LLC.

Description: § 4(d) Rate Filing: Discovery Gas Transmission LLC's Negotiated Rates Filing to be effective 5/1/2022.

Filed Date: 4/29/22.

Accession Number: 20220429–5313.

Comment Date: 5 p.m. ET 5/11/22.

Docket Numbers: RP22–893–000.

Applicants: Equitrans, L.P.

Description: § 4(d) Rate Filing: Negotiated Rate Capacity Release Agreements—5/1/2022 to be effective 5/1/2022.

Filed Date: 5/2/22.

Accession Number: 20220502–5030.

Comment Date: 5 p.m. ET 5/16/22.

Docket Numbers: RP22–896–000.

Applicants: Enable Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rate Filing—May 1 2022 CERC LA to be effective 5/1/2022.

Filed Date: 5/2/22.

Accession Number: 20220502–5057.

Comment Date: 5 p.m. ET 5/16/22.

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.

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: May 2, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–09768 Filed 5–5–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP22–201–000]

Texas Eastern Transmission, LP; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on April 22, 2022 Texas Eastern Transmission, LP filed a prior notice request for authorization, in accordance with 18 CFR 157.205 and 157.208 of the Federal Energy Regulatory Commission's (Commission) regulations and Texas Eastern's blanket certificate issued in Docket Nos. CP82–535–000 to offset and replace a portion of 24-inch diameter pipeline in Westmoreland County and Indiana County Pennsylvania, at a crossing of the Conemaugh River; Texas Eastern estimates that the cost of the project will be about $15 million.

Specifically, Texas Eastern proposes to install a total of approximately 2,660 feet of 24-inch diameter pipeline at a crossing of the Conemaugh River. The replacement project includes approximately 2,260 feet of new pipeline that will be installed via horizontal direction drill, most of which will be placed adjacent to the existing Line 12 pipeline river crossing, and approximately 398 feet of pipeline to be installed via open-cut-trench method. The replacement project also includes the discontinued use of approximately 1,674 feet of the existing 24-inch Line 12 pipeline facilities, approximately 1,280 feet of which will be capped, grouted, and remain in place and an additional 394 feet on the west side of the river that will be removed, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions concerning this application should be directed to Estela D. Lozano Director, Regulatory,-Texas Eastern Transmission, LP P.O. Box 1642 Houston, Texas 77251–1642 Phone: (713) 627–4522 Facsimile: (713) 627–5947 Email: *estela.lozano@enbridge.com.*

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this Notice the Commission staff will either: Complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: You can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on July 1, 2022. How to file protests, motions to intervene, and comments is explained below.

[1] 18 CFR (Code of Federal Regulations) 157.9.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[2] any person [3] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[4] and must be submitted by the protest deadline, which is July 1, 2022. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [5] and the regulations under the NGA [6] by the intervention deadline for the project, which is July 1, 2022. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before July 1, 2022. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How to File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP22–201–000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov)* under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select General'' and then select ''Protest'', ''Intervention'', or ''Comment on a Filing''; or [7]

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP22–201–000.

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: Estela D. Lozano Director, Regulatory, Texas Eastern Transmission, LP P.O. Box 1642 Houston, Texas 77251–1642 Phone: (713) 627–4522 Facsimile: (713) 627–5947 Email: *estela.lozano@enbridge.com.*

Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: May 2, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–09773 Filed 5–5–22; 8:45 am]

BILLING CODE 6717–01–P

[2] 18 CFR 157.205.

[3] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[4] 18 CFR 157.205(e).

[5] 18 CFR 385.214.

[6] 18 CFR 157.10.

[7] Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project. The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf.*

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–1779–000]

Marion County Solar Project, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Marion County Solar Project, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 23, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: May 2, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–09771 Filed 5–5–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OP–OFA–015]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed April 26, 2022 10 a.m. EST Through May 2, 2022 10 a.m. EST

Pursuant to 40 CFR 1506.9

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20220061, Final, BLM, WY, Proposed RMP Amendment and Final EIS for Wild Horse Management in the Rock Springs and Rawlins Field Offices, Wyoming, Review Period Ends: 06/06/2022, Contact: Kimberlee Foster 307–352–0256.

EIS No. 20220062, Revised Draft, USACE, MS, Memphis Metropolitan Stormwater—North DeSoto County Feasibility Study, DeSoto County, Mississippi, Comment Period Ends: 06/20/2022, Contact: Andrea Carpenter-Crowther 901–544–0817.

Dated: May 2, 2022.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2022–09746 Filed 5–5–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2022–0223; FRL–9724–01–OCSPP]

Notice of Receipts of Requests To Voluntarily Cancel Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is issuing a notice of receipt of a request by a registrant to voluntarily cancel a certain pesticide registration. EPA intends to grant the request at the close of the comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit its further review of the request, or unless the registrant withdraws its request. If the request is granted, any sale, distribution, or use of the product listed in this notice will be permitted after the registration has been cancelled only if such sale, distribution, or use is consistent with the terms as described in the final order.

DATES: Comments must be received on or before November 2, 2022.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2022–0223, 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.*

Submit written withdrawal request by mail to: Registration Division (7502P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. ATTN: Christopher Green.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Christopher Green, Registration Division (7502P), Office of Pesticide Programs,

Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–2707; email address: *green.christopher@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *Regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets.*

II. What action is the Agency taking?

This notice announces receipt by the Agency of a request from a registrant to cancel a certain pesticide product registered under FIFRA section 3 (7 U.S.C. 136a) or 24(c) (7 U.S.C. 136v(c)). The registration is listed in sequence by registration number (or company number and 24(c) number) in Table 1 of this unit.

Unless the Agency determines that there are substantive comments that warrant further review of the request or the registrant withdraws their request, EPA intends to issue an order in the **Federal Register** canceling the affected registration.

TABLE 1—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Company No.	Product name	Active ingredients
432–1623	432	Storcide II Grain, Bin and Warehouse Insecticide	Deltamethrin & Chlorpyrifos-methyl.

Table 2 of this unit includes the name and address of record for the registrant of the product in Table 1 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration number of the product listed in this unit.

TABLE 2—REGISTRANT REQUESTING VOLUNTARY CANCELLATION

EPA Company No.	Company name and address
432	Bayer Environmental Science, A Division of Bayer CropScience, LP, 700 Chesterfield Parkway West, Chesterfield, MO 63017.

III. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**.

Section 6(f)(1)(B) of FIFRA (7 U.S.C. 136d(f)(1)(B)) requires that before acting on a request for voluntary cancellation, EPA must provide a 30-day public comment period on the request for voluntary cancellation or use termination. In addition, FIFRA section 6(f)(1)(C) (7 U.S.C. 136d(f)(1)(C)) requires that EPA provide a 180-day comment period on a request for voluntary cancellation or termination of any minor agricultural use before granting the request, unless:

1. The registrants request a waiver of the comment period, or

2. The EPA Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment.

The registrant in Table 1 of Unit II has not requested that EPA waive the 180-day comment period. Accordingly, EPA will provide a 180-day comment period on the proposed requests.

IV. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation should submit such withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. If the product has been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling.

V. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are currently in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. For this voluntary cancellation request, the registrant indicates that the registrant has no existing stocks of the affected product listed in Table 1 of Unit II. Therefore, no existing stocks provision is needed for the registrant. The cancellation will be effective on the date of publication of the cancellation order in the **Federal Register**. Thereafter, registrants will be prohibited from selling or distributing the pesticide identified in Table 1 of Unit II, except for export consistent with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal. Persons other than the registrant will generally be allowed to sell, distribute, or use existing stocks until such stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled product.

Authority: 7 U.S.C. 136 *et seq.*

Dated: April 29, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2022–09697 Filed 5–5–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2020–0701; FRL–9764–01–ORD]

Webinar Workshop To Obtain Input on Initial Draft Materials for the Lead (Pb) Integrated Science Assessment (ISA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of workshop.

SUMMARY: The Environmental Protection Agency (EPA) is preparing an Integrated Science Assessment (ISA) as part of the review of the primary and secondary National Ambient Air Quality Standards (NAAQS) for Lead (Pb). As part of the Pb review, EPA is announcing a public workshop to evaluate preliminary draft materials that will inform the development of the Pb ISA. The workshop is being organized by EPA's Center for Public Health and Environmental Assessment (CPHEA) within the Office of Research and Development and will be held by webinar and teleconference on May 26, June 7, June 22, and June 29, 2022. The workshop will be open to attendance by interested public observers on a first-come, first-served basis and participation will be by webinar and teleconference only.

DATES: The workshop will be held on May 26, June 7, June 22, and June 29, 2022.

ADDRESSES: The workshop will be held by webinar and teleconference. The website information and call-in number for the webinar are available to registered participants. To register, visit *https://www.epa.gov/isa/integrated-science-assessment-isa-lead.*

FOR FURTHER INFORMATION CONTACT: Please direct questions regarding workshop registration or logistics to Canden Byrd; telephone: 919–293–1660; or email: *EPA-Workshops@icf.com.* For technical information, contact Evan Coffman; telephone: 919–541–0567; fax: 919–541–1818; or email: *Coffman.Evan@epa.gov;* or Meredith Lassiter; phone: 919–541–3200; fax: 919–541–1818; or email: *Lassiter.Meredith@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Information About the Workshop

Section 108(a) of the Clean Air Act directs the Administrator to identify certain air pollutants which, among other things, ''cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare''; and to issue air quality criteria for them. The air quality criteria are to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air. . . .''. Under section 109 of the Act, EPA is then to establish NAAQS for each pollutant for which EPA has issued criteria. Section 109(d)(1) of the Act subsequently requires periodic review and, if appropriate, revision of existing air quality criteria to reflect advances in scientific knowledge on the effects of the pollutant on public health or welfare. EPA is also required to review and, if appropriate, revise the NAAQS, based on the revised air quality criteria (for more information on the NAAQS review process, see *https://www.epa.gov/naaqs*).

CPHEA is holding a workshop to inform the Agency's evaluation of the scientific evidence for the review of Pb. The purpose of the workshop is to obtain input on the scientific content of preliminary draft materials that will inform the development of the draft ISA. Workshop sessions will include discussion of preliminary draft materials from subject areas which may include exposure assessment, toxicokinetics, toxicology, epidemiology, air quality/exposure, fate and transport, biogeochemistry, plant and animal physiology, ecotoxicology, and ecological population biology. These preliminary materials are not being released as an external draft, but will be provided to the panelists to guide discussions and inform the development of the draft ISA for Pb. This workshop is planned to help ensure that the ISA, once developed, is up-to-date and focuses on the key evidence necessary to inform the underlying scientific basis for the review of the Pb primary and secondary NAAQS. EPA is planning to release the first external review draft of the Pb ISA for review by the Clean Air Scientific Advisory Committee (CASAC) and the public in early 2023.

II. Workshop Information

Members of the public may attend the teleconference as observers. Space in the teleconference may be limited, and reservations will be accepted on a first-come, first-served basis. Registration for the workshop is available online at *https://www.epa.gov/isa/integrated-science-assessment-isa-lead.*

Wayne Cascio,

Director, Center for Public Health and Environmental Assessment, Office of Research and Development.

[FR Doc. 2022–09732 Filed 5–5–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Termination of Receiverships

The Federal Deposit Insurance Corporation (FDIC or Receiver), as Receiver for each of the following insured depository institutions, was charged with the duty of winding up the affairs of the former institutions and liquidating all related assets. The Receiver has fulfilled its obligations and made all dividend distributions required by law.

NOTICE OF TERMINATION OF RECEIVERSHIPS

Fund	Receivership name	City	State	Termination date
10181	Florida Community Bank	Immokalee	FL	05/01/2022
10423	Tennessee Commerce Bank	Franklin	TN	05/01/2022

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary, including but not limited to releases, discharges, satisfactions, endorsements, assignments, and deeds. Effective on the termination dates listed above, the Receiverships have been terminated, the

Receiver has been discharged, and the Receiverships have ceased to exist as legal entities.

(Authority: 12 U.S.C. 1819)

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on May 2, 2022.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2022–09700 Filed 5–5–22; 8:45 am]

BILLING CODE 6714–01–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–XXXX; Docket No. 2022–0001; Sequence No. 7]

Information Collection; General Services Administration Regulation; Construction Payrolls and Basic Records

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Notice of request for comments regarding a new request for an OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve a new information collection requirement.

DATES: Submit comments on or before July 5, 2022.

ADDRESSES: Submit comments identified by Information Collection 3090–XXXX; Payrolls and Basic Records Clause to: *https://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching for ''Information Collection 3090–XXXX; Payrolls and Basic Records Clause''. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 3090–XXXX; Payrolls and Basic Records Clause''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 3090–XXXX; Payrolls and Basic Records Clause'' on your attached document. If your comment cannot be submitted using *https://www.regulations.gov,* call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite Information Collection 3090–XXXX; Payrolls and Basic Records Clause, in all correspondence related to this collection. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to- three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Ms. Johnnie McDowell, Procurement Analyst, General Services Administration, at telephone 202–718–6112 or via email at *gsarpolicy@gsa.gov.* for clarification of content.

SUPPLEMENTARY INFORMATION:

A. Purpose

The Federal Acquisition Regulation (FAR) Clause 52.222–8 Payrolls and Basic Records requires United States construction contracts in excess of $2,000 to submit weekly for each week in which any contract work is performed a copy of all payrolls to the Contracting Officer. The clause allows contractors to submit the required weekly payroll information using the DOL WH–347 form or any other form desired. GSA is proposing to deviate from the FAR clause to require these construction contractors to use the GSA Electronic Payroll Template and its portal to submit the required weekly payroll data. The proposed revision will increase the efficiency of the weekly payroll certification process for the contractor, GSA and the contractor's employee through the use of a standardized automated process. The current manual process for reviewing weekly certified payroll data requires an enormous amount of labor hours and has a large probability of human error *i.e.* non-identification or delayed identification of errors in pay for covered workers. Delays in identifying payroll errors are costly to the contractor who will need to pay retroactive wage adjustments and the employee will have suffered reduced economic purchase power due to the error in wages.

B. Annual Reporting Burden

GSA bases the following burden estimates for certified payrolls on SAM.gov reports for Fiscal Year 2021. The report indicated 182 construction contractors for GSA projects were subject to the Davis-Bacon or Related Act. GSA's automation of the data collection process will not increase the existing data collection burden from the DOL Wage and Hour Division (WHD) the Office of Management and Budget (OMB) Information Control No. 1235–0008, Davis-Bacon Certified Payroll or 1235–0018, Records to be kept by Employers—Fair Labor Standards Act.

Respondents: 182 (170 prime contractors plus 12 subcontractors).

Responses per Respondent: 52 (1 for each week of the year).

Total Annual Responses: 9,464 (182 respondents × 52 responses).

Hours per Response: 33 minutes (weighted average of 56 minutes (DOL estimated time to input information plus 1 minute recordkeeping for initial entry) + 31 minutes (estimated time to certify payroll in new system plus 1 minute recordkeeping)).

Total Burden Hours: 5,205 ((9,464 annual responses × 33 minutes)/60 minutes).

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary, whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 3090–XXXX, Payrolls and Basic Records Clause, in all correspondence.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2022–09790 Filed 5–5–22; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

National Advisory Council for Healthcare Research and Quality: Request for Nominations for Members

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of request for nominations for members.

SUMMARY: The National Advisory Council for Healthcare Research and Quality (the Council) advises the Secretary of HHS (Secretary) and the Director of the Agency for Healthcare

Research and Quality (AHRQ) with respect to activities proposed or undertaken to carry out AHRQ's statutory mission. AHRQ produces evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and works within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used. Seven new members will be appointed to replace seven current members whose terms will expire in November 2022.

DATES: Nominations should be received on or before 60 days after date of publication.

ADDRESSES: Nominations should be sent by email to Jaime Zimmerman at *NationalAdvisoryCouncil@ahrq.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Zimmerman, AHRQ, at (301) 427–1456.

SUPPLEMENTARY INFORMATION: 42 U.S.C. 299c provides that the Secretary shall appoint to the Council twenty-one appropriately qualified individuals. At least seventeen members shall be representatives of the public and at least one member shall be a specialist in the rural aspects of one or more of the professions or fields listed below. In addition, the Secretary designates, as ex officio members, representatives from other Federal agencies, principally agencies that conduct or support health care research, as well as Federal officials the Secretary may consider appropriate. 42 U.S.C. 299c(c)(3).

Seven current members' terms will expire in November 2022. To fill these positions, we are seeking individuals who: (1) Are distinguished in the conduct of research, demonstration projects, and evaluations with respect to health care; (2) are distinguished in the fields of health care quality research or health care improvement; (3) are distinguished in the practice of medicine; (4) are distinguished in other health professions; (5) represent the private health care sector (including health plans, providers, and purchasers) or are distinguished as administrators of health care delivery systems; (6) are distinguished in the fields of health care economics, information systems, law, ethics, business, or public policy; and (7) represent the interests of patients and consumers of health care, 42 U.S.C. 299c(c)(2). Individuals are particularly sought with experience and success in these activities. AHRQ will accept nominations to serve on the Council in a representative capacity.

The Council meets in the Washington, DC, metropolitan area, generally in Rockville, Maryland, approximately three times a year to provide broad guidance to the Secretary and AHRQ's Director on the direction of and programs undertaken by AHRQ.

Seven individuals will be selected by the Secretary to serve on the Council beginning with the meeting in the spring of 2023. Members generally serve 3-year terms. Appointments are staggered to permit an orderly rotation of membership.

Interested persons may nominate one or more qualified persons for membership on the Council. Self-nominations are accepted. Nominations shall include: (1) A copy of the nominee's resume or curriculum vitae; and (2) a statement that the nominee is willing to serve as a member of the Council. Selected candidates will be asked to provide detailed information concerning their financial interests, consultant positions and research grants and contracts, to permit evaluation of possible sources of conflict of interest. Please note that once a candidate is nominated, AHRQ may consider that nomination for future positions on the Council.

The Department seeks a broad geographic representation. In addition, AHRQ conducts and supports research concerning priority populations, which include: Inner city; rural; low income; minority; women; children; elderly; and those with special health care needs, including those who have disabilities, need chronic care, or need end-of-life health care. See 42 U.S.C. 299(c). AHRQ also includes in its definition of priority populations those groups identified in Section 2(a) of Executive Order 13985 as members of underserved communities: Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. Nominations of persons with expertise in health care for these priority populations are encouraged.

Dated: May 2, 2022.

Marquita Cullom,

Associate Director.

[FR Doc. 2022–09728 Filed 5–5–22; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–22–0824; Docket No. CDC–2022–0059]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled the National Syndromic Surveillance Program (NSSP). The NSSP promotes and advances development of a syndromic surveillance system for the timely exchange of syndromic data.

DATES: CDC must receive written comments on or before July 5, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0059 by any of the following methods:

- *Federal eRulemaking Portal www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

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. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

National Syndromic Surveillance Program (NSSP) (OMB Control No. 0920–0824, Exp. 7/31/2022)—Revision—Center for Surveillance, Epidemiology and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Syndromic surveillance uses syndromic data and statistical tools to detect, monitor, and characterize unusual activity for further public health investigation or response. Syndromic data include electronic extracts of electronic health records (EHRs) from patient encounter data from emergency departments, urgent care, ambulatory care, and inpatient healthcare settings, as well as laboratory data. Though these data are being captured for different purposes, they are monitored in near real-time as potential indicators of an event, a disease, or an outbreak of public health significance. On the national level, these data are used to improve nationwide situational awareness and enhance responsiveness to hazardous events and disease outbreaks to protect America's health, safety, and security.

The BioSense Program was created by congressional mandate as part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and was launched by the CDC in 2003. The BioSense Program has since been expanded into the National Syndromic Surveillance Program (NSSP) which promotes and advances development of a syndromic surveillance system for the timely exchange of syndromic data.

CDC requests a three-year approval for a Revision for NSSP (OMB Control No. 0920–0824, Exp. 7/31/2022). This Revision includes a request for approval to continue to receive onboarding data from state, local and territorial public health departments about healthcare facilities in their jurisdiction; registration data needed to allow users access to the BioSense Platform tools and services; and data sharing permissions so that state, local and territorial health departments can share data with other state, local and territorial health departments and CDC.

NSSP features the BioSense Platform and a collaborative Community of Practice. The BioSense Platform is a secure integrated electronic health information system that CDC provides, primarily for use by state, local and territorial public health departments. It includes standardized analytic tools and processes that enable users to rapidly collect, evaluate, share, and store syndromic surveillance data. NSSP promotes a Community of Practice in which participants collaborate to advance the science and practice of syndromic surveillance. Health departments use the BioSense Platform to receive healthcare data from facilities in their jurisdiction, conduct syndromic surveillance, and share the data with other jurisdictions and CDC.

The BioSense Platform provides the ability to analyze healthcare encounter data from EHRs, as well as laboratory data. All EHR and laboratory data reside in a cloud-enabled, web-based platform that has authorization to operate from CDC. The BioSense Platform sits in the secure, private Government Cloud which is simply used as a storage and processing mechanism, as opposed to on-site servers at CDC. This environment provides users with easily managed on-demand access to a shared pool of configurable computing resources such as networks, servers, software, tools, storage, and services, with limited need for additional IT support. Each site (*i.e.,* state or local public health department) controls its data within the cloud and is provided with free secure data storage space with tools for posting, receiving, controlling and analyzing their data; an easy-to-use data display dashboard; and a shared environment where users can collaborate and advance public health surveillance practice. Each site is responsible for creating its own data use agreements with the facilities that are sending the data, retains ownership of any data it contributes to its exclusive secure space, and can share data with CDC or users from other sites.

NSSP has three different types of information collection:

(1) Collection of onboarding data about healthcare facilities needed for state, local, and territorial public health departments to submit EHR data to the BioSense Platform;

(2) Collection of registration data needed to allow users access to the BioSense Platform tools and services; and

(3) Collection of data sharing permissions so that state and local health departments can share data with other state and local health departments and CDC.

Healthcare data shared with CDC can include: EHR data received by state and local public health departments from facilities including hospital emergency departments and inpatient settings, urgent care, and ambulatory care; mortality data from state and local vital statistics offices; laboratory tests ordered and their results from a national private sector laboratory company; and EHR data from the Department of Defense (DoD) and the Department of Health and Human Services (HHS) National Disaster Medical System (NDMS) Disaster Medical Assistance Teams (DMATs).

Respondents include state, local, and territorial public health departments. The only burden incurred by the health departments are for submitting onboarding data about facilities to CDC, submitting registration data about users to CDC, and setting up data sharing permissions with CDC. The estimated annual burden is 671 hours. There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)	Total burden (in hours)
State, Local, and Territorial Public Health Departments.	Onboarding	20	100	10/60	333
State, Local, and Territorial Public Health Departments.	Registration	20	100	10/60	333
State, Local, and Territorial Public Health Departments.	Data Sharing Permissions.	20	1	15/60	5
Total					671

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–09787 Filed 5–5–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–22–22EN; Docket No. CDC–2022–0056]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on proposed collection project titled Synopsis of State Oral Health Programs. This project collects data on state oral health infrastructure and capacity, including select indicators to monitor oral health status and trends and compare to other states, to inform planning and evaluation of oral health programs and policies, to measure state progress towards the Healthy People oral health objectives, and to educate the public and policy makers regarding cross-cutting public health programs.

DATES: Written comments must be received on or before July 5, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0056 by either of the following methods:

Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.

Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

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. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Synopsis of State Oral Health Programs—Existing Collection in Use Without an OMB Control Number—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This request is to collect information about human resources, programs, and infrastructure in oral health departments within a state health department for all 50 states and Washington, DC. Oral health affects our ability to eat, speak, smile, and show emotions. Oral health also affects a person's self-esteem, school performance, and attendance at work or school. Oral diseases—which range from cavities and gum disease to oral cancer—cause pain and disability for millions of Americans and cost taxpayers billions of dollars each year. CDC supports states in their efforts to reduce oral disease and improve oral

health by using effective interventions. CDC provides state and territorial health departments with funding, guidance, and technical assistance to monitor oral disease across populations and to implement and evaluate oral health interventions.

The Association of State and Territorial Dental Directors (ASTDD) is a national non-profit organization representing the directors and staff of state public health agency programs for oral health. It was organized in 1948 and is one of 20 affiliates of the Association of State and Territorial Health Officials (ASTHO). ASTDD formulates and promotes the establishment of national dental public health policy. In addition, ASTDD; assists state dental programs in the development and implementation of programs and policies for the prevention of oral diseases; builds awareness and strengthens dental public health professionals' knowledge and skills by developing position papers and policy statements; provides information on oral health to health officials and policy makers; and conducts conferences for the dental public health community. The word ''state'' is used to indicate U.S. states, the District of Columbia, U.S. territories, and other U.S.-associated jurisdictions, except where explicitly noted otherwise.

In 1994, ASTDD originated the annual Synopses of Dental Programs to share information among dental directors and partners. The Synopses of State Oral Health Programs (herby referred to as State Synopses) described program activities and successes and the challenges that programs faced during the previous year. In 1997, ASTDD changed the format to a more structured questionnaire. Since 1998, ASTDD has been supported to collect data through cooperative agreements with CDC. This collection is necessary because no other agency or entity produces similar analyses or reports, and the Synopsis questionnaire is the only national data collection source tracking states' efforts to improve oral health and contributions to progress toward the national targets for Healthy People objectives for oral health.

OMB approval is requested for three years. CDC requests approval for an estimated 299 annual burden hours. Participation is voluntary and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State Oral Health Director or designated program contact.	2022 Synopses of State Dental Public Health Programs.	51	1	5	299
Total					299

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–09783 Filed 5–5–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–22–22ES; Docket No. CDC–2022–0058]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed generic information collection project titled Assessing Respirator Perceptions, Experiences, and Maintenance. NIOSH proposes using surveys, interviews, focus groups, and physiological monitoring to assess current perceptions in respirator use as well as gaps in respirator use, maintenance, and programs.

DATES: CDC must receive written comments on or before July 5, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0058 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

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. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Assessing Respirator Perceptions, Experiences, and Maintenance—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), is requesting approval of a new Generic information collection for a period of three years under the project titled ''Assessing Respirator Perceptions, Experiences, and Maintenance.''

The National Personal Protective Technology Laboratory (NPPTL) is a division of NIOSH. NPPTL was established in 2001, at the request of Congress, with the mission of preventing disease, injury, and death for the millions of working men and women relying on personal protective technology (PPT). As the nation's respirator approver for all workplaces (42 CFR part 84), the development of NPPTL filled a need for improved personal protective equipment (PPE) and focused research into PPT. To this end, NPPTL conducts respiratory protection research to examine exposures to inhalation hazards, dermal hazards, and any other hazardous environmental threats within an occupational setting.

Federal regulations exist regarding the use of respirators in the workplace. The Occupational Safety and Health Administration (OSHA) requires employers whose hazard management includes the use of respirators to have a respiratory protection program, which has specified components. Thus, the information collected from human subjects about their use of respirators is generally consistent across NPPTL studies with only the use conditions changing (*e.g.,* respirator type or management implementation practices related to cleaning/decontamination, fit testing, and training). NPPTL requests a generic information collection package for information collected from individual workers and managers related to the perceptions, maintenance, and evaluation of respirator use on the job.

Different types of data collection including surveys, focus groups, interviews, and physiological monitoring will be used to: (1) Assess workers' health and safety knowledge, attitudes, skills, and other personal attributes as they relate to their respiratory protection use and maintenance, (2) identify and overcome barriers that workers face while using respiratory protection to prevent exposure to contaminants and other hazards, (3) understand organizations' maintenance of respiratory protection programs (RPP), directives, and guidelines that support worker best practices, and (4) determine appropriate training, interventions, and programs that support activities around respirator use and maintenance. Data collection may focus on respirator types ubiquitous to the industry being studied, new to the industry being studied, or novel to any industry. These data collection efforts may occur either electronically or in the field.

Respondents are expected to include a variety of employees from occupations such as public safety and emergency response, healthcare, and social assistance occupations who wear or manage respirator use on the job. Expected respondent job roles include industrial hygienists, occupational health professionals, infection control professionals, physicians, nurse practitioners, nurses, infection preventionists, fire department chiefs, battalion chiefs, sheriffs, shift supervisors, firefighters, police officers, and paramedics.

CDC request OMB approval for an estimated 13,071 burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Industry employees who wear respirators or oversee respirator use.	Informed consent	10,150	1	5/60	846
Industry employees who wear respirators or oversee respirator use.	Perceptions-based survey instrument.	3,450	2	15/60	1,725
Industry employees who wear respirators or oversee respirator use.	Knowledge-based survey instrument	2,000	1	30/60	1,000
Industry employees who wear respirators or oversee respirator use.	Interview/Focus group	250	2	1	500
Industry employees who wear a respirator as a part of their job.	Physiological Monitoring: Heart rate, blood pressure, blood oxygen saturation, breathing rate.	1,000	1	9	9,000
Total					13,071

Jeffrey M. Zirger,
Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–09785 Filed 5–5–22; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–22–22ER; Docket No. CDC–2022–0057]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Formative Respirator and Personal Protective Clothing Laboratory Testing. NIOSH proposes using questionnaires, physiological monitoring/measurements, anthropometric measurements, respirator fit measurements, self-perception data, and biomechanical measurements to assess gaps in respirator and personal protective clothing use among the Unites States working population.

DATES: CDC must receive written comments on or before July 5, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0057 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

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. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Formative Respirator and Protective Clothing Laboratory Testing—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), is requesting approval of a new generic information collection for a period of three years under the project titled Formative Respirator and Personal Protective Clothing Laboratory Testing.

The National Personal Protective Technology Laboratory (NPPTL) is a division of NIOSH, which operates within the CDC. NIOSH is the federal institute specifically dedicated to generating new knowledge in the field of occupational safety and health and is responsible for transferring that knowledge into practice for the betterment of workers.

NPPTL was established in 2001, at the request of Congress, with the mission of preventing disease, injury, and death for the millions of working men and women relying on personal protective technology (PPT). PPT plays an important role in keeping many workers within various industries safe while performing their professional duties. To achieve their mission, NPPTL conducts scientific research, develops guidance and authoritative recommendations, disseminates information, and responds to requests for workplace health hazard evaluations. The development of NPPTL filled a need for improved PPT and focused research into PPT.

Respiratory protection is the cornerstone of NPPTL's efforts. One of the primary responsibilities of NPPTL is to test and approve respirators used in U.S. occupational settings. This function ensures a standard level of quality and filtration efficiency for all respirators used within a U.S. workplace setting. The NPPTL Respirator Approval Program exists to increase the level of worker protection from airborne particulates, chemicals, and vapors.

In addition to respirators, NPPTL conducts research on other types of PPT, including chemical-resistant clothing, hearing protection, gloves, eye and face protective devices, hard hats, sensors to detect hazardous substances, and communication devices used for safe deployment of emergency workers. The NPPTL's PPT research examines exposure to inhalation hazards, dermal hazards, and any other hazardous environmental threats within an occupational setting.

PPT performance requirements and test methods are specified within: (1) Federal regulations by NIOSH, the Food and Drug Administration (FDA), and the Mine Safety and Health Administration (MSHA); and (2) voluntary consensus

standards published by organizations such as the American National Standards Institute (ANSI), American Society for Testing and Materials (ASTM) International, and International Organization for Standardization (ISO). Thus, the information collected from human subjects in a laboratory setting is generally consistent across NPPTL studies with only the boundary conditions changing (*e.g.,* environmental conditions such as heat or humidity, human subject activity such as simulated surgery or climbing a ladder, and distance between two subjects communicating by spoken word). Additionally, novel PPT designs may be examined or compared to commercially available products under similar boundary conditions to examine adherence to regulations and/or standards. NPPTL requests a new Generic information collection package for laboratory-collected information for testing respirators and personal protective clothing.

NIOSH estimates that up to 1,500 individuals could be burdened per year. Recruitment for all laboratory studies includes individuals from the general population rather than specific industries or working status. These individuals are all adults between the ages of 18 and 65 years. CDC requests OMB approval for an estimated 11,903 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Members of the general public.	Informed Consent	470	1	30/60	235
	Health Screening Questionnaire	470	6	1	2820
	Demographics Questionnaire	470	1	30/60	235
	Job-related Data: Occupational Tasks, postures used, duration of exposure.	470	1	15/60	118
	Physiological Measurements: Chest-worn heart rate monitor strap, COSMED Kb5, SQ2020–1F8 temperature logger, TOSCA 500 pulse oximeter, koken breathing waveform recording mask.	200	6	1.5	1800
	Biological Measurements: Cortisol (stress) levels, pregnancy tests, hydration status, lipids, inflammatory markers, heat shock proteins.	100	6	15/60	150
	Anthropometric Measurements: Calipers/digital measuring of facial and body dimensions.	500	1	15/60	125
	Respirator Fit Measurements: Filter cassettes with air pumps, fit-testing equipment, QLFT/sodium saccharin solution.	225	100	15/60	5,625
	Self-Perception Data: Level of exertion, perceived comfort level, heat sensation, fatigue.	500	6	15/60	750
	Biomechanics Measurements: Force plate, stopwatch, accelerometers.	30	3	30/60	45
Total					11,903

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–09784 Filed 5–5–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–22–22ET; Docket No. CDC–2022–0060]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Traveler-based SARS–CoV–2 Genomic Surveillance. The information collection will monitor for the importation of SARS–CoV–2 variants among arriving international air travelers at select U.S. airports.

DATES: CDC must receive written comments on or before July 5, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0060 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and

Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

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. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Traveler-based SARS–CoV–2 Genomic Surveillance—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The traveler-based SARS–CoV–2 genomic surveillance project was developed as a surveillance platform for early detection of imported and emerging SARS–CoV–2 variants among international air travelers arriving into the United States. Despite layered mitigation measures, international travel facilitates spread of SARS–CoV–2, including novel variants of concern (VOCs). Although SARS–CoV–2 genomic sequencing has increased significantly during the pandemic, there is still a gap in early detection of emerging variants among arriving travelers.

To address this gap, in September 2021, the Travelers' Health Branch, in collaboration with private partners, implemented a voluntary SARS–CoV–2 genomic surveillance program with the goal of early detection of novel VOCs. Surveillance for new and emerging variant strains among travelers can provide researchers and public health officials critical time to collect information about the transmissibility, virulence, and effectiveness of existing vaccines, diagnostics, and therapeutics. The project is conducted with external partners and groups within DGMQ and across CDC, including the Office of Advanced Molecular Detection. The program began at New York's John F. Kennedy International Airport in September 2021 and later expanded to include Newark Liberty International, San Francisco International, and Hartsfield-Jackson Atlanta International airports. Information collection for this project is currently approved under a Public Health Emergency PRA Waiver.

Project data is collected as follows: A volunteer sample of travelers, 18 years and older, from selected flights from South Asia, South America, Europe, and southern Africa, complete an informed consent form and fill-out a questionnaire on enrollment at the airport. The questionnaire includes demographic, travel, and clinical information. The voluntary surveillance project also includes laboratory data collection as follows: Airport collection of nasal samples from arriving travelers and follow-up collection of individual at-home saliva samples 3–5 days later. Travelers participating in individual, at home sample collection also complete an electronic health information questionnaire prior to submission of their samples and have the opportunity to fill out an evaluation survey.

CDC requests OMB approval for an estimated 169,433 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Participant with sample collected in-airport.	Participant information intake form (for pooled testing).	88,400	1	1	88,400
Participant with sample collected at home.	Participant intake form (for individual at-home testing).	44,200	1	1.5	66,300
Participant with sample collection at-home.	Evaluation Survey Form	44,200	1	20/60	14,733
Total					169,433

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–09786 Filed 5–5–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–0210]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on September 27, 2021 to obtain comments from the public and affected entities. CDC did not receive comments related to the FRN. This notice serves to allow an additional 30 days for public and affected entities' comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products (OMB Control No. 0920–0210, Exp. 04/30/2022)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Cigarette smoking is the leading preventable cause of premature death and disability in the U.S. Each year more than 480,000 deaths occur as the result of cigarette smoking-related diseases. The CDC, Office on Smoking and Health (OSH) has the primary responsibility for the HHS smoking and health program. Since 1986, as required by the Comprehensive Smoking Education Act of 1984, which amended the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1335a), CDC has collected information about the ingredients used in cigarette products. Respondents are commercial cigarette manufacturers, packagers, or importers (or their representatives), who are required by the CSEA to submit ingredient reports to HHS on an annual basis.

Respondents are not required to submit specific forms; however, they are required to submit a list of all ingredients used in their products. CDC requires the ingredient report to be submitted by chemical name and Chemical Abstract Service (CAS) Registration Number, consistent with accepted reporting practices for other companies currently required to report ingredients added to other consumer products.

Ingredient reports are due annually on March 31. Information is submitted to CDC by mailing or faxing a written report on the respondent's letterhead. All faxed lists should be followed up with a mailed original. Electronic mail submissions are not accepted. Mail Annual Ingredient submissions to Attention: FCLAA Program Manager, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS S107–7, Atlanta, GA 30341–3717.

Upon receipt and verification of the annual ingredient report, OSH issues a Certificate of Compliance to the respondent. CDC also uses the information to report to Congress (as deemed appropriate) the health effects of these ingredients.

CDC requests OMB approval for an estimated 358 annual burden hours. OMB approval is requested for three years. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Business Entities	N/A	55	1	6.5

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–09782 Filed 5–5–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1761–N]

Medicare Program; Public Meeting for New Revisions to the Healthcare Common Procedure Coding System (HCPCS) Coding—June 7–10, 2022

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the dates and times of virtual Healthcare Common Procedure Coding System (HCPCS) public meetings to be held in June 2022 to discuss our preliminary coding, Medicare benefit category, and payment determinations for new revisions to the HCPCS Level II code set, as well as how to register for those meetings. The June meetings will also include preliminary Medicare benefit category and payment determinations for codes effective January 1, 2020 to April 1, 2022, continuous glucose monitor and related supplies and accessories coding and payment determinations, and additional items added by CMS to address Medicare benefit category or payment determinations. The public meeting agendas (including the specific Healthcare Common Procedure Coding System (HCPCS) code applications that will be discussed), meeting guidelines and the information to join these meetings are published at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings.*

DATES:

Virtual Meeting Dates: Tuesday, June 7, 2022, 9 a.m. to 5 p.m., eastern daylight time (e.d.t.), Wednesday, June 8, 2022, 9 a.m. to 5 p.m. e.d.t., Thursday, June 9, 2022, 9 a.m. to 5 p.m. e.d.t. and Friday, June 10, 2022, 9 a.m. to 5 p.m. e.d.t.

Deadline for Primary Speaker Registrations and Presentation Materials: The deadline for primary speakers to register and submit any supporting PowerPoint presentation, as well as any relevant studies published after the date the applicant submitted its HCPCS code application, is 5 p.m., e.d.t., Tuesday, May 24, 2022.

Deadline for 5-Minute Speaker Registrations: The deadline for registering to be a 5-minute speaker is 5 p.m., e.d.t., Tuesday, May 24, 2022.

Deadline for Registration for all Other Attendees: All individuals who plan to attend the virtual public meetings to listen, but do not plan to speak, must register to attend. Attendees can attend more than one meeting. Except for individuals who require special assistance, the deadline to register for each public meeting is the date of that public meeting. Individuals who plan to attend one or more of the virtual public meetings and require special assistance must register and request special assistance services by 5 p.m., e.d.t., Tuesday, May 24, 2022.

Registration Link: The registration link will be posted in the Guidelines for Participation in HCPCS Public Meetings document on the CMS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings* and in an announcement on the HCPCS General Information page at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo.* The same website also contains detailed information on how attendees can join the virtual public meetings using Zoom, including dial-in information for primary speakers, 5-minute speakers, and all other attendees.

Deadline for Submission of Written Comments: In addition to the primary speaker presentation materials noted above, CMS will accept written comments from any stakeholder pertaining to a HCPCS code application or agenda item scheduled for discussion at the public meetings. The deadline for submission of written comments pertaining to a specific HCPCS code application or agenda item is 5 p.m., e.d.t., on the date of the virtual public meeting at which the applicable HCPCS code application or agenda item is scheduled for discussion. As part of CMS' response to the COVID–19 public health emergency (PHE), written comments will only be accepted when emailed to: *HCPCS@cms.hhs.gov.*

ADDRESSES: *Virtual Meeting Location:* The June 7–10, 2022 HCPCS public meetings will be held virtually via Zoom only.

FOR FURTHER INFORMATION CONTACT: Sundus Ashar, (410) 786 0750, *Sundus.ashar1@cms.hhs.gov,* or *HCPCS@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, Congress enacted the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554). Section 531(b) of BIPA mandated that the Secretary establish procedures that permit public consultation for coding and payment determinations for new durable medical equipment (DME) under Medicare Part B of title XVIII of the Social Security Act (the Act). In the November 23, 2001 **Federal Register** (66 FR 58743), we published a notice providing information regarding the establishment of the annual public meeting process for DME.

In 2020, we implemented changes to our Healthcare Common Procedure Coding System (HCPCS) coding procedures, including the establishment of quarterly coding cycles for drugs and biological products and biannual coding cycles for non-drug and non-biological items and services.

In the December 28, 2021 **Federal Register** (86 FR 73860), we published a final rule that established procedures for making Medicare benefit category and payment determinations for new items and services that are DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations under Medicare Part B.

II. Virtual Meeting Registration

Because of the ''Notice of the Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID–19) Pandemic'' [1] issued on February 18, 2022, there will not be an in-person meeting. The June 7–10, 2022 HCPCS public meetings will be virtual and available for remote audio attendance and participation only via Zoom.

A. Required Information for Registration

The following information must be provided when registering online to attend:

- Name;
- Company name and address (if applicable);
- Direct-dial telephone;
- Email address;
- Any special assistance requests (which, as stated above, will be considered if the registration is submitted by 5:00 p.m., e.d.t., Tuesday, May 24, 2022); and
- Whether the registrant is a primary speaker or a 5-minute speaker for an agenda item.

B. Additional Information

1. Primary Speakers

Each applicant that submitted a HCPCS code application that will be

[1] *https://www.whitehouse.gov/briefing-room/presidential-actions/2022/02/18/notice-on-the-continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic-2/.*

discussed at the virtual public meetings is permitted to designate a primary speaker. As stated above, we will accept PowerPoint presentations and relevant studies published after the date the applicant submitted its HCPCS code application if those materials are emailed to: *HCPCS@cms.hhs.gov* by 5:00 p.m., e.d.t., Tuesday, May 24, 2022. Due to the timeframe needed for the planning and coordination of the HCPCS virtual public meetings, materials that are not submitted in accordance with these deadlines cannot be accommodated.

All PowerPoint presentation materials must not exceed 10 pages. Relevant studies that were published after the date the applicant submitted its HCPCS code application are not subject to this page limit.

Fifteen minutes is the total time interval for each presentation. In establishing the public meeting agenda, we may group multiple, related code requests under the same agenda item.

On the day of the virtual meeting that the primary speaker attends and speaks on a HCPCS code application, before 5 p.m., e.d.t., the primary speaker must email a brief written summary (one paragraph) of their comments and conclusions to: *HCPCS@cms.hhs.gov.*

Every primary speaker must also declare at the beginning of their presentation at the meeting, as well as in their written summary, whether they have any financial involvement with the manufacturer of the item that is the subject of the HCPCS code application that the primary speaker presented, or any competitors of that manufacturer with respect to the item. This includes any payment, salary, remuneration, or benefit provided to that speaker by the applicant.

2. 5-Minute Speakers

As noted above, the deadline for registering to be a 5-minute speaker is 5:00 p.m., e.d.t., Tuesday, May 24, 2022.

On the day of the virtual meeting that the 5-minute speaker attends and speaks on a HCPCS code application or agenda item, before 5 p.m., e.d.t., the 5-minute speaker must email a brief written summary of their comments and conclusions to: *HCPCS@cms.hhs.gov.* CMS will not accept any other written materials from a 5-minute speaker.

Every 5-minute speaker must also declare at the beginning of their presentation at the meeting, as well as in their written summary, whether they have any financial involvement with the manufacturer of the item that is the subject of the HCPCS code application or agenda item that the 5-minute speaker presented, or any competitors of that manufacturer with respect to the item. This includes any payment, salary, remuneration, or benefit provided to that speaker by the applicant.

C. Additional Virtual Meeting/ Registration Information

Prior to registering to attend a virtual public meeting, all potential participants and other stakeholders are advised to review the public meeting agendas at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings* which identify our preliminary coding, Medicare benefit category, and payment determinations, and the date each item will be discussed. All potential participants and other stakeholders are also encouraged to regularly check the HCPCS section of the CMS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings* for publication of the draft agendas, including a summary of each HCPCS code application, our preliminary coding, Medicare benefit category, and payment determinations.

The HCPCS section of the CMS website also includes details regarding the public meeting process for new revisions to the HCPCS code set, including information on how to join the meeting remotely, and guidelines for an effective presentation. The HCPCS section of the CMS website also contains a document titled ''Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures,'' which is a description of the HCPCS coding process, including a detailed explanation of the procedures CMS uses to make HCPCS coding determinations.

When CMS refers to HCPCS code or HCPCS coding application above, CMS may also be referring to circumstances when a HCPCS code has already been issued but a Medicare benefit category and/or payment has not been determined. At this meeting, CMS may or may not be able to provide preliminary Medicare benefit category and payment determinations for HCPCS codes that were effective April 1, 2022, or that will be considered during this public meeting for coding actions. CMS is working diligently to address Medicare benefit category and payment determinations for new items and services that may be DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations under Medicare Part B. Please check the CMS website listed above for the final agenda.

III. Written Comments From Meeting Attendees Who Are Not Speakers

Written comments from anyone who is not a primary speaker or 5-minute speaker will only be accepted when emailed to: *HCPCS@cms.hhs.gov* before 5 p.m., e.d.t., on the date of the virtual public meeting at which the HCPCS code application that is the subject of the comments is discussed.

The Administrator of CMS, Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: May 3, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–09780 Filed 5–5–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Supplementary Comment Period; Release of Unaccompanied Children From ORR Custody (OMB #0970–0552)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), recently requested public comment on proposed revisions to forms that allow the Unaccompanied Children (UC) Program to process release of UC from ORR custody and provide services after release. In response to comments received, ORR is now providing a supplemental opportunity to provide comments on versions of revised forms that display the available options for dropdown fields. ORR invites any supplementary or new public comments that may arise with the added context of the dropdown options.

DATES: Comments due no later than June 6, 2022

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: ORR received several comments on this information collection in response to the **Federal Register** notice published on February 25, 2021 (86 FR 11536) and provided responses to those comments in its final submission to OMB. Summaries of the comments and ORR's responses can be accessed at *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202109-0970-019.* Some of the comments requested that ORR make available copies of the revised forms that display the available options for dropdown fields. In response to this request, ORR updated the screenshots for the three forms that contain dropdown fields. Those forms are:

- Discharge Notification (Form R–2) (*https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=202109-0970-019&icID=242800*)
- Release Request (Form R–4) (*https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=202109-0970-019&icID=249540*)
- Safety and Well-Being Call Report (Form R–6) (*https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=202109-0970-019&icID=242803*)

ORR invites supplementary comments from those who previously submitted comments, as well as new comments from anyone who did not previously submit comments.

Respondents: ORR grantee and contractor staff and released children and sponsors.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden minutes per response	Annual total burden hours
Verification of Release (Form R–1)	216	253	10	9,108
Discharge Notification (Form R–2)	216	290	10	10,440
ORR Release Notification—ORR Notification to ICE Chief Counsel Release of UC to Sponsor and Request to Change Address (Form R–3)	216	270	5	4,860
Release Request (Form R–4)—Grantee Case Managers	216	254	25	22,860
Release Request (Form R–4)—Contractor Case Coordinators	170	321	20	18,190
Safety and Well-Being Call (R–6)	216	253	45	40,986
Estimated Annual Burden Hours Total				106,444

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; *Flores* v. *Reno Settlement Agreement*, No. CV85–4544–RJK (C.D. Cal. 1996).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–09842 Filed 5–4–22; 11:15 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

RIN 0985–AA17

Request for Information: Older Americans Act Regulations

AGENCY: Administration for Community Living, Department of Health and Human Services.

ACTION: Request for information.

SUMMARY: The Acting Assistant Secretary for Aging and Administrator of the Administration for Community Living (ACL) seeks information on recommended changes, additions, or deletions to Code of Federal Regulation's section on Grants to State and Community Programs on Aging; Grants to Indian Tribes for Support and Nutrition Services; Grants for Supportive and Nutritional Services to Older Hawaiian Natives; and Allotments for Vulnerable Elder Rights Protection Activities, including Subpart A—State Long-Term Care Ombudsman Program.

DATES: Information must be submitted electronically by 11:59 p.m. (EST) by June 6, 2022.

ADDRESSES: Interested persons are encouraged to submit electronic comments to: Administration on Aging, *OAAregulations@acl.hhs.gov.* Include ''OAA Regulations'' in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Caldwell Jackson, (202) 795–7368 *Caldwell.Jackson@acl.hhs.gov.* The email is a resource mailbox established to receive public input regarding Older Americans Act regulations and should not be used to request information beyond the scope of this public input opportunity.

SUPPLEMENTARY INFORMATION: The Administration for Community Living's (ACL) Administration on Aging (AoA) is requesting information to gather feedback on recommended changes, additions, or deletions to regulations for programs authorized under Titles III, VI, and VII of the Older Americans Act, 42 U.S.C. 3001 *et seq.*

First passed in 1965, the Older Americans Act (the Act) authorizes supportive, nutrition, evidence-based disease prevention and health promotion, caregiver, legal, long-term care ombudsman, and other services provided via states, territories, tribes and tribal organizations, area agencies on aging, and local service providers. The Act was last reauthorized on March 25, 2020. Current regulations for programs authorized under the Act date from 1988, and have not been substantively revised, with the exception of portions of 45 CFR part 1321—Grants to State and Community Programs on Aging, specific to State responsibilities regarding the State Long-Term Care Ombudsman Program, and 45 CFR part 1324 Allotments for Vulnerable Elder Rights Protection Activities, Subpart A—State Long-Term Care Ombudsman Program, which were published in 2015. In the absence of valid and current regulations, there is the potential for significant variation in the interpretation and implementation of these provisions among States.

Public Input

Through this Request for Information (RFI), ACL is seeking input from individuals and organizations regarding supportive, nutrition, evidence-based disease prevention and health promotion, caregiver, legal, long-term care ombudsman, and other services provided via states, tribes and tribal organizations, area agencies on aging, and local service providers under the Act. Specifically, we would like to learn from respondents based on their experience about: (1) Challenges faced by older adults, elders, and family caregivers in receiving services under the Act, and (2) challenges faced by

states, territories, tribes and tribal organizations, area agencies on aging and service providers in delivering services under the Act. We also seek feedback on how OAA programs can advance equity, in alignment with Executive Order 13985 *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.* In this regard, please keep in mind the following:

- All submissions will be considered and reviewed by ACL.
- ACL seeks recommendations to address practical matters regarding regulations to implement the Older Americans Act, as reauthorized in 2020. (We may not be able to include all recommendations.)
- If respondents have multiple recommendations, respondents may make multiple recommendations in the same submission.

Submission Questions

1. State the regulation for which the comment applies:
   a. 45 CFR part 1321—Grants to State and Community Programs on Aging;
   b. 45 CFR part 1322—Grants to Indian Tribes for Support and Nutrition Services;
   c. 45 CFR part 1323—Grants for Supportive and Nutritional Services to Older Hawaiian Natives; or
   d. 45 CFR part 1324 Allotments for Vulnerable Elder Rights Protection Activities, including Subpart A—State Long-Term Care Ombudsman Program.
2. State the citation to which the comment applies, if applicable (for example, ''45 CFR part 1321.1'').
3. State the nature of the comment:
   a. Deletion.
   b. Addition.
   c. Change.
4. Provide detail on the reason for ACL to consider the comment for potential inclusion in a revision of Older Americans Act regulations.
5. Provide detail on any benefits, including how equity will be advanced, and/or barriers that might result from incorporating the recommendation in a revision of Older Americans Act regulations.

Please Note: This RFI is being issued for information and planning purposes only. It should not be construed as a solicitation or an obligation on the part of the federal government or the Administration for Community Living (ACL). ACL does not intend to issue any grant or contract awards based on responses to this invitation, or to otherwise pay for the preparation of any information submitted or for the government's use of such information. ACL is not authorized to receive personally identifiable information (PII) through this RFI other than the contact information of the person submitting the information. Please do not include any PII in your submission. For example, do not include names, addresses, phone or Social Security numbers of any individuals. We will redact responses that contain PII.

How the Information Will Be Used

ACL is planning to update regulations for programs authorized under Titles III, VI, and VII of the Older Americans Act. The information gathered through this RFI will be used to inform ACL's approach to updating these regulations.

Background

Congress passed the Older Americans Act (OAA) in 1965 in response to concern by policymakers about a lack of community social services for older persons. The original legislation established authority for grants to states for community planning and social services, research and development projects, and personnel training in the field of aging. The law also established the Administration on Aging (AoA) to administer the newly created grant programs and to serve as the federal focal point on matters concerning older persons.

Although older individuals may receive services under many other federal programs, today the OAA is considered to be a major vehicle for the organization and delivery of social and nutrition services to this group and their caregivers. It authorizes a wide array of service programs through a national network of 56 state agencies on aging, 618 area agencies on aging, nearly 20,000 service providers, 281 Tribal organizations, representing 400 Tribes, and 1 Native Hawaiian organization. The OAA was most recently reauthorized on March 25, 2020.

Dated: May 2, 2022.

Alison Barkoff,

Acting Assistant Secretary for Aging and Administrator, Administration for Community Living.

Dated: May 2, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–09713 Filed 5–5–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1998–P–0074]

Grated Parmesan Cheese 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 the temporary permit issued to Kraft Foods Inc. to market test a product designated as ''100% Grated Parmesan Cheese'' that deviates from the standards of identity for parmesan cheese and grated cheeses. Kraft Foods Inc.'s temporary permit is amended to identify Lactalis Heritage Dairy, Inc. (LHD) as the permit holder. This amendment will allow the permit holder to continue to test market the product and collect data on consumer acceptance.

FOR FURTHER INFORMATION CONTACT: Marjan Morravej, Office of Nutrition and Food Labeling (HFS–820), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371; or 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: In the **Federal Register** of April 6, 1999 (64 FR 16743), we issued a notice announcing that we had issued a temporary permit to Kraft Foods Inc. (now a part of Kraft Heinz, 200 East Randolph St., Suite 7600, Chicago, IL 60601), to market test a product identified as ''100% Grated Parmesan Cheese.'' We issued the permit to facilitate market testing of a product that deviates from the requirements of the standard of identity for parmesan cheese (21 CFR 133.165) and grated cheeses (21 CFR 133.146) in that the product is formulated by using a different enzyme technology that fully cures the cheese in 6 months rather than 10 months.

In the **Federal Register** of December 29, 2000 (65 FR 83040), we issued a notice announcing that we were extending the temporary market permit issued to Kraft Foods Inc. The extension allows the applicant to continue to measure consumer acceptance of the product and assess the commercial feasibility of the product, in support of

a petition to amend the standard of identity for parmesan cheese. The new expiration date of the permit will be either the effective date of a final rule amending the standard of identity for parmesan cheese that may result from the petition or 30 days after denial of the petition.

In 2011, Kraft Foods Inc. spun off its North American grocery business to a new company called Kraft Foods Group. In 2015, Kraft Foods Group and H.J. Heinz Company merged to become Kraft Heinz. In September 2020, Kraft Heinz entered into an agreement to sell its natural, grated, cultured, and specialty cheese businesses in the United States, including its Kraft parmesan cheese business, to B.S.A. S.A., the parent company of the Lactalis Group (Lactalis) and its subsidiary, LHD. As of November 29, 2021, LHD has assumed responsibility for production and sale of all parmesan cheese subject to the temporary permit.

Under our regulations at 21 CFR 130.17(f), we are modifying the temporary permit issued to Kraft Foods Inc. for ''100% Grated Parmesan Cheese'' to identify LHD, 540 West Madison St., Suite 300, Chicago, IL 60661, as the permit holder. All other conditions and terms of this permit remain the same.

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09750 Filed 5–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidance for Testosterone; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled ''Draft Guidance for Testosterone.'' The revised draft guidance, when finalized, will provide product-specific recommendations on, among other things, the information and data needed to demonstrate bioequivalence (BE) to support abbreviated new drug applications (ANDAs) for testosterone pellet.

DATES: Submit either electronic or written comments on the draft guidance by July 5, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for ''Draft Guidance for Testosterone.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

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

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993–0002, 301–796–2398, *PSG-Questions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and to provide a meaningful opportunity for the public to consider and comment on the guidances. This notice announces the availability of a revised draft guidance on a generic testosterone pellet.

FDA initially approved ANDA 080911 for TESTOPEL (testosterone pellet) in July 1972. FDA issued a draft guidance for industry on generic testosterone pellet in August 2011. We are now issuing a revised draft guidance for industry on generic testosterone pellet (''Draft Guidance for Testosterone'').

In July 2012, Actient Pharmaceuticals, manufacturer, at that time, of TESTOPEL, ANDA 080911,[1] submitted a citizen petition requesting, among other things, that FDA refrain from approving any ANDA referencing TESTOPEL unless certain conditions are satisfied, including conditions related to demonstrating BE (Docket No. FDA–2012–P–0737, available at *https://www.regulations.gov*). FDA is reviewing the issues raised in the petition and will consider any comments on the draft guidance entitled ''Draft Guidance for Testosterone'' before responding to the citizen petition.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on the information and data to demonstrate BE to support ANDAs for testosterone pellet. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: May 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09737 Filed 5–5–22; 8:45 am]

BILLING CODE 4164–01–P

[1] ANDA 080911 for TESTOPEL is currently held by Endo Pharmaceuticals, Inc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0357]

Pharmacy Compounding Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pharmacy Compounding Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on June 8, 2022, from 9:30 a.m. to 5:15 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2021–N–0357. The docket will close on June 7, 2022. Submit either electronic or written comments on this public meeting by June 7, 2022. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 7, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 7, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before May 24, 2022, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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–2021–N–0357 for ''Pharmacy Compounding Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

FOR FURTHER INFORMATION CONTACT: Takyiah Stevenson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 240–402–2507, Fax: 301–847–8533, email: *PCAC@fda.hhs.gov;* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Background: Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, to be exempt from the following three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

Section 503B of the FD&C Act describes the conditions that must be satisfied for drug products compounded in an outsourcing facility to be exempt from: (1) Section 502(f)(1), (2) section 505, and (3) section 582 (21 U.S.C. 360eee–1) (concerning drug supply chain security requirements) of the FD&C Act.

One of the conditions that must be satisfied for a drug product to qualify for the exemptions under section 503A of the FD&C Act is that the licensed pharmacist or licensed physician compounds the drug product using bulk drug substances (as defined in 21 CFR 207.3) that: (1) Comply with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if an applicable monograph does not exist, are drug substances that are components of drugs approved by the Secretary of Health and Human Services (the Secretary); or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under section 503A(c) of the FD&C Act (the 503A Bulks List) (see section 503A(b)(1)(A)(i) of the FD&C Act).

One of the conditions that must be satisfied to qualify for the exemptions under section 503A or section 503B of the FD&C Act is that the drug that is compounded does not appear on a list published by the Secretary of drugs that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (Withdrawn or Removed List) (see sections 503A(b)(1)(C) and 503B(a)(4) of the FD&C Act). The Withdrawn or Removed List is codified at 21 CFR 216.24.

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss the following four bulk drug substances nominated for inclusion on the 503A Bulks List: Ammonium tetrathiomolybdate, enclomiphene citrate, ferric subsulfate, and glutathione. The chart below identifies the use(s) FDA reviewed for each of the four bulk drug substances being discussed at this advisory committee meeting. The nominators of these substances or another interested party will be invited to make a short presentation supporting the nomination.

Bulk drug substance	Uses evaluated
Ammonium Tetrathiomolybdate	Wilson disease, use as copper (Cu) chelation therapy for the treatment of breast cancer, kidney cancer, prostate cancer, colorectal cancer, esophageal cancer, and malignant pleural mesothelioma.
Enclomiphene Citrate	To increase serum testosterone, luteinizing hormone (LH), and follicle-stimulating hormone (FSH) to normal levels in the treatment of secondary hypogonadism.
Ferric Subsulfate	For use as an astringent and hemostatic agent during minor surgical procedures.

Bulk drug substance	Uses evaluated
Glutathione	Skin lightening, cystic fibrosis, asthma, chronic obstructive pulmonary disease, chronic lung disease, oxidative stress, reduction of the side effects of chemotherapy, inhibition of chemical induced carcinogenesis, prevention of radiation injury, treatment of heavy metal poisoning (cadmium and mercury), acetaminophen toxicity, autism spectrum disorder, Alzheimer's disease, Parkinson's disease, major depressive disorder, schizophrenia, helicobacter pylori infection, human immunodeficiency virus infection, tuberculosis, otitis media, peripheral obstructive arterial disease, anemia, diabetes, and septic shock.

The committee will also discuss revisions FDA is considering to the Withdrawn or Removed List. FDA now is considering whether to amend the rule to add one more entry to the list: Lorcaserin Hydrochloride: All drug products containing lorcaserin hydrochloride. As previously explained in the **Federal Register** of July 2, 2014 (79 FR 37687 at 37689 through 37690), the list may specify that a drug may not be compounded in any form, or, alternatively, may expressly exclude a particular formulation, indication, dosage form, or route of administration from an entry on the list. Moreover, a drug may be listed only with regard to certain formulations, indications, routes of administration, or dosage forms because it has been found to be unsafe or not effective in those particular formulations, indications, routes of administration, or dosage forms. FDA plans to seek the committee's advice concerning the inclusion of this drug on the list.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before May 24, 2022, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 10:35 a.m. to 10:50 a.m., 12:15 p.m. to 12:30 p.m., 2:25 p.m. to 2:40 p.m., 3:45 p.m. to 4 p.m., and 4:50 p.m. to 5:05 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 16, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 17, 2022.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Takyiah Stevenson (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09797 Filed 5–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0109]

Fostering Medical Device Improvement: Food and Drug Administration Activities and Engagement With the Voluntary Improvement Program; Draft Guidance for Industry and Food and Drug Administration Staff; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program.'' FDA is issuing this draft guidance to describe its policy regarding FDA's participation in the Voluntary Improvement Program (VIP). The VIP is a voluntary program facilitated through the Medical Device Innovation Consortium (MDIC) that evaluates the capability and performance of a medical device manufacturer's practices using third-party appraisals, and is intended to guide improvement to enhance the quality of devices. The VIP builds on the framework piloted through FDA's 2018 Case for Quality Voluntary Medical Device Manufacturing and Product Quality Pilot Program (CfQ Pilot Program) and incorporates some of the successes and learnings from the pilot. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by July 5, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by July 5, 2022.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0109 for ''Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

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

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: *With regard to the draft guidance:* Francisco Vicenty, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1534, Silver Spring, MD 20993–0002, 301–796–5577.

With regard to the proposed collection of information: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601, Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

As part of Center for Devices and Radiological Health's (CDRH) 2016–2017 strategic priority to ''Promote a Culture of Quality and Organizational Excellence,'' CDRH envisions a future where the medical device ecosystem is inherently focused on device features and manufacturing practices that have the greatest impact on product quality and patient safety. Among its other regulatory activities, FDA evaluates manufacturers' compliance with regulations governing the design and production of devices. Compliance with 21 CFR part 820, ''Quality System Regulation,'' is a baseline requirement for medical device manufacturing firms.

In an effort to elevate and enhance manufacturing practices and behaviors through which quality and safety of medical devices can be improved, FDA has collaborated with various stakeholders, brought together through the MDIC public-private partnership, to develop the CfQ Pilot Program. FDA announced the voluntary CfQ Pilot Program in the **Federal Register** on December 28, 2017 (82 FR 61575).

As in the CfQ Pilot Program, the VIP oversees third-party appraisers who evaluate voluntary industry participants, and the VIP assesses the capability and performance of key business processes using a series of integrated best practices. Those practices are detailed in the Information Systems Audit and Control Association Capability Maturity Model Integration (CMMI) system. CMMI provides a roadmap that guides improvement towards disciplined and consistent processes for achieving key business objectives, including quality and performance. VIP uses a version of the CMMI appraisal appropriate for the medical device industry. This appraisal tool is referred to as the Medical Device Discovery Appraisal Program (MDDAP) model. The baseline appraisal using the MDDAP model covers 11 practices areas, including Estimating, Planning, and Configuration Management. As part of the VIP, and as in the CfQ Pilot Program, the VIP provides firms and FDA with information about the firm's capability and performance for activities covered in the third-party appraisal.

Details and results from the 2018 CfQ Pilot Program are outlined in MDIC's Case for Quality Pilot Report, available at *https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/case-quality-pilot-activities.*

This voluntary program is currently only available to eligible manufacturers of medical devices regulated by CDRH and whose marketing applications are reviewed under the applicable provisions of the Federal Food, Drug, and Cosmetic Act (including under sections 510(k), 513, 515, and 520). The voluntary CfQ Pilot Program was implemented for devices regulated by CDRH, and products regulated by the Center for Biologics Evaluation and Research (CBER) were not part of the CfQ Pilot Program. CBER is interested in hearing from manufacturers of device products regulated by CBER under sections 510(k), 513, 515, and 520 (21 U.S.C. 360(k), 360c, 360e, and 360j) about their interest in participating in such a program. CBER requests comments from stakeholders regarding the possible application of this program to CBER-regulated devices.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all CDRH guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* and *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 20039 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Voluntary Improvement Program

OMB Control Number 0910–NEW

The VIP is a voluntary program facilitated through the MDIC public-private partnership that evaluates the capability and performance of a medical device manufacturer's practices using third-party appraisals and is intended to guide improvement to enhance the quality of devices. FDA is issuing the draft guidance entitled ''Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program'' to describe its policy regarding FDA's participation in the VIP. As part of the VIP process, FDA receives information about participating device manufacturers' capability and performance for activities covered in third-party appraisals.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Site manufacturer application	1	400	400	0.08 (5 minutes)	33
Aggregate data reporting	1	4	4	8	32
Summary of site appraisal	1	400	400	20	8,000
Total					8,065

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers in table have been rounded.

Based on device registration and listing data and informal feedback from stakeholders, we anticipate approximately 400 sites may participate in the VIP annually.

The estimated Average Burdens per Response are largely based on our experience with the voluntary CfQ Pilot Program and were determined in consultation with our subject matter experts who are familiar with this program.

Site Manufacturer Application

Third-party appraisers forward participating site manufacturers'

applications to FDA. FDA confirms whether certain information in the application is consistent with FDA's existing records. This helps the third-party appraiser to determine the manufacturers' eligibility for participation in the VIP. We expect each application will take approximately 5 minutes to submit.

Aggregate Data Reporting

The third-party appraiser provides FDA with aggregated data across all participating manufacturer sites quarterly. The aggregate data is used to identify broad industry trends and patterns that FDA may consider in the benefit-risk considerations FDA routinely uses to inform planning, improve FDA resource allocations, improve review efficiency, and inform risk-based inspection planning. We expect that it will take approximately 8 hours to prepare and submit the aggregate data.

Summary of Site Appraisal

The third-party appraiser provides FDA with a summary of the appraisal result for each participating site. FDA intends to consider this information in the benefit-risk considerations FDA routinely uses to inform planning, improve FDA resource allocations, improve review efficiency, and inform risk-based inspection planning for firms that demonstrate capability and transparency around their manufacturing and product performance. We expect it will take approximately 20 hours to complete each summary.

The VIP and Certain Regulatory Submissions

FDA expects to gain insights into a participant's manufacturing processes and control capabilities intended to satisfy recommendations for certain PMA or HDE submissions (*e.g.,* PMA/HDE 30-Day Change Notices, PMA/HDE Manufacturing Site Change Supplements, PMA/HDE Manufacturing Modules). Thus, participants in the VIP may be able to avail themselves of efficiencies that would prevent duplicate information and/or allow for least burdensome submissions to FDA. FDA plans to improve stakeholder opportunities to use modified templates for such submissions.

The draft guidance also refers to previously approved collections of information. These collections of information are subject to review by the OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
7	Recalls	0910–0432
803	Medical Device Reporting	0910–0437
807, subparts A through D	Establishment Registration and Listing	0910–0625

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09734 Filed 5–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0576]

Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational Device Exemptions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with investigational device exemptions.

DATES: Submit either electronic or written comments on the collection of information by July 5, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 5, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 5, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as

well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–N–0576 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational Device Exemptions.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Investigational Device Exemptions—21 CFR Part 812

OMB Control Number 0910–0078—Extension

This information collection supports implementation of section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), which governs exemption for devices for investigational use. An investigational device exemption (IDE) allows a device to be used in investigations involving human subjects in which the safety and effectiveness of the device is being studied. For more information regarding IDE, please visit our website at *https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide.* FDA has promulgated regulations in part 812 (21 CFR part 812) intended to encourage the discovery and development of useful devices intended for human use. The regulations set forth the scope and applicability of exemption requirements for devices for investigational use, as well as establish application procedures, corresponding instruction, and provisions for emergency research. The regulations also provide for requesting waivers from the requirements; and explain sponsor responsibilities, including requirements for Institutional Review Board (IRB) review and approval. Finally, the regulations in part 812, subpart G (§§ 812.140, 812.145, and 812.150) provide for required recordkeeping, the inspection of records, and the preparation and submission of reports to FDA and/or IRBs that oversee medical device investigations.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
812.10; waivers	1	1	1	1	1
812.20, 812.25, and 812.27; applications, investigational plans, and supplements	229	1	229	80	18,320
812.27(b)(4)(i); prior investigations within the U.S	400	1	400	1	400
812.27(b)(4)(ii); prior investigations outside the U.S	100	1	100	0.25	25
812.28; acceptance of data from clinical investigations conducted outside the U.S., and supporting information	1,500	1	1,500	10.25	15,375

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
812.28(c); waivers	10	1	10	1	10
812.35 and 812.150; application supplements	654	5	3,270	6	19,620
812.36(c); treatment IDE applications	1	1	1	120	120
812.36(f); treatment IDE reports	1	1	1	20	20
812.150; non-significant risk study reports	1	1	1	6	6
Total			5,513		53,897

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate of the average reporting burden is based on our continued experience with the information collection. We have adjusted the currently approved burden to reflect an increase we attribute to Agency rulemaking that has become effective (OMB control number 0910–AG48) since our last evaluation. Regulations in part 812 were amended to provide for reporting associated with the acceptance of data from clinical investigations conducted outside the United States.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
812.2(c)(3); records regarding leftover specimens not individually identifiable used in certain studies	700	1	700	4	2,800
812.28(d); records for clinical investigations conducted outside U.S	1,500	1	1,500	1	1,500
812.140; retention of records	1,249	3.09	3,865	1.9937	7,706
Total					12,006

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In the guidance document ''Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable'' (April 2006), available for download at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-informed-consent-vitro-diagnostic-device-studies-using-leftover-human-specimens-are-not,* FDA communicates its enforcement policy with regard to the informed consent regulations (as required by section 520(g) of the FD&C Act and 21 CFR part 50) for in vitro diagnostic device studies that are conducted using leftover specimens and that meet the criteria for exemption from IDE regulation at 21 CFR 812.2(c)(3). We include burden that may be attributable to FDA recommendations that sponsors of studies document certain information, in table 2, row 1. We have otherwise adjusted our estimate upward of the average recordkeeping burden attributable to provisions in part 812 to reflect those requirements associated with clinical investigations conducted outside the United States, and in recognition of the required retention period for records.

Dated: April 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09751 Filed 5–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0131]

Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients With Type 2 Diabetes Mellitus; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus.'' This guidance provides recommendations for feasibility and early feasibility clinical studies for certain medical devices intended to therapeutically improve glycemic control in patients with Type 2 Diabetes Mellitus. These medical devices are intended to therapeutically reduce glycated hemoglobin in Type 2 Diabetes Mellitus patients independent of medication (*e.g.,* insulin) delivery.

DATES: The announcement of the guidance is published in the **Federal Register** on May 6, 2022.

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

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a

third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–0131 for ''Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

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

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: April Marrone, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2604, Silver Spring, MD 20993–0002, 240–402–6510.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance provides recommendations for the design of feasibility and early feasibility clinical studies for certain medical devices intended to therapeutically improve glycemic control in patients with Type 2 Diabetes Mellitus (T2DM). T2DM is a metabolic disorder that is characterized by high blood sugar levels, insulin resistance, and relative lack of insulin. In 2020, it was estimated that 10.5 percent of the United States population, or roughly 34.2 million Americans, have diabetes and that T2DM accounts for 90 percent to 95 percent of all diabetes cases.[1]

Due to the prevalence of T2DM in the United States, many medical device manufacturers and researchers seek to develop therapeutic medical devices that are intended to improve glycemic control in patients with T2DM. Historically, there have been several legally marketed devices that help patients manage T2DM, including medical devices intended to measure or monitor blood sugar (*e.g.,* blood glucose monitors, continuous glucose monitors) or dose and deliver insulin (*e.g.,* insulin pens, pumps, syringes). Medical devices that are therapeutically intended to improve glycemic control in patients with T2DM are an increasing area of interest. Manufacturers frequently request the Agency's feedback regarding feasibility and early feasibility clinical studies for these medical devices. This guidance represents the Agency's initial thinking on feasibility and early feasibility clinical studies for these medical devices. FDA's recommendations may change as more information becomes available.

A notice of availability of the draft guidance appeared in the **Federal Register** of May 20, 2021 (86 FR 27438). FDA considered comments received and revised the guidance as appropriate in response to the comments, including revisions to clarify the scope of devices included in the guidance and revisions to clarify or provide examples of certain terminology used in the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on feasibility and early feasibility clinical studies for certain medical devices intended to therapeutically improve glycemic control in patients with T2DM. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological

[1] Center for Disease Control, National Diabetes Statistics Report 2020: Estimates of Diabetes and its Burden in the United States, available at *https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.*

Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 19045 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120
814, subparts A through E	Premarket Approval	0910–0231
812	Investigational Device Exemption	0910–0078
''Requests for Feedback on Medical Device Submissions: The Q-Submission Program''.	Q-submissions; Pre-submissions	0910–0756
50, 56	Protection of Human Subjects and Institutional Review Boards.	0910–0130

Dated: April 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09738 Filed 5–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Global Affairs: Virtual Stakeholder Listening Session in Preparation for the 75th World Health Assembly

Time and date: The session will be held on Friday, May 13, 2022, from 10:00 a.m.–12:00 p.m. Eastern Time (ET).

Place: The session will be held virtually, and registration is required. Please RSVP by May 6, 2022 by sending your full name, email address, and organization to *OGA.RSVP@hhs.gov.* OGA encourages early registration.

Status: Open, but requiring RSVP to *OGA.RSVP@hhs.gov* to register.

Purpose: The U.S. Department of Health and Human Services (HHS)—charged with leading the U.S. delegation to the 75th World Health Assembly—will hold an informal Stakeholder Listening Session on Friday, May 13, 10:00 a.m.–12:00 p.m. ET. The listening session will be held virtually, and the meeting link will be shared with registered participants prior to the session.

The Stakeholder Listening Session will help the HHS Office of Global Affairs prepare the U.S. delegation to the World Health Assembly by taking full advantage of the knowledge, ideas, feedback, and suggestions from all communities interested in and affected by agenda items to be discussed at the 75th World Health Assembly. The U.S. Government will consider contributions received from the stakeholders as it develops the U.S. positions.

The listening session will be organized by agenda item, and participation is welcome from stakeholder communities, including:

- Public health and advocacy groups;
- State, local, and Tribal groups;
- Private industry;
- Minority health organizations; and
- Academic and scientific organizations.

All agenda items to be discussed at the 75th World Health Assembly can be found at this website: *https://apps.who.int/gb/e/e_wha75.html.*

RSVP: Registration is required for the event. Please send your full name, email address, and organization to *OGA.RSVP@hhs.gov* to register. Please RSVP no later than Friday, May 6, 2022.

Written comments are welcome and encouraged, even if you are planning on attending the virtual session. Please send written comments to the email address: *OGA.RSVP@hhs.gov.*

We look forward to hearing your comments related to the 75th World Health Assembly agenda items.

Dated: May 2, 2022.

Susan C. Kim,

Chief of Staff, Office of Global Affairs.

[FR Doc. 2022–09710 Filed 5–5–22; 8:45 am]

BILLING CODE 4150–38–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Transition to Independence Study Section.

Date: June 9–10, 2022.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Giuseppe Pintucci, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 205-H, Bethesda, MD 20892, (301) 827–7969, *Pintuccig@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and

Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 2, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09716 Filed 5–5–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. 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 Heart, Lung and Blood Advisory Council.

Date: June 14, 2022.

Closed: 10:00 a.m. to 12:00 p.m.

Agenda: To Review and Evaluate Grant Applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Open: 12:00 p.m. to 5:00 p.m.

Agenda: To Discuss Program Policies and Issues.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Virtual Access: The meeting will be videocast and can be accessed from the NIH Videocast. *https://www.nhlbi.nih.gov/about/advisory-and-peer-review-committees/advisory-council.* Please note, the link to the videocast meeting will be posted within a week of the meeting date.

Contact Person: Laura K. Moen, Ph.D., Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 206–Q, Bethesda, MD 20892, 301–827–5517, *moenl@mail.nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their 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: *www.nhlbi.nih.gov/meetings/nhlbac/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 2, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09714 Filed 5–5–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences, Special Emphasis Panel.

Date: June 14, 2022.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rahat (Rani) Khan, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892, (301) 594–7319, *khanr2@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: May 2, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09693 Filed 5–5–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Statement of Delegation of Authority

Notice is hereby given that I have delegated to the Director, National Institutes of Health (NIH), the authorities vested in the Secretary of Health and Human Services under Section 2 of the Accelerating Access to Critical Therapies for ALS Act (Pub. L. 117–79), as amended, to award grants to participating entities for purposes of scientific research utilizing data from expanded access to investigational drugs for individuals who are not otherwise eligible for clinical trials for the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis.

These authorities may be redelegated. Exercise of this authority shall be in accordance with established policies, procedures, guidelines, and regulations as prescribed by the Secretary. The Secretary retains the authority to submit reports to Congress and promulgate regulations.

This delegation is effective immediately. I hereby affirm and ratify any actions taken by you or your subordinates that involved the exercise

of the authorities delegated herein prior to the effective date of the delegation.

Xavier Becerra,

Secretary.

[FR Doc. 2022–09776 Filed 5–5–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: Heart, Lung, and Blood Initial Review Group; Heart, Lung, and Blood Program Project Study Section.

Date: June 17, 2022.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Melissa H. Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–R, Bethesda, MD 20892, (301) 827–7951, *nagelinmh2@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood 1Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 2, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09715 Filed 5–5–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Career Development Program to Promote Diversity in Health Research.

Date: June 10, 2022.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Sun Saret, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–S, Bethesda, MD 20892, (301) 435–0270, *sun.saret@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 2, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09711 Filed 5–5–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Digestive Diseases and Nutrition C Study Section DDK–C COMMITTEE.

Date: June 15–17, 2022.

Time: 5:00 p.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: NIDDK, DEM 2, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Maria E. Davila–Bloom, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7017, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7637, *davila-bloomm@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: May 2, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09717 Filed 5–5–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; 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 Human Genome Research Institute Initial Review Group; Genome Research Study Section.

Date: June 2, 2022.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 300, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Dr. Sarah Wheelan, Scientific Review Officer, National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100, Bethesda, MD 20817, 301–435–1580, *wheelansj@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: May 2, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09696 Filed 5–5–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7050–N–16]

30-Day Notice of Proposed Information Collection: OMB TITLE: COVID–19 Supplemental Payment Requests, OMB Control No.: 2502–0619

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 an additional 30 days of public comment.

DATES: *Comments Due Date:* June 6, 2022.

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 an additional 30 days of public comment.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_submission@omb.eop.gov* or *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. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on August 30, 2021 at 86 FR 48438.

A. Overview of Information Collection

Title of Information Collection: COVID–19 Supplemental Payment Requests.

OMB Approval Number: 2502–0619.

OMB Expiration Date: May 31, 2022.

Type of Request: Revision of a currently approved collection.

Form Number: HUD Form 52671–E.

Description of the need for the information and proposed use: Form 52671–E, will continue to be completed by owners of properties with Section 8 Housing Assistance Payment contracts, Section 202 and Section 811 Project Rental Assistance contracts, Section 202/162 Project Assistance contracts, and Section 202 Senior Preservation Rental Assistance contacts, who wish to receive a supplemental payment to offset operating cost increases to prevent, prepare, and respond to the effects of COVID–19. HUD expects to reissue the form in 2022 with minor updates to reflect additional funding periods and other Housing Notice cross-references. HUD anticipates using DocuSign to complete targeted follow-up with respondents for the portion of HUD 52671–E, submissions that involve delayed certification of completed installation for capital equipment purchases. DocuSign templates used under this collection may be updated periodically with new dates and to improve clarity about the requirements, as needed.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 23,200.

Estimated Number of Responses: 46,400.

Frequency of Response: 2.

Average Hours per Response: .55 hours per response.

Total Estimated Burden: 25,520.

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.

(5) 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.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Colette Pollard,

Department Reports Management Officer, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2022–09794 Filed 5–5–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7050–N–14]

30-Day Notice of Proposed Information Collection: Comment Request; Implementation of the Housing for Older Persons Act of 1995 (HOPA), OMB Control No: 2529–0046

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* June 6, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_submission@omb.eop.gov* or *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. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. 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.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on July 15, 2021 at 86 FR 37340.

A. Overview of Information Collection

Title of Information Collection: Implementation of the Housing for Older Persons Act of 1995 (HOPA).

OMB Control Number: 2529–0046.

Type of Request: Proposed reinstatement without change of an expired, previously approved information collection requirement.

Description of the need for the information and proposed use: The Fair Housing Act [42 U.S.C.3601 *et seq.*], prohibits discrimination in the sale, rental, occupancy, advertising, insuring, or financing of residential dwellings based on *familial status* (individuals living in households with one or more children under 18 years of age). However, under § 3607(b)(2) of the Act, Congress exempted three (3) categories of ''*housing for older persons*'' from liability for familial status discrimination: (1) Housing provided under any State or Federal program which the Secretary of HUD determines is ''*specifically designed and operated to assist elderly persons (as defined in the State or Federal program*)''; (2) housing ''*intended for, and solely occupied by persons 62 years of age or older*''; and (3) housing ''*intended and operated for occupancy by at least one person 55 years of age or older per unit* ['55 or older' housing].'' In December 1995, Congress passed the Housing for Older Persons Act of 1995 (HOPA) [Public Law 104–76, 109 STAT. 787] as an amendment to the Fair Housing Act. The HOPA modified the ''55 or older'' housing exemption provided under § 3607(b)(2)(C) of the Fair Housing Act by eliminating the requirement that a housing provider must offer ''*significant facilities and services specifically designed to meet the physical or social needs of older persons.*'' In order to qualify for the HOPA exemption, a housing community or facility must meet each of the following criteria: (1) *At least 80 percent of the occupied units* in the community or facility must be occupied by at least one person who is 55 years of age of older; (2) the housing provider must publish and adhere to policies and procedures that demonstrate the *intent* to operate housing for persons 55 years of age or older; and (3) the housing provider must demonstrate compliance with ''*rules issued by the Secretary for verification of occupancy, which shall . . . provide for* [age] *verification by reliable surveys and affidavits.*''

The HOPA did not significantly increase the record-keeping burden for the ''55 or older'' housing exemption. It describes in greater detail the documentary evidence which HUD will consider when determining, during a familial status discrimination complaint investigation, whether or not a housing facility or community qualified for the ''55 or older'' housing exemption as of the date on which the alleged Fair Housing Act violation occurred.

The HOPA information collection requirements are necessary to establish a housing provider's eligibility to claim the ''55 or older'' housing exemption as an affirmative defense to a familial status discrimination complaint filed with HUD under the Fair Housing Act. The information will be collected in the normal course of business in connection with the sale, rental, or occupancy of dwelling units situated in qualified senior housing facilities or communities. The HOPA's requirement that a housing provider must demonstrate the intent to operate a ''55 or older'' housing community or facility by publishing, and consistently enforcing, age verification rules, policies and procedures for current and prospective occupants reflects the usual and customary practice of the senior housing industry. Under the HOPA, a ''55 or older'' housing provider should conduct an initial occupancy survey of the housing community or facility to verify compliance with the HOPA's ''*80 percent occupancy*'' requirement and should maintain such compliance by periodically reviewing and updating existing age verification records for each occupied dwelling unit at least once every two years. The creation and maintenance of such occupancy/age verification records should occur in the normal course of individual sale or rental housing transactions and should require minimal preparation time. Further, a senior housing provider's operating rules, policies and procedures are not privileged or confidential in nature, because such information must be disclosed to current and prospective residents, and to residential real estate professionals.

The HOPA exemption also requires that a summary of the occupancy survey results must be made available for public inspection. This summary need not contain confidential information about individual residents; it may simply indicate the total number of dwelling units that are actually occupied by persons 55 years of age or older. While the supporting age verification records may contain confidential information about individual occupants, such information would be protected from disclosure unless the housing provider claims the ''55 or older'' housing exemption as an affirmative defense to a jurisdictional familial status discrimination complaint filed with HUD under the Fair Housing Act. HUD's Office of Fair Housing and Equal Opportunity will only require a housing provider to disclose such confidential information to HUD if and

when HUD investigates a jurisdictional familial status discrimination complaint filed against the housing provider under the Fair Housing Act, and if and when the housing provider claims the ''55 or older'' housing exemption as an affirmative defense to the complaint.

Agency form number(s), if applicable: None.

Members of affected public: The HOPA requires that small businesses and other small entities that operate housing intended for occupancy by persons 55 years of age or older must routinely collect and update reliable age verification information necessary to meet the eligibility criteria for the HOPA exemption. The record keeping requirements are the responsibility of the housing provider that seeks to qualify for the HOPA exemption.

Estimation of the total numbers of hours needed to prepare the information collection, including the number of respondents, frequency of response, and hours of response:

Housing providers claiming eligibility for the HOPA's ''55 or older'' housing exemption must demonstrate ongoing compliance with the HOPA exemption requirements. The HOPA does not authorize HUD to require submission of this information by individual housing providers as a means of certifying that their housing communities or facilities qualify for the exemption. Further, since the HOPA has no mandatory registration requirement, HUD cannot ascertain the actual number of housing facilities and communities that are currently collecting this information with the intention of qualifying for the HOPA exemption. Accordingly, HUD has estimated that approximately 1,000 housing facilities or communities would seek to qualify for the HOPA exemption. HUD has estimated that the occupancy/age verification data would require routine updating with each new housing transaction within the facility or community, and that the number of such transactions per year might vary significantly depending on the size and nature of the facility or community. HUD also estimated the average number of housing transactions per year at ten (10) transactions per community. HUD concluded that the publication of policies and procedures is likely to be a one-time event, and in most cases will require no additional burden beyond what is done in the normal course of business. The estimated total annual burden hours are 5,500 hours [See Table below].

Type of collection activity	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
One: Collect reliable age verification records for at least one occupant per dwelling unit to meet the HOPA's minimum ''80% occupancy'' requirement	1,000	1	1,000	1	1,000	$18.18	$18.18
Two: Publication of & adherence to policies & procedures that demonstrate intent to operate ''55 or older'' housing	1,000	1	1,000	2	2,00	18.18	36,360
Three: Periodic updates of age verification records	1,000	1	1,000	2.50	2,500	18.18	45,450

B. Solicitation of Public Comments

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed information collection in order to:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of HUD's program functions;

(2) Evaluate the accuracy of HUD's assessment of the paperwork burden that may result from the proposed information collection;

(3) Enhance the quality, utility, and clarity of the information which must be collected; and

(4) Minimize the burden of the information collection on responders, including the use of appropriate automated collection techniques or other forms of information technology (*e.g.,* permitting electronic submission of responses).

(5) 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 technolog

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35, as amended.

Colette Pollard,

Department Reports Management Officer, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2022–09791 Filed 5–5–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7056–N–12]

60-Day Notice of Proposed Information Collection: Equity in Housing Counseling Survey, OMB Control No.: 2502–0623

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:* July 5, 2022.

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, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400(this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number). 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: Equity in Housing Counseling Survey.

OMB Approval Number: 2502–0623.

OMB Expiration Date: 09/30/2022.

Type of Request: Revision of a currently approved collection.

Form Number: None.

Description of the need for the information and proposed use: The purpose of the survey and the listening session is to collect information from HUD Participating Housing Counseling agencies that will be used to identify and develop innovative programming and best practices for the Department's Housing Counselling Program under Section 106 of the Housing and Community Development Act of 1974.

Respondents: Not-For-Profit Institutions.

Estimated Number of Respondents: 1,244.

Estimated Number of Responses: 1,244.

Frequency of Response: 1.

Average Hours per Response: 3.25.

Information collection/ affected public	Form name/form number collection tool	Number of respondents	Frequency of response	Responses per year	Average burden hours per response	Annual burden hours	Hourly cost per response (hourly wage rate)	Total annual respondent cost
Not for-profits Institutions	Equity in Housing Counseling Survey.	1,219	1	1,219	.25	304.75	$50.71	$15,453.87
Not for-profits Institutions	Equity in Housing Counseling Listening Sessions.	25	1	25	3	75	50.71	3,803.25
Totals	.....	1,244	.....	1,244	.....	380	.....	19,257.12

Total Estimated Burden: 380 hours.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Janet M. Golrick,

Acting, Chief of Staff, Office of Housing—Federal Housing Administration.

[FR Doc. 2022–09777 Filed 5–5–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7050–N–15]

30-Day Notice of Proposed Information Collection: Comment Request Housing Discrimination Claim Form HUD–903.1, HUD–903.1A, HUD–903.1B, HUD–903.1C, HUD–903.1F, HUD–903.1CAM, HUD–903.1KOR, HUD–903.1RUS, HUD–903–1_Somali, OMB Control No.: 2529–0011

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed reinstatement, with revised title and minor text revisions, of an expired, previously approved information collection for HUD Form Series HUD–903.1, HUD–903.1A, HUD–903.1B, HUD–903.1C, HUD–903.1F, HUD–903.1CAM, HUD–903.1KOR, HUD–903.1RUS, and HUD–903–1_Somali will be submitted to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act of 1995. HUD is soliciting comments from all interested parties on the proposed reinstatement of this information collection.

DATES: Comment Due Date: June 6, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_submission@omb.eop.gov* or *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. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. 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. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on June 25, 2021 at 86 FR 33721, HUD is submitting this proposed reinstatement, with revised title and minor text revisions, of an expired, previously approved information collection to the OMB for review, as required by the Paperwork Reduction Act of 1995 [44 U.S.C. chapter 35, as amended].

HUD has revised the previous title of the HUD Form Series HUD–903.1 information collection from ''Housing Discrimination Information Form'' to ''Housing Discrimination Claim Form (''Form'').'' This revised title emphasizes that submitting a Housing Discrimination Claim Form to HUD is *not* equivalent to filing a jurisdictional housing discrimination complaint with HUD. The proposed minor text revisions comply with the procedures described

in HUD's Fair Housing Act regulation at 24 CFR part 103, subpart B, Subsections 103.10, 103.15, 103.20, 103.25, 103.30, 103.35, and 103.40. The revised Form also provides a complete list of mailing addresses, email addresses, and fax numbers for HUD's ten (10) Regional Fair Housing and Equal Opportunity (FHEO) Offices.

The proposed minor text revisions to HUD Form Series HUD–903.1 will not increase the information collection burden for aggrieved persons. Both the previous and revised Forms ask an aggrieved person to provide their full name; address; phone and/or email contact information; and alternative contact information. Both Forms also ask the aggrieved person to answer five (5) preliminary questions that may establish HUD's authority (jurisdiction) to file and investigate a Fair Housing Act complaint.

The proposed minor text revisions to HUD Form Series HUD–903.1 will not increase the total annual burden hours for aggrieved persons who submit the Form to HUD via the internet. Therefore, HUD does not believe that the time for completing the online version of the Form will exceed the current 45-minute time limit for internet submissions.

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed reinstatement, with revised title and minor text revisions, of an expired, previously approved collection of information concerning alleged discriminatory housing practices under the Fair Housing Act [42 U.S.C. 3601 *et seq.*]. The Fair Housing Act prohibits discrimination in the sale, rental, occupancy, advertising, and insuring of residential dwellings; and in residential real estate-related transactions; and in the provision of brokerage services, based on race, color, religion, sex, handicap [disability], familial status, or national origin. The Fair Housing Act also makes it unlawful to coerce, intimidate, threaten, or interfere with any person who has (1) exercised their fair housing rights; or (2) aided or encouraged another person to exercise their fair housing rights.

Any person who claims to have been injured by a discriminatory housing practice, or any person who believes that they will be injured by a discriminatory housing practice that is about to occur, may file a complaint with HUD not later than one year after the alleged discriminatory housing practice occurred or terminated. HUD has designed Housing Discrimination Claim Form HUD–903.1 to promote consistency in the documents that, by statute, must be provided to persons against whom complaints are filed [''*respondents*''], and for the convenience of the general public. Section 103.25 of HUD's Fair Housing Act regulation describes the information that must be included in each complaint filed with HUD. For purposes of meeting the Act's one-year time limitation for filing complaints with HUD, complaints need not be initially submitted on the Form that HUD provides. Housing Discrimination Claim Form HUD–903.1 (English language), HUD–903.1A (Spanish language), HUD–903.1B (Chinese language), HUD–903.1C (Arabic language), HUD–903.1F (Vietnamese language), HUD–903.1CAM (Cambodian language), HUD–903.1KOR (Korean language), HUD–903.1RUS (Russian language), and HUD–903–1_ (Somali language) may be submitted to HUD by mail, in person, by facsimile, by email, or via the internet to HUD's Office of Fair Housing and Equal Opportunity (FHEO). FHEO staff uses the information provided on the Form to verify HUD's authority to investigate the aggrieved person's allegations under the Fair Housing Act.

A. Overview of Information Collection

Proposed Revised Title of Information Collection: Housing Discrimination Claim Form.

OMB Control Number: 2529–0011.

Type of Request: Proposed reinstatement, with revised title and minor text revisions, of an expired, previously approved information collection

Form Number: HUD–903.1.

Description of the need for the information and proposed use: HUD uses the Housing Discrimination Claim Form HUD–903.1 (Form) to collect pertinent information from persons wishing to file housing discrimination complaints with HUD under the Fair Housing Act. The Fair Housing Act makes it unlawful to discriminate in the sale, rental, occupancy, advertising, or insuring of residential dwellings; or to discriminate in residential real estate-related transactions; or in the provision of brokerage services, based on race, color, religion, sex, handicap [disability], familial status, or national origin. The Fair Housing Act also makes it unlawful to coerce, intimidate, threaten, or interfere with any person who has (1) exercised their fair housing rights; or (2) aided or encouraged another person to exercise their fair housing rights.

Any person who claims to have been injured by a discriminatory housing practice, or any person who believes that they will be injured by a discriminatory housing practice that is about to occur, may file a complaint with HUD not later than one year after the alleged discriminatory housing practice occurs or terminates. The Form promotes consistency in the collection of information necessary to contact persons who file housing discrimination complaints with HUD. It also aids in the collection of information necessary for initial assessments of HUD's authority to investigate alleged discriminatory housing practices under the Fair Housing Act. This information may subsequently be provided to persons against whom complaints are filed [''*respondents*''], as required under section 810(a)(1)(B)(ii) of the Fair Housing Act.

Agency form numbers, if applicable: Form HUD–903.1 (English), Form HUD–903.1A (Spanish), Form HUD–903.1B (Chinese), Form HUD–903.1C (Arabic), Form HUD–903.1F (Vietnamese), Form HUD–903.1CAM (Cambodian), Form HUD–903.1KOR (Korean), Form HUD–903.1RUS (Russian), and Form HUD–903–1_(Somali).

Members of affected public: Individuals or households; businesses or other for-profit, not-for-profit institutions; State, Local, or Tribal Governments.

Estimation of the total number of hours needed to prepare the information collection, including the number of respondents, frequency of response, and hours of responses: During FY 2020, HUD staff received approximately 21,846 information submissions from persons wishing to file housing discrimination complaints with HUD. Of this total, HUD received 1,298 complaint submissions by telephone. The remaining 20,548 complaint submissions were transmitted to HUD by mail, in-person, by email, and via the internet. HUD estimates that an aggrieved person requires approximately 45 minutes in which to complete this Form. The Form is completed once by each aggrieved person. Therefore, the total number of annual burden hours for this Form is 15,411 hours.

$20{,}548 \times 1$ (frequency) $\times$ .45 minutes (.75 hours) = 15,411 hours.

Annualized cost burden to complainants: HUD does not provide postage-paid mailers for this information collection. Accordingly, aggrieved persons choosing to submit this Form to HUD by regular mail must pay the United States Postal Service's (USPS) prevailing First Class Postage rate. As of the date of this Notice, the annualized cost burden per person, based on a one-time submission of this

Form to HUD via the USPS's First Class Postage rate, is Fifty-five Cents ($0.55) per person. During FY 2020, FHEO staff received approximately 1,533 submissions of potential complaint information by mail. Based on this number, HUD estimates that the total annualized cost burden for aggrieved persons who submit this Form to HUD by mail is $843.00. Aggrieved persons may also submit this Form to HUD in person, by facsimile, by email, or electronically via the internet.

Status of the proposed information collection: Proposed reinstatement, with revised title and minor text revisions, of an expired, previously approved collection of pertinent information from persons wishing to file Fair Housing Act complaints with HUD.

B. Solicitation of Public Comments

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 information collection is necessary for the performance of the agency's functions;

(2) Whether the agency's estimate of burdens imposed by the information collection is accurate;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burdens of the information collection on aggrieved persons, including the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

(5) 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.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35, as amended.

Colette Pollard,

Department Reports Management Officer, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2022–09793 Filed 5–5–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7052–N–04]

60-Day Notice of Proposed Information Collection: HUD-Administered Small Cities Program Performance Assessment Report OMB Control No.: 2506–0020

AGENCY: Office of Community Planning and Development, 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: July 5, 2022*

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: Anna Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–5535 (this is not a toll-free number) or email at email at *Anna.P.Guido@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Robert Peterson, Director of State and Small Cities Division, Office of Block Grant Assistance, Department of Housing and Urban Development, email Robert Peterson at *Robert.C.Peterson@hud.gov* or telephone 202–402–4211, (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Anna Guido at (202) 402–5535 or *Anna.P.Guido@hud.gov.*

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: HUD-Administered Small Cities Program Performance Assessment Report.

OMB Approval Number: 2506–0020.

Type of Request: Extension of currently approved collection.

Form Number: HUD–4052.

Description of the need for the information and proposed use: Section 104(e) of the Housing and Community Development Act (HCDA) of 1974 require that each grantee must submit a performance and evaluation report to HUD. An extension without change of a currently approved collection is requested for the annual performance assessment report, submitted by the grantees in the Small Cities program enabling HUD to track program progress.

Estimated Number of Respondents: 40.

Estimated Number of Responses: 40.

Frequency of Response: 1.0.

Average Hours per Response: 4.0.

Total Estimated Burdens: 160.

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.

James Arthur Jemison II,

Principal Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 2022–09775 Filed 5–5–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWYD04000.L16100000.DP0000.19X]

Notice of Availability of the Proposed Resource Management Plan Amendment and Final Environmental Impact Statement for Wild Horse Management for the Bureau of Land Management Rock Springs and Rawlins Field Offices, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) has prepared a Final Environmental Impact Statement (EIS) and Proposed Resource Management Plan (RMP) Amendment for Wild Horse Management within the Rock Springs and Rawlins Field Offices of Wyoming and by this notice is announcing its availability and the opening of a protest period on the RMP Amendment.

DATES: The BLM planning regulations state that any person who meets the conditions as described in the regulations may protest the BLM's Proposed RMP Amendment. A person who meets the conditions and files a protest must file the protest within 30 days of the date that the Environmental Protection Agency (EPA) publishes its Notice of Availability in the **Federal Register**. The BLM will issue a Record of Decision no earlier than 30 days from the date of the Notice of Availability published by the EPA.

ADDRESSES: Instructions for filing a protest with the Director of the BLM regarding the Proposed RMPs may be found online at *https://www.blm.gov/filing-a-plan-protest* and at 43 CFR 1610.5–2.

You may review the Final EIS and Proposed RMP Amendment online at the RMP ePlanning website, (*https://go.usa.gov/xeyxa*). Hard copies are also available for review at the following BLM offices:

- Rawlins Field Office, 1300 North Third, Rawlins, WY 82301–2407.
- Rock Springs Field Office, 280 Highway 191 North, Rock Springs, WY 82901–3447.

FOR FURTHER INFORMATION CONTACT: Kimberlee Foster, Field Manager, BLM Rock Springs Field Office at 307–352–0256. 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: The BLM manages wild horses under the authority of the Wild Free-Roaming Horses and Burros Act of 1971, as amended, to ensure healthy wild horse herds thrive on healthy rangelands in balance with other resources. The Act requires the BLM to manage wild horses at Appropriate Management Levels (AML) to achieve a ''thriving natural ecological balance.'' It also requires BLM to remove wild horses that have strayed onto private lands if the landowner requests their removal.

In June 2010, the Rock Springs Grazing Association (RSGA) filed a lawsuit (*Rock Springs Grazing Association* v. *Salazar,* No. 11–CV–00263–NDF) in the U.S. District Court for the District of Wyoming, contending the BLM violated Section 4 of the Wild Free-Roaming Horses and Burros Act (16 U.S.C. 1334) by failing to remove strayed animals from private lands controlled by the RSGA in southern Wyoming's checkerboard pattern of alternating public and private lands. In April 2013, the court approved a Consent Decree and Joint Stipulation for Dismissal that resolved the lawsuit and required the BLM to evaluate potential changes to its management of wild horses on checkerboard lands by considering an RMP revision for the Rock Springs and Rawlins field offices. The BLM initiated the planning effort and developed this Final EIS to meet the terms of the Consent Decree, which directs the BLM to analyze and consider certain wild horse management actions.

If approved, management actions analyzed in this Final EIS would amend the 1997 Green River RMP and the 2008 Rawlins RMP. The planning area for this Final EIS and proposed RMP Amendment includes the four herd management areas that contain checkerboard land and are addressed in the Consent Decree, encompassing approximately 2,811,401 acres managed by the Rock Springs and Rawlins Field Offices.

The BLM manages approximately 1,920,314 acres of surface estate in the planning area. Private land in the planning area totals approximately 814,086 acres. The Proposed RMP Amendment would change management as follows: (1) The Rock Springs Field Office portion of the Adobe Town Herd Management Area (HMA) would no longer be designated as an HMA and would be managed for zero wild horses. For the Rawlins Field Office portion of the HMA, all checkerboard land and the portion of the HMA north of the existing Corson Springs southern allotment boundary fence would no longer be designated as an HMA and would be managed for zero wild horses. The remainder of the HMA would be retained and managed with an AML of 259–536; (2) the entire Great Divide Basin HMA would no longer be designated as an HMA and would be managed for zero wild horses; (3) the entire Salt Wells Creek HMA would no longer be designated as an HMA and would be managed for zero wild horses; and (4) the boundary of the White Mountain HMA would remain the same and would continue to include checkerboard land.

All protests must be in writing and submitted, as set forth in the **DATES** and **ADDRESSES** sections earlier. The BLM Director will render a written decision on each protest. The decision will be mailed to the protesting party. The decision of the BLM Director shall be the final decision of the Department of the Interior on each protest. Responses to protest issues will be compiled and formalized in a BLM Director's Protest Resolution Report made available following issuance of the decisions.

Before including your address, phone number, email address, or other personally identifying information in your protest, you should be aware that your entire protest—including your personally identifying information—may be made publicly available at any time. While you can ask the BLM in your protest to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2, 43 CFR 1610.5

Andrew Archuleta,

State Director, Wyoming.

[FR Doc. 2022–09556 Filed 5–5–22; 8:45 am]

BILLING CODE 4310–22–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1227]

Certain Routers, Access Points, Controllers, Network Management Devices, Other Networking Products, and Hardware and Software Components Thereof; Commission Determination To Review in Part a Final Initial Determination Finding No Violation of Section 337 and, on Review, To Affirm the Finding of No Violation; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part a final initial determination (''ID'') issued by the presiding administrative law judge (''ALJ'') on December 7, 2021, finding no violation of section 337 in the above-referenced investigation and, on review, to affirm the finding of no violation. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Michael Liberman, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2392. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On October 28, 2020, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based on a complaint filed by Q3 Networking LLC of Frisco, Texas (''Q3''). 85 FR 68367–68 (Oct. 28, 2020). The complaint alleged a violation of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain routers, access points, controllers, network management devices, other networking products, and hardware and software components thereof by reason of infringement of certain claims of U.S. Patent Nos. 7,609,677 (''the '677 patent''); 7,895,305 (''the '305 patent''); 8,797,853 (''the '853 patent''); and 7,457,627 (''the '627 patent''). The complaint also alleged the existence of a domestic industry. The notice of investigation named as respondents: CommScope Holding Company, Inc. of Hickory, North Carolina; CommScope, Inc. of Hickory, North Carolina; Arris US Holdings, Inc. of Suwanee, Georgia; Ruckus Wireless, Inc. of Sunnyvale, California; Hewlett Packard Enterprise Co. of Palo Alto, California; Aruba Networks, Inc. of Santa Clara, California; and Netgear, Inc. of San Jose, California (collectively, ''Respondents''). *Id.* at 68368. The Commission's Office of Unfair Import Investigations was not named as a party in this investigation. *Id.*

Subsequently, the Commission permitted complainant to amend the complaint and notice of investigation to correct the corporate name of respondent Aruba Networks, Inc. to respondent Aruba Networks, LLC. Order 15 (Mar. 5, 2021), *unreviewed by* Notice (Mar. 22, 2021). The Commission also partially terminated the investigation by withdrawal of the '627 patent. Order No. 26 (July 1, 2021), *unreviewed by* Notice (Jul. 26, 2021).

On December 7, 2021, the ALJ issued the final ID in this investigation, holding that no violation of section 337 has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation, of certain routers, access points, controllers, network management devices, other networking products, and hardware and software components thereof by reason of infringement of claims 1–6 of the '677 patent; claims 1 and 8 of the '305 patent; and claims 1–9 of the '853 patent.[1]

The ID found that the accused products do not infringe the asserted claims of any of the asserted patents. The ID also found that the domestic industry requirement (both technical and economic prongs) has not been satisfied with respect to the '853, '305, and '677 patents. The ID further found that it has not been shown by clear and convincing evidence that the asserted claims of the '853, '305, and '677 patents are invalid.

On December 20, 2021, Complainant Q3 filed a petition for review of various portions of the ID. Also, on December 20, 2021, Respondents filed a contingent petition for review of various portions of the ID. On December 28, 2021, both Respondents and Complainant filed replies in response to the petition for review and the contingent petition for review, respectively.

Having examined the record in this investigation, including the final ID, the petitions for review, and the responses thereto, the Commission has determined to review in part the ID (1) with respect to the economic prong of the domestic industry requirement, and on review, to take no position, and (2) in order to correct certain non-substantive citation errors pertaining to the ID's technical prong findings regarding the '305 patent, and on review, to correct those errors. Specifically, the Commission cites to the following questions and answers from RX–1210C on pages 166–73 of the ID: (i) Q/A 17 instead of Q/A 16 in the first full paragraph on page 166; (ii) Q/A 32 instead of Q/A 28 on lines 3 and 10 in the first full paragraph on page 167; (iii) Q/A 24 instead of Q/A 22 in the first paragraph on page 168; (iv) Q/A 25 instead of Q/A 23 in the second paragraph on page 168; (v) Q/A 26 instead of Q/A 24 in the first paragraph on page 169; (vi) Q/A 29 instead of Q/A 28 in the second paragraph on page 169; (vii) Q/A 21–27 & 29 instead of Q/A 19–25 on page 169; (viii) Q/A 33–35 instead of Q/A 29–32 and Q/A 35 instead of Q/A 31 in the first paragraph on page 170 of the ID; (ix) Q/A 35 instead of Q/A 29–32 in the second paragraph on page 170 of the ID; (x) Q/A 35–36 instead of Q/A 32 in the first paragraph on page 171 of the ID; (xi) Q/A 37 instead of Q/A 33 in the second paragraph on page 171 of the ID, in the first full paragraph on page 172 of the ID, and in the first paragraph of page 173; and (xii) Q/A 38–41 instead of Q/A 34–37 and Q/A 39 instead of Q/A 35 in the last paragraph on page 173. The Commission has determined not to review the remainder of the ID, including the ID's finding of no violation of section 337 in this investigation.[2] [3]

[1] By failing to assert that Respondents infringe claims 2–3, 5, 6, 9, and 11–14 of the '305 patent and claim 8 of the '677 patent in its prehearing and posthearing briefs Complainant abandoned the above-referenced claims under Ground Rule 7(c).

[2] With respect to the '853 patent, Vice Chair Stayin would review the ID's claim construction of the term ''overall transmission capacity,'' and find the term should be given its plain and ordinary meaning. Nonetheless, Vice Chair Stayin agrees that even under this revised construction the accused products do not infringe the asserted claims of the '853 patent, and the domestic industry products do not practice the claims of the '853 patent, for many of the reasons articulated in the ID. Accordingly, he joins the Commission's decision to affirm the ID's findings of no violation as to the '853 patent.

[3] Chair Kearns and Vice Chair Stayin note that they do not read anything in the ID (*see, e.g.,* ID at 207 and 260–61) as foreclosing a finding of a violation of section 337, under appropriate facts, based on direct infringement by a respondent where the accused article is combined post-importation with other articles to infringe an asserted patent claim.

The investigation is hereby terminated.

The Commission vote for this determination took place on May 3, 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: May 3, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–09818 Filed 5–5–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Pneumatic Compression Devices and Components Thereof, DN 3618;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (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 United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.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: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Precision Holdings USA Inc. and Innovamed Health LLC on May 2, 2022. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain pneumatic compression devices and components thereof. The complainant names as respondents: ManaMed Inc. of Las Vegas, NV; Grandway Healthcare Limited of China; Vive Health LLC d/b/a Coretech of Naples, FL; and Medline Industries Inc. of Northfield, IL. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders and impose a bond upon respondents alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondent, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3618'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of 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

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

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,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: May 2, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–09743 Filed 5–5–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Barcode Scanners, Scan Engines, Mobile Computers With Barcode Scanning Functionalities, Products Containing the Same, and Components Thereof, DN 3619;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (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 United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.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: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Honeywell International Inc. and Hand Held Products, Inc. on May 02, 2022. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain barcode scanners, scan engines, mobile computers with barcode scanning functionalities, products containing the same, and components thereof. The complainant names as respondents: Zebra Technologies Corporation of Lincolnshire, IL; and Symbol Technologies, Inc. of Holtsville, NY. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders and impose a bond upon respondents alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondent, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3619'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of 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,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: May 2, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–09755 Filed 5–5–22; 8:45 am]

BILLING CODE 7020–02–P

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–991]

Bulk Manufacturer of Controlled Substances Application: Patheon Pharmaceuticals Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Patheon Pharmaceuticals Inc. has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTAL INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 5, 2022. Such persons may also file a written request for a hearing on the application on or before July 5, 2022.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.''

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on February 3, 2022, Patheon Pharmaceuticals Inc., 2110 East Galbraith Road, Cincinnati, Ohio 45237–1625, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid	2010	I

The company plans to manufacture the above-listed controlled substance as Active Pharmaceutical Ingredient (API) that will be further synthesized into Food and Drug Administration-approved dosage forms. No other activities for this drug code are authorized for this registration.

Matthew J. Strait,

Deputy Assistant Administrator.

[FR Doc. 2022–09779 Filed 5–5–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

[OMB 1140–0066]

Agency Information Collection Activities; Proposed eCollection of eComments Requested; Manufacturers of Ammunition, Records and Supporting Data of Ammunition Manufactured and Disposed of

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Department of Justice (DOJ), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection (IC) is also being published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until July 5, 2022.

FOR FURTHER INFORMATION CONTACT: If you have additional comments regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, contact: Jason Gluck, Firearms Industry Programs Branch, Firearms Explosives Industries Division, Enforcement Programs Services, by mail at 99 New York Ave. NE, Washington, DC 20226, by email at *FIPB-informationcollection@atf.gov,* or telephone at 202–648–7190.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and, if so, how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection (check justification or form 83):* Extension without Change of a Currently Approved Collection.

2. *The Title of the Form/Collection:* Manufacturers of Ammunition, Records and Supporting Data of Ammunition, Manufactured and Disposed of

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other (if applicable): None.

Abstract: This collection is a recordkeeping requirement for manufacturers of ammunition. Bureau of Alcohol, Tobacco, Firearms, and Explosives personnel may also use these records during criminal investigations and compliance inspections to enforce the Gun Control Act.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 188 respondents will respond to this collection once annually, and it will take each respondent approximately 2 minutes to complete their responses.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 6.2 or 6 hours, which is equal to 188 (total respondents) * 1 (# of response per respondent) * .033 (2 minutes or the time taken to prepare each response).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Mail Stop 3.E–405A, Washington, DC 20530.

Dated: May 3, 2022.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2022–09807 Filed 5–5–22; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0029]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection; Annual Reporting Requirement for Manufacturers of Listed Chemicals

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice, Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until July 5, 2022.

FOR FURTHER INFORMATION CONTACT: If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 776–2265.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Annual Reporting Requirement for Manufacturers of Listed Chemicals.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form number: N/A. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected public (Primary): Business or other for-profit.

Affected public (Other): None.

Abstract: Pursuant to 21 U.S.C. 830(b)(2) and 21 CFR 1310.05(d), manufacturers of listed chemicals must file annual reports of manufacturing, inventory, and use data for the listed chemicals they manufacture. These reports allow DEA to monitor the volume and availability of domestically manufactured listed chemicals, which may be subject to diversion for the illicit production of controlled substances.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* Each respondent for this information collection completes one response per year. DEA estimates there are 50 respondents, and that each response takes 0.25 hours to complete.

6. *An estimate of the total public burden (in hours) associated with the proposed collection:* DEA estimates this collection takes a total of 12.5 annual burden hours.

If additional information is required, please contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.

Dated: May 3, 2022.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2022–09804 Filed 5–5–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1110–0069]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection

AGENCY: Criminal Justice Information Services Division, Federal Bureau of Investigation, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Criminal Justice Information Services Division, Federal Bureau of Investigation, Department of Justice, is submitting the following information collection request to the

Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The Department of Justice encourages public comment and will accept input until July 5, 2022.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Gerry Lynn Brovey, Supervisory Information Liaison Specialist, FBI, CJIS, Resources Management Section, Administrative Unit, Module C–2, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306; phone: 304–325–4320 or email *glbrovey@fbi.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

➢ Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Federal Bureau of Investigation, Criminal Justice Information Services Division, including whether the information will have practical utility;

➢ Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

➢ Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

➢ Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a currently approved collection.

2. *The Title of the Form/Collection:* Flash/Cancellation/Transfer Notice.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Agency form number I–12. The applicable component within the Department of Justice is the Federal Bureau of Investigation, Criminal Justice Information Services Division.

4. *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* City, county, state, federal and tribal law enforcement agencies. This collection is needed to indicate on an individual's criminal history that the individual is being supervised to ensure the supervisory agency is notified of any additional criminal history activity. Acceptable data is stored as part of the Next Generation Identification (NGI) system of the FBI.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated 1,057 respondents will complete each form within approximately 8 minutes. The total number of respondents is reoccurring with an annual response of 174,337.

6. *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 23,245 total annual burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: May 3, 2022.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2022–09806 Filed 5–5–22; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request, Award Closure Statement Documents: Detailed Statement of Cost, Government Property Certification, and Property Inventory Listing

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL) Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Closeout Documents.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by July 5, 2022.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting Latonya Torrence by telephone at 202–693–3708 (this is not a toll-free number), TTY 1–877–889–5627 (this is not a toll-free number), or by email at *Torrence.Latonya@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Grants Management, 200 Constitution Avenue NW, Room N–4716, Washington, DC 20210; by email: *Torrence.Latonya@dol.gov;* or by fax 202–693–2705.

FOR FURTHER INFORMATION: Contact Latonya Torrence by telephone at 202–693–3708 (this is not a toll-free number) or by email at *Torrence.Latonya@dol.gov*.

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The purpose of this ICR is to notify Federal award recipients of the necessity to submit the required data on the Closeout Documents, which consist of the Detailed Statement of Cost (DSC), Government Property Close-Out Inventory Certification, and Property Inventory Listing (if applicable).

These forms help to ensure grant award recipients provide a final documented accounting of activities conducted under the Federal award by allowing funds to be traced to a level of expenditure for establishing that such funds have been used in accordance with Federal statues, regulations and terms and conditions of the award. The Uniform Guidance (31.U.S.C. 503), last amended 10/18/2021, 2 CFR 200.302, 2

CFR 200.308, 2 CFR 200.313, 2 CFR 200.316 and 2 CFR 200.344 and the terms and conditions of all DOL awards, authorize this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention 1205–0NEW. Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including 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).

Agency: DOL–ETA.

Type of Review: New.

Title of Collection: Award Closure Statement Documents.

Forms: Detailed Statement of Cost, Government Property Certification, and Property Inventory Listing.

OMB Control Number: 1205–0NEW.

Affected Public: State workforce agencies, local governments, non-profit organizations, educational institutions, consortia of any and/or all of the above.

Estimated Number of Respondents: 1,100.

Frequency: Annually.

Total Estimated Annual Responses: 1,100.

Estimated Average Time per Response: Varies.

Estimated Total Annual Burden Hours: 1,100 hours.

Total Estimated Annual Other Cost Burden: $0.

Authority: 44 U.S.C. 3506(c)(2)(A).

Angela Hanks,

Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2022–09665 Filed 5–5–22; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2012–0038]

The Standard on Personal Protective Equipment (PPE) for Shipyard Employment; 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 Standard on Personal Protective Equipment (PPE) for Shipyard Employment.

DATES: Comments must be submitted (postmarked, sent, or received) by July 5, 2022.

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 for assistance in locating docket submissions.

Instructions: All submissions must include the agency name and OSHA docket number (OSHA–2012–0038) for the Information Collection Request (ICR). OSHA will place all comments and requests to speak, including personal information, in the public docket, which may be 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 a 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–95) (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, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the 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 efforts in obtaining information (29 U.S.C. 657).

Subpart I specify several paperwork requirements which are described below.

Section 1915.152(b) requires the employer to assess work activities to

determine whether there are hazards present, or likely to be present, which necessitate the worker's use of PPE. If such hazards are present, or likely to be present, the employer must: (1) Select the type of PPE that will protect the affected workers from the hazards identified in the occupational hazard assessment; (2) communicate PPE selection decisions to the affected workers; (3) select PPE that properly fits each affected worker; and (4) maintain documentation to verify that the required occupational hazard assessment has been performed. The verification must contain the following information: Occupation or trade assessed, the date(s) of the hazard assessment, and the name of the person performing the hazard assessment.

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, 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 collection of information requirements contained in the Standard on Personal Protective Equipment (PPE) for Shipyard Employment (29 CFR part 1915, subpart I). The agency is requesting an adjustment increase in burden from 201 hours to 220 hours, a difference of 19 burden hours. This increase is the due to an increase in the number of affected establishments covered by the Shipyard Industry.

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 contained in the Standard on Personal Protective Equipment (PPE) for Shipyard Employment (29 CFR part 1915, subpart I).

Type of Review: Extension of a currently approved collection.

Title: Personal Protective Equipment Standard for Shipyard Employment (29 CFR part 1915, subpart I).

OMB Control Number: 1218–0215.

Affected Public: Business or other for-profits.

Number of Respondents: 4,693.

Total Responses: 2,607.

Frequency of Response: On occasion.

Average Time per Response: An estimated 5 minutes for employers to record the hazard assessment.

Estimated Burden Hours: 220.

Estimated Cost (Operation and Maintenance): $0.

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 (Docket No. OSHA–2012–0038). 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, on April 27, 2022.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2022–09701 Filed 5–5–22; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL FOUNDATION ON THE ARTS AND HUMANITIES

National Endowment for the Arts

Proposed Collection; Comment Request; 30-Day Notice for the ''2022 Arts Supplement to the General Social Survey''

AGENCY: National Endowment for the Arts.

ACTION: Notice.

SUMMARY: The National Endowment for the Arts (NEA), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to ensure the requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the NEA is soliciting comments concerning the proposed information collection on arts participation in the U.S: Clearance Request for NEA 2022 Arts Supplement to the General Social Survey. Copies of this ICR, with applicable supporting

documentation, may be obtained by visiting *www.Reginfo.gov.*

DATES: Written comments must be submitted to the office listed in the address section below within 30 days from the date of this publication in the **Federal Register**.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this Notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''National Endowment for the Arts'' under ''Currently Under Review;'' then check ''Only Show ICR for Public Comment'' checkbox. Once you have found this information collection request, select ''Comment,'' and enter or upload your comment and information. Alternatively, comments should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the National Endowment for the Arts, Office of Management and Budget, Room 10235, Washington, DC 20503 202/395–7316, within 30 days from the date of this publication in the **Federal Register**.

SUPPLEMENTARY INFORMATION: The NEA is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Agency: National Endowment for the Arts.

Title: 2022 Arts Supplement to the General Social Survey.

OMB Number: 3135–0132.

Frequency: One time.

Affected Public: American adults.

Estimated Number of Respondents: 750.

Estimated Time per Respondent: 10 minutes.

Total Burden Hours: 125 hours.

Total Annualized Capital/Startup Costs: 0.

Total Annual Costs (operating/maintaining systems or purchasing services): 0.

Description

This request is for clearance of the 2022 Arts Supplement to the General Social Survey (GSS) to be conducted by the National Opinion Research Center on behalf of the National Science Foundation. The Arts Supplement to the GSS will provide important data on the impact the COVID–19 pandemic has had on recent arts participation. The survey data will also complement data collected through the planned 2022 Survey of Public Participation in the Arts. The data are circulated to interested researchers, and they are the basis for a range of NEA reports and independent research publications. An arts supplement to the GSS was also conducted in 2012 and 2016. The data will be made available to the public through the agency's data archive, the National Archive of Data on Arts and Culture (NADAC). These data will also be used by the NEA as a contextual measure for one or more of its strategic goals.

Dated: May 3, 2022.

Meghan Jugder,

Support Services Specialist, Office of Administrative Services & Contracts, National Endowment for the Arts.

[FR Doc. 2022–09789 Filed 5–5–22; 8:45 am]

BILLING CODE 7537–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–391; NRC–2021–0104]

Tennessee Valley Authority; Watts Bar Nuclear Plant, Unit 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued an exemption in response to an April 15, 2022, request from Tennessee Valley Authority (the licensee), as supplemented by letter dated April 25, 2022. The licensee requested one-time exemptions to allow the use of the less restrictive work hour limitations described in NRC regulations, for additional 60-day periods for the Watts Bar Nuclear Plant, Unit 2.

DATES: The exemptions were issued on April 29, 2022.

ADDRESSES: Please refer to Docket ID NRC–2021–0104 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0104. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The Request for Exemption from Requirements of paragraph 26.205(d)(4) of title 10 of the *Code of Federal Regulations* (10 CFR), 26.206(d)(6), and 10 CFR 26.205(d)(7) is available in ADAMS under Accession No. ML22105A579. The Watts Bar Nuclear Plant, Unit 2—Response to Request for Additional Information and Clarification Regarding Request for Exemption from Requirements of 10 CFR 26.205(d)(4), 26.205(d)(6) and 26.205(d)(7), ''Fitness for Duty Programs—Work Hours,'' is available in ADAMS under Accession No. ML22115A232.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Kimberly Green, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1627, email: *Kimberly.Green@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the exemptions is attached.

Dated: May 2, 2022.

For the Nuclear Regulatory Commission.

Kimberly J. Green,

Senior Project Manager, Plant Licensing Branch II–2, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

Attachment—Exemption

NUCLEAR REGULATORY COMMISSION

Docket No. 50–391

Tennessee Valley Authority Watts Bar Nuclear Plant, Unit 2 Exemption

I. Background

The Tennessee Valley Authority (TVA, the licensee) is the holder of Facility Operating License No. NPF–96 which authorizes operation of Watts Bar Nuclear Plant (Watts Bar), Unit 2. The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the Nuclear Regulatory Commission (NRC, the Commission) now or hereafter in effect.

The facility consists of two pressurized-water reactors located in Rhea County in Tennessee.

II. Request/Action

By letter dated April 15, 2022, as supplemented by letter dated April 25, 2022 (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML22105A579 and ML22115A232, respectively), TVA requested one-time exemptions from the work hour requirements in Title 10 of the *Code of Federal Regulations* (10 CFR), part 26, ''Fitness for Duty Programs,'' section 26.205(d)(7), pursuant to 10 CFR 26.9, ''Specific exemptions.''

Section 26.205(d)(7) of 10 CFR provides, in part, that licensees may, as an alternative to the minimum days off requirements in 10 CFR 26.205(d)(3), ensure that individuals subject to the work hour controls in Section 26.205(d) do not work more than a weekly average of 54 hours, calculated using an averaging period of up to 6 weeks. Section 26.205(d)(4) of 10 CFR provides that during the first 60 days of a unit outage, licensees need not meet the requirements of 10 CFR 26.205(d)(3) or (d)(7) for individuals specified in 10 CFR 26.4(a)(1) through 10 CFR 26.4(a)(4), while those individuals are working on outage activities. However, 10 CFR 26.205(d)(4) also provides that the licensee shall ensure that the individuals specified in 10 CFR 26.4(a)(1) through (a)(3) have at least 3 days off in each successive (*i.e.,* non-rolling) 15-day period and that the individuals specified in 10 CFR 26.4(a)(4) have at least 1 day off in any 7-day period. Section 26.205(d)(6) states that the 60-day periods in 10 CFR 26.205(d)(4) and (d)(5) may be extended for each individual in 7-day increments for each non-overlapping 7-day period the individual has worked not more than 48 hours during the unit or security system outage or increased threat condition, as applicable.

Watts Bar, Unit 2, entered a refueling outage on March 1, 2022. During this refueling outage, the licensee also commenced a steam generator replacement (SGR) project. The outage, including the SGR project, was originally planned to be completed in mid-May, 2022, and TVA intended to administer work hour controls in accordance with 10 CFR 26.204(d)(4) and (d)(6). However, primarily due to adverse weather conditions and the emergent discovery of issues while removing the original steam generators and installing the replacement steam generators, the outage was delayed such that it is now scheduled to be completed by early June 2022. Due to these delays, TVA will not be able to complete outage activities within the period of time when outage work hour controls would be permitted in accordance with 10 CFR 26.205(d)(4), as extended by the allowances in 10 CFR 26.205(d)(6). Therefore, TVA requested one-time exemptions from 10 CFR 26.205(d)(7) to allow personnel to work less restrictive hours for an additional period to support the refueling outage.

Within the exemption request, TVA has identified two categories of affected personnel. Category A personnel are identified as those individuals performing activities directly in support of the SGR project; these activities constitute maintenance activities, as discussed in 10 CFR 26.4, ''FFD [fitness for duty] program applicability to categories of individuals,'' section (a)(4). Category A personnel include specialized craft workers such as, pipefitters, boilermakers, operating engineers, electricians, and iron workers. Category B personnel are identified as those individuals performing normal outage shutdown, startup, maintenance, fuel handling, and modification activities, which are not related to the SGR project, and are covered by 10 CFR 26.4(a)(1), (a)(2), and (a)(4). Category B personnel includes operations, health physics, chemistry, and maintenance personnel.

For Category A personnel, TVA requested a one-time exemption from the requirements of 10 CFR 26.205(d)(7) that would be applicable for a period not to exceed 60 days beyond the end of the current 60-day unit outage period in 10 CFR 26.205(d)(4) that began on March 1, 2022. During this exemption period, TVA would continue to administer work hour controls for Category A personnel in accordance with the outage-related minimum day off requirements listed in 10 CFR 26.205(d)(4), and TVA would also administer certain additional mitigating actions discussed in Section V of the Enclosure to the submittal letter. The exemption period for Category A personnel would conclude either at the end of the additional 60-day period (*i.e.,* no later than June 29, 2022) or when Watts Bar, Unit 2, is connected to the electrical grid, whichever occurs first.

For Category B personnel, TVA requested a one-time exemption from the requirements of 10 CFR 26.205(d)(7) that would begin upon completion of refueling outage Schedule Milestone SGM0184 (the SGR project schedule milestone for turnover of the polar crane from the SGR project team to the TVA outage team). During the exemption period, Category B personnel would be permitted to work in accordance with the minimum day off requirements in 10 CFR 26.205(d)(4) for a 60-day period. Similar to the provisions of 10 CFR 26.205(d)(6) for outages, this 60-day period could be extended for each individual in 7-day increments for each non-overlapping 7-day period of the 60-day period during which the individual has worked not more than 48 hours. Following the conclusion of the 60-day period for a given individual, normal (non-outage) work hour controls, would resume for that individual, in accordance with the requirements of 10 CFR 26.205(d)(7). The exemption period for Category B personnel would conclude when Watts Bar, Unit 2, is connected to the electrical grid.

III. Discussion

Pursuant to 10 CFR 26.9, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 26 when the exemptions are authorized by law and will not endanger life or property or the common defense and security; and are otherwise in the public interest.

A. The Exemption Is Authorized by Law

The exemption for Category A personnel would authorize a one-time exemption from the requirements of 10 CFR 26.205(d)(7) to allow the use the less restrictive work hour controls provided in 10 CFR 26.205(d)(4) for up to an additional 60 days, no later than June 29, 2022, or until the reactor unit is connected to the electrical grid, whichever occurs first, to allow SGR activities to be completed. The

exemption for Category B personnel would authorize a one-time exemption from the requirements of 10 CFR 26.205(d)(7) to allow the use the less restrictive work hour controls provided in 10 CFR 26.205(d)(4) for a 60-day period that would begin upon completion of refueling outage Schedule Milestone SGM0184 and may be extended as described in 10 CFR 26.205(d)(6) (Category B personnel), or until the reactor unit is connected to the electrical grid, whichever occurs first, to allow normal outage activities to be completed. As stated above, 10 CFR 26.9 allows the NRC to grant exemptions from the requirements of 10 CFR part 26. The NRC staff has determined that granting of the exemptions is permissible under the Atomic Energy Act of 1954, as amended, and other regulatory requirements. Therefore, the exemptions are authorized by law.

B. The Exemption Will Not Endanger Life or Property

The underlying purpose of subpart I of 10 CFR part 26 is to ensure that cumulative fatigue does not compromise the abilities of individuals to perform their duties safely and competently. The underlying purpose of 10 CFR 26.205(d)(7) is to provide a method for licensees to manage worker fatigue while a unit is in operation by limiting the number of hours that can be worked on a weekly basis, as averaged over a 6-week period. The underlying purpose of 10 CFR 26.205(d)(4) is to provide licensees flexibility in scheduling required days off while accommodating more intense work schedules associated with a unit outage. The underlying purpose of 10 CFR 26.205(d)(6) is to allow the flexibilities provided by 10 CFR 26.205(d)(4) to be extended when directly justified by an individual's actual work history.

For Category B personnel, TVA requested an exemption from the requirements of 10 CFR 26.205(d)(7) that would begin upon completion of refueling outage Schedule Milestone SGM0184 (the SGR project schedule milestone for turnover of the polar crane from the SGR project team to the TVA outage team). During the exemption period, Category B personnel would be permitted to work in accordance with the minimum day off requirements in 10 CFR 26.205(d)(4) for a 60-day period. In addition, similar to the provisions of 10 CFR 26.205(d)(6) for outages, this 60-day period could be extended for each individual in 7-day increments for each non-overlapping 7-day period of the 60-day period during which the individual has worked not more than 48 hours. TVA cited Position C.10 from Regulatory Guide 5.73, ''Fatigue Management for Nuclear Power Plant Personnel,'' which discusses the expectation that licensees should confirm that an individual transitioning from an outage at one plant to another ''has had a 34-hour break period within the 9 days that precede the day on which the individual begins working for the receiving licensee.'' TVA stated that prior to the start of the additional 60-day period, Category B personnel would have a minimum of 3 consecutive days off.

The NRC staff reviewed the schedules that had been worked by Category B personnel in various positions leading up to when TVA submitted the exemption request, as well as the originally planned work schedule for the remainder of the outage for Category B personnel (discussed in Table 1 of Enclosure 1 of TVA's submittal letter) to determine whether it would be appropriate to allow for a 60-day period for Category B personnel to use the flexibilities in 10 CFR 26.206(d)(4) and (d)(6), in addition to the 60 days of the current unit outage, from a fatigue management standpoint. The NRC staff noted that, for all positions except for Chemistry, individuals will have worked less than the 54-hour-per-week limit established for normal operating conditions in accordance with 10 CFR 26.205(d)(7) leading up to the start of the additional 60-day period for Category B personnel.

With regards to Chemistry personnel, the NRC staff noted that, under the most extreme scheduling case in accordance with the scheduling plan discussed in Table 1 of Enclosure 1 of TVA's submittal (including the 3 consecutive days off that will be provided to personnel), Chemistry personnel could potentially have worked up to 56 hours per week starting on March 14, 2022, and through the remainder of the first 60 days of the unit outage. However, this slight increase in the average hours worked per week, above the 10 CFR 26.205(d)(7) limits, is expected to be offset by the fact that the workers will be guaranteed 3 consecutive days off prior to transitioning into the exemption period for Category B personnel.

The NRC staff further noted that, in accordance with the 60-day limit established by 10 CFR 26.205(d)(4), Chemistry personnel who are not eligible for an extension under 10 CFR 26.205(d)(6) would need to return to a 54-hour work week, in accordance with 10 CFR 26(d)(7), starting at the end of the first 60-days of the unit outage. Therefore, depending on the actual date on which Schedule Milestone SGM0184 is completed, there is a possibility that Chemistry personnel will have returned to a 54-hour work week leading up to the start of the exemption period for Category B personnel.

Because Category B workers will be working a normal (or, in the case of Chemistry personnel, a near-normal) work schedule, in accordance with 10 CFR 26.205(d)(7), leading up to the additional 60-day period, the NRC staff determined that administering the minimum days off during the exemption period in accordance with the requirements in 10 CFR 26.205(d)(4) and (d)(6) will allow TVA to adequately manage cumulative fatigue among Category B personnel.

For Category A personnel, TVA requested authorization to apply the flexibilities allowed by 10 CFR 26.205(d)(4) for an additional period of up to 60 days beyond the first 60 days of the refueling outage that began on March 1, 2022. TVA identified several mitigating factors to justify this request. For example, TVA stated that, during the first 60 days of the refueling outage that began on March 1, 2022, when Category A personnel were scheduled to work 72-hour work weeks, they were given additional time off when available. This is reflected by the per-week work hour averages shown for various worker positions in Table 2 of Enclosure 1 of TVA's submittal letter. Additionally, TVA stated that during the exemption period it will implement alternative controls and mitigating actions, including the following:

- Personnel will not work more than 16 work-hours in any 24-hour period, and they will not work more than 72 work-hours in any 7-day period, excluding shift turnover.
- A minimum 10-hour break will be provided between successive work periods.
- 12-hour shifts will be limited to 72 work hours in a 7-day rolling period.
- A minimum of 3 days off will be provided in each subsequent 15-day period after the first 60 days of the outage.
- The calculation of work hours and days will include all work hours and days off during the applicable calculation periods, including those work hours and days off preceding initiation of the exemption period.
- Requirements will be established for behavioral observation and self-declaration during the period of the exemption. Specifically, the station will perform targeted management and peer to peer fatigue observations and the station will provide briefings with station personnel on the capability and process for personnel to self-declare fatigue.

• Prior to personnel going to the field, the process will include discussion of self-declaration of fatigue, with regards to both self-awareness and keeping watch on crew members.

• The station will promote fatigue awareness and perform targeted observations of fatigue signs using an observation program.

The NRC staff reviewed TVA's scheduling plan for Category A personnel. Because Category A workers have been provided with 1 day off every 7 days, and because, as discussed in Section IV of Enclosure 1 of TVA's submittal letter, those workers have typically worked consistent 12-hour schedules, there is a reasonable expectation that the day off, plus the time after a worker's preceding shift and before a worker's subsequent shift, will provide about 36 consecutive hours of time off once every 7 days. Furthermore, 10 CFR 26.205(d)(2)(ii) requires that licensees shall ensure that individuals have, at a minimum, a 34-hour break in any 9-day period. Based on these considerations, the NRC staff determined that Category A personnel will receive at least a 34-hour break within the 9 days that precede the 60-day exemption period.

The NRC staff noted that compliance with the 34-hour break requirement discussed in 10 CFR 26.205(d)(2)(ii) does not, on its own, constitute adequate management of cumulative fatigue for workers, and that this requirement is intended to be implemented with the other work hour control requirements discussed in the other sections of 10 CFR 26.205. However, the NRC staff considered the required minimum 34-hour break period in conjunction with the fact that, leading up to the 60-day exemption period, Category A personnel will not have worked the full 72 hours per week allowed in accordance with the minimum days off required by 10 CFR 26.205(d)(4) for personnel performing maintenance activities in accordance with 10 CFR 26.4(a)(4). As shown by Table 2 of Enclosure 1 of the licensee's submittal letter, personnel will have only worked, on average, 58 to 66 hours of the allowed 72 hours per week. Because personnel will have been working, on average, 6 to 14 hours less than the maximum number of hours that are permitted by regulation during outage conditions, there is added assurance that cumulative fatigue can be adequately managed by the minimum 34-hour period they must provide prior to the start of the subsequent 60-day period.

One additional factor that the NRC staff considered for Category A personnel is the fact that a significant portion of the work being performed by these personnel consists of maintenance activities that will be subject to verification (*e.g.,* via non-destructive examination) or post-maintenance testing. This provides some assurance that potential fatigue-related errors that may occur will be identified and resolved. However, the NRC staff did not rely exclusively on the additional assurance provided by activities such as non-destructive evaluation (NDE) as a basis for its determination that the exemption would not endanger life or property, because (in accordance with Position C.2 of Regulatory Guide 5.73) individuals performing NDE are not necessarily subject to work hour controls and, as such, their performance could be potentially degraded by fatigue.

The NRC staff determined that the added scheduling margin from Category A personnel not having worked full 72-hour weeks leading up to the exemption period, along with adherence to the alternative work hour controls discussed in Section V of Enclosure 1 of TVA's submittal letter, will allow TVA to adequately manage cumulative fatigue among Category A personnel during the requested 60-day exemption period.

Because TVA proposed adequate alternative controls and mitigation measures for managing cumulative fatigue among Category A and Category B personnel for the duration of the requested one-time exemptions, the NRC staff determined that the requested one-time exemptions will not endanger life or property.

C. The Exemption Is Consistent With the Common Defense and Security

The proposed exemptions would authorize one-time exemptions from the requirements of 10 CFR 26.205(d)(7) to allow the use of the less restrictive work hour limitations provided in 10 CFR 26.205(d)(4) for up to an additional 60 days for Category A personnel, and for 60 days, which may be extended in accordance with 10 CFR 26.205(d)(6), for Category B personnel. The proposed exemptions are not applicable to security personnel nor do they have any relation to security issues. Therefore, the common defense and security is not impacted by these exemptions.

D. The Exemption Is in the Public Interest

In considering whether the requested exemptions would be in the public interest, the NRC staff considered several factors, including:

• The extent to which the need for an exemption was reasonably avoidable by the licensee;

• the interests of the licensee;

• the public health and safety interests of the communities that are impacted by the safe operation of the plant; and

• the potential adverse impacts on communities resulting from the further-extended shutdown of the unit, which would be prolonged if fewer resources were to be available as a result of TVA needing to resume usual (non-outage) work hours prior to completion of the refueling outage.

Regarding the extent to which the issues that led to the outage delays could have been foreseen and prevented, TVA noted in the Enclosure to the supplemental letter that the SGR project was originally scheduled to occur during the fall 2023 outage, but that it was moved up to the spring 2022 outage due to in-service inspection results on one of the aging steam generators that indicated degradation warranting expedited replacement. This discovery also resulted in the decision to commence with the spring 2022 outage early (early March, as opposed to mid-April), to limit the runtime of the affected steam generator. This resulted in significant impact on the planning for the project. However, despite the accelerated nature of project planning necessitated by these circumstances, TVA also discussed its consideration of potential schedule risks in planning the project, as depicted in Table 1 in the Enclosure to the supplemental letter, which included margin built into the schedule to account for various potential issues/delays, including weather-related delays. TVA also provided, in Revised CNL–22054 Table 4 of the Enclosure to the supplemental letter, explanations for the various emergent discovery issues that delayed the project after it commenced, including the reasons that several of these delays could not have been reasonably foreseeable.

The NRC staff considered the fact that TVA took reasonable measures, in accordance with its processes, to consider possible issues that may arise and incorporated appropriate margin into the schedule. The NRC staff considered TVA's explanations for issues that did arise and determined that a substantial portion of the delays experienced were not foreseeable and preventable. The NRC staff also noted that the decision to move up the SGR project was conservative in nature and was intended to ensure that the unit did not operate with unacceptable steam

generator degradation that could have been potentially adverse to safety.

In the Enclosure to the supplemental letter, TVA discussed the potential impact of the requested exemption on the broader community. Earlier completion of the outage will potentially allow for a return of the unit to an operating status in time to support summer energy demands. TVA stated that, without exemption, and with the resulting delayed restart of the Unit 2, TVA will be challenged from a reliability and environmental compliance perspective, as the area supplied by the unit transitions further into a period of the year characterized by warmer weather and higher loads. TVA discussed the likelihood that additional generation from the company's fossil-fuel-based sites would be necessary to make up for the lost generation from an extended outage of Watts Bar, Unit 2, which would result in reliance on a lower-reliability, higher-emission sources of electricity production.

The NRC staff considered the balance of public interest considerations, weighing the potential impact of the Watts Bar, Unit 2, outage needing to be further extended if the exemption were not approved, due to the reduced availability of personnel under a resumption of normal (non-operational) work hours. The NRC staff also considered the potential impacts resulting from an increase in overall cumulative fatigue due to personnel working longer work hours for an extended period, beyond that of a typical outage under the established regulatory limits. As explained above, TVA proposed adequate alternative controls and mitigation measures for managing cumulative fatigue among Category A personnel for the duration of the requested one-time exemption, and TVA will have adequately managed fatigue for Category B personnel leading up to the start of the requested exemption period. Based on these considerations, the NRC staff concluded that: There is not expected to be a significant impact on public health and safety as a result of the increase in cumulative fatigue; earlier conclusion of the Watts Bar, Unit 2, refueling outage may allow TVA to meet elevated electrical demands without reliance on additional fossil fuel sources; and TVA took reasonable measures in its project planning to foresee and prevent project/outage delays where possible. Therefore, the NRC staff finds that approval of the requested exemptions is consistent with the public interest.

E. Environmental Considerations

The Commission has determined that granting the exemptions from the requirements 10 CFR 26.205(d)(7) involves (1) no significant hazards consideration, (2) no significant change in the types or significant increase in the amounts of any effluents that may be released offsite, (3) no significant increase in individual or cumulative public or occupational radiation exposure, (4) no significant construction impact, and (5) no significant increase in the potential for or consequences from radiological accidents.

(1) Under 10 CFR 50.92(c), there is no significant hazards consideration if the action does not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The proposed exemptions are administrative in nature because they extend the timeframe when less restrictive hours can be worked for Category A and Category B personnel. The proposed exemptions have no effect on systems, and components (SSCs) and no effect on the capability of the SSCs to perform their design function. The proposed exemptions do not make any changes to the facility or operating procedures and do not alter the design, function, or operation of any plant equipment. Therefore, the exemptions do not increase the probability or consequences of an accident previously evaluated.

The proposed exemptions do not make any changes to the facility or operating procedures and do not alter the design, function, or operation of any plant equipment. Similarly, the proposed exemptions do not authorize any physical changes to any SSCs involved in the mitigation of any accidents. Therefore, the exemptions do not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed exemptions do not authorize alteration of the design basis or any safety limits for the plant. The exemptions would not impact station operation or any SSC that is relied upon for accident mitigation. Therefore, the exemptions do not involve a significant reduction in a margin of safety.

For these reasons, the NRC has determined that approval of the exemptions requested involves no significant hazards consideration.

(2) The proposed exemptions do not authorize any changes to the design basis requirements for the SSCs at Watts Bar, Unit 2, that function to limit the release of non-radiological effluents, radiological liquid effluents, or radiological gaseous effluents during and following postulated accidents. Additionally, the exemptions do not change any requirements with respect to the conduct of radiation surveys and monitoring. Therefore, there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite.

(3) The proposed exemptions do not affect the limits on the release of any radioactive material or the limits provided in 10 CFR part 20 for radiation exposure to workers or members of the public. Additionally, the exemptions will not increase or decrease the amount of work activities that must be completed in order to connect the reactor unit to the electrical grid. Therefore, there is no significant increase in individual or cumulative public or occupational radiation exposure.

(4) The exemptions do not involve any changes to a construction permit; therefore, there is no significant construction impact.

(5) The proposed exemptions do not alter any of the assumptions or limits in the licensee's accident analyses. Therefore, there is no significant increase in the potential for or consequences from radiological accidents.

(6) In addition, the requirements from which these exemptions are sought involve other requirements of an administrative, managerial, or organizational nature. Accordingly, the exemptions meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(25)(vi)(I). Therefore, in accordance with 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the NRC's consideration of these exemption requests.

IV. Conclusions

Accordingly, the Commission has determined that, pursuant to 10 CFR 26.9, the exemptions are authorized by law, will not endanger life or property or the common defense and security, and are otherwise in the public interest.

The Commission hereby grants Tennessee Valley Authority a one-time exemption from 10 CFR 26.205(d)(7) for Category A personnel (*i.e.,* those performing maintenance or directing maintenance activities as discussed in 10 CFR 26.205(d)(4) and in direct support of the spring 2022 SGR project)

to allow the use of the minimum days off requirements discussed in 10 CFR 26.205(d)(4) for a 60-day period starting on May 1, 2022 (following the current 60-day outage period that began on March 1, 2022). While the exemption is in effect, TVA will also implement alternate work hour controls for Category A personnel, as discussed in Section V of Enclosure 1 to their submittal letter dated April 15, 2022. The exemption for Category A personnel shall end either at the end of the approved 60-day period (not to exceed June 29, 2022) or at the time when Watts Bar, Unit 2, is connected to the electrical grid, whichever occurs first.

The Commission hereby grants Tennessee Valley Authority a one-time exemption from 10 CFR 26.205(d)(7) for Category B personnel (*i.e.,* those individuals performing normal outage shutdown, startup, maintenance, fuel handling, and modification activities, who are covered by 10 CFR 26.4(a)(1), (a)(2), and (a)(4), and are not directly related to the SGR project) to allow the use of the work minimum day off requirements discussed in 10 CFR 26.205(d)(4) for a 60-day period that shall begin upon completion of Schedule Milestone SGM0184 (*i.e.,* turnover of the polar crane from SGR project team to the TVA outage team). This 60-day period may be extended for each individual subject to the exemption in 7-day increments for each non-overlapping 7-day period the individual has worked not more than 48 hours during the 60-day period as described in 10 CFR 26.205(d)(6). Following the conclusion of the 60-day period for a given individual, normal (non-outage) work hour controls, in accordance with requirements of 10 CFR 26.205(d)(7), shall resume for that individual. The exemption for Category B personnel shall end when Watts Bar, Unit 2, is connected to the electrical grid.

Dated at Rockville, Maryland, this 29th day of April, 2022.

For the Nuclear Regulatory Commission.

/RA/

Gregory F. Suber,

Deputy Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2022–09709 Filed 5–5–22; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0162]

Safety Review of Light-Water Power-Reactor Construction Permit Applications

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft interim staff guidance; reopening of comment period.

SUMMARY: On December 14, 2021, the U.S. Nuclear Regulatory Commission (NRC) solicited public comment on its draft interim staff guidance (ISG), ''Safety Review of Light-Water Power-Reactor Construction Permit Applications.'' The public comment period closed on January 28, 2022. The NRC has decided to reopen the comment period for this draft ISG for an additional 15 days to receive comments on two topics addressed by comments submitted during the initial comment period.

DATES: The comment period for the document published on December 14, 2021 (86 FR 71101) has been reopened. Submit comments by May 23, 2022. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0162. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Carolyn Lauron, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–2736, email: *Carolyn.Lauron@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0162 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0162.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The draft ISG for the ''Safety Review of Light-Water Power-Reactor Construction Permit Applications'' is available in ADAMS under Accession No. ML21165A157.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2021–0162 in your comment submission.

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

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include

identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

On December 14, 2021, the NRC solicited comments on its draft ISG, ''Safety Review of Light-Water Power-Reactor Construction Permit Applications.'' The purpose of this ISG is to clarify existing guidance and to assist the NRC staff in determining whether an application to construct a light-water power-reactor facility meets the minimum requirements to issue a construction permit. The public comment period closed on January 28, 2022. The NRC has decided to reopen the public comment period on this document until May 23, 2022 to receive comments on two topics addressed by comments submitted during the initial comment period.

III. Comments Requested

In considering the comments submitted during the initial comment period, the NRC staff noted two topics that would benefit from additional public feedback and consideration before the ISG is issued final. The NRC staff requests public comments on the following questions:

1. If the NRC were to develop an acceptance review template for light-water power-reactor construction permit applications, what specific information should the template provide that is not currently available in the draft ISG or the NRC's primary review guidance for a construction permit application, NUREG–0800, ''Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: [Light-Water Reactor] Edition?''

2. Are there specific review areas where the draft ISG requests a level of detail in the construction permit application that is inconsistent with previous construction permit applications? If so, which specific review areas are involved and how is the level of detail inconsistent with previous construction permit applications?

Comments in response to these questions and on the draft ISG should be submitted in accordance with the instructions described in Section I.B.

Dated: May 2, 2022.

For the Nuclear Regulatory Commission.

Brian W. Smith,

Director, Division of New and Renewed Licenses, Office of Nuclear Reactor Regulation.

[FR Doc. 2022–09702 Filed 5–5–22; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2022–17; MC2022–54 and CP2022–59]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 10, 2022.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2022–17; *Filing Title:* USPS Notice of Amendment to Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 10, Filed Under Seal; *Filing Acceptance Date:* May 2, 2022; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* May 10, 2022.

2. *Docket No(s).:* MC2022–54 and CP2022–59; *Filing Title:* USPS Request to Add Priority Mail Express & Priority Mail Contract 132 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 2, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* May 10, 2022.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2022–09796 Filed 5–5–22; 8:45 am]

BILLING CODE 7710–FW–P

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[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–363, OMB Control No. 3235–0413]

Proposed Collection; Comment Request; Extension: Rule 17Ad–16

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''PRA''), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17Ad–16 (17 CFR 240.17Ad–16) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17Ad–16 requires a registered transfer agent to provide written notice to the appropriate qualified registered securities depository when assuming or terminating transfer agent services on behalf of an issuer or when changing its name or address. In addition, transfer agents that provide such notice shall maintain such notice for a period of at least two years in an easily accessible place. This rule addresses the problem of certificate transfer delays caused by transfer requests that are directed to the wrong transfer agent or the wrong address.

We estimate that the transfer agent industry submits 15,917 Rule 17Ad–16 notices to appropriate qualified registered securities depositories. The staff estimates that the average amount of time necessary to create and submit each notice is approximately 15 minutes per notice. Accordingly, the estimated total industry burden is 3,979.25 hours per year (15 minutes multiplied by 15,917 notices filed annually).

Because the information needed by transfer agents to properly notify the appropriate registered securities depository is readily available to them and the report is simple and straightforward, the cost is relatively minimal. The average internal compliance cost to prepare and send a notice is approximately $86 (15 minutes at $344 per hour).[1] This yields an industry-wide internal compliance cost estimate of $1,368,862 (15,917 notices multiplied by $86 per notice).

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within by July 5, 2022.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: May 2, 2022.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09719 Filed 5–5–22; 8:45 am]

BILLING CODE 8011–01–P

[1] The estimated hourly wages used in this analysis were derived from reports prepared by the Securities Industry and Financial Markets Association. *See* Securities Industry and Financial Markets Association, Office Salaries in the Securities Industry—2022 (2022), modified to account for an 1800-hour work year and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead.

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17118; California Disaster Number CA–00343 Declaration of Economic Injury]

Administrative Declaration Amendment of an Economic Injury Disaster for the State of California

AGENCY: Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Economic Injury Disaster Loan (EIDL) declaration for the State of CALIFORNIA dated 08/26/2021.

Incident: Tamarack Fire.

Incident Period: 07/04/2021 through 10/31/2021.

DATES: Issued on 05/02/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 05/26/2022.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the Administrator's EIDL declaration for the State of California, dated 08/26/2021, is hereby amended to establish the incident period for this disaster as beginning 07/04/2021 and continuing through 10/31/2021.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2022–09736 Filed 5–5–22; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17436 and #17437; Florida Disaster Number FL–00171]

Administrative Declaration of a Disaster for the State of Florida

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Florida dated 05/02/2022.

Incident: Severe Storms and Tornadoes.

Incident Period: 01/16/2022.

DATES: Issued on 05/02/2022.

Physical Loan Application Deadline Date: 07/01/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 02/02/2023.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Lee

Contiguous Counties:
Florida: Collier, Charlotte, Hendry, Glades

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	2.875
Homeowners without Credit Available Elsewhere	1.438
Businesses with Credit Available Elsewhere	5.660
Businesses without Credit Available Elsewhere	2.830
Non-Profit Organizations with Credit Available Elsewhere	1.875
Non-Profit Organizations without Credit Available Elsewhere	1.875
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	2.830
Non-Profit Organizations without Credit Available Elsewhere	1.875

The number assigned to this disaster for physical damage is 17436 C and for economic injury is 17437 0.

The State which received an EIDL Declaration # is Florida.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2022–09739 Filed 5–5–22; 8:45 am]

BILLING CODE 8026–03–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36607]

Hamilton Northwestern Railroad Co.—Acquisition and Operation Exemption—in Allegan County, Mich.

Hamilton Northwestern Railroad Co. (HNW), a noncarrier, has filed a verified notice of exemption pursuant to 49 CFR 1150.31 to acquire and operate approximately 6.10 miles of track in Allegan County, Mich., extending from a point of connection with a line of CSX Transportation, Inc. (CSXT), at milepost 19.00 in Holland, Mich., to milepost 12.90 in Hamilton, Mich. (the Line).[1]

This transaction is related to a concurrently filed verified notice of exemption in *Hamilton Hartford Group, LLC—Continuance in Control Exemption—Hamilton Northwestern Railroad,* Docket No. FD 36608, in which Hamilton Hartford Group, LLC, seeks to continue in control of HNW upon HNW's becoming a Class III rail carrier.

According to the verified notice, the Line was once a part of CSXT's network of rail lines in Western Michigan but was abandoned in 2003. *See* CSXT Consummation Notice, Jul. 7, 2003, *CSX Transp., Inc.—Aban. Exemption—in Allegan Cnty., Mich.,* AB 55 (Sub-No. 619X). HNW states that, after abandonment, the Line was sold several times as private industry track and was ultimately acquired by its current owner, Endeavor Ag and Energy, LLP (Endeavor), a noncarrier. HNW, therefore, states that the proposed transfer of the Line would not involve a Board-regulated railroad line. However, HNW states that it has a signed agreement to purchase the Line, that it intends to reestablish common carrier service over the Line, and that the Line would once again become a regulated line of railroad upon the latter of the effective date of this exemption or upon the closing of HNW's purchase of the Line.

According to HNW, it will not be subject to any limitations on its ability to interchange on the Line with a third-party connecting carrier. HNW certifies that its projected annual revenue will not exceed $5 million and that the proposed transaction will not result in HNW's becoming a Class I or II rail carrier.

HNW has also filed a petition for waiver of 49 CFR 1150.32(b), which states that a notice of exemption will be effective 30 days after the notice is filed. HNW asks the Board to waive that provision and allow this notice to become effective by May 6, 2022, so that HNW can assume operations and minimize the risk of a disruption of rail service on the Line. HNW's request will be addressed in a separate decision, in which the Board will establish the effective date of the exemption.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than May 13, 2022 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36607, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on HNW's representative, Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606–3208.

According to HNW, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: May 3, 2022.

By the Board, Valerie O. Quinn, Acting Director, Office of Proceedings.

Regena Smith-Bernard,

Clearance Clerk.

[FR Doc. 2022–09767 Filed 5–5–22; 8:45 am]

BILLING CODE 4915–01–P

[1] HNW filed its verified notice of exemption on April 6, 2022, seeking operating authority over the Line. On April 22, 2022, HNW filed a supplement clarifying that it seeks to acquire the Line as a line of railroad as well as operate over it. In light of the supplement, April 22, 2022, is deemed the filing date of the verified notice.

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36608]

Hamilton Hartford Group, LLC—Continuance in Control Exemption—Hamilton Northwestern Railroad Co.

Hamilton Hartford Group, LLC (HHG), a noncarrier, filed a verified notice of exemption under 49 CFR 1180.2(d)(2) to continue in control of Hamilton Northwestern Railroad Co. (HNW), a noncarrier controlled by HHG, upon HNW's becoming a Class III rail carrier.[1]

This notice of exemption is related to a concurrently filed notice of exemption in *Hamilton Northwestern Railroad—Acquisition & Operation Exemption—in Allegan County, Mich.,* Docket No. FD 36607, in which HNW seeks to acquire and operate approximately 6.10 miles of track in Allegan County, Mich.

According to the verified notice of exemption, HHG controls one railroad, the West Michigan Railroad Co. (WMI), which operates in Michigan.

HHG represents that: (1) The line which HNW seeks authority to acquire and operate over does not connect with the lines of any existing rail carriers controlled by HHG; (2) the proposed transaction is not part of a series of anticipated transactions that would connect the line with any other railroads in the HHG corporate family; and (3) the transaction does not involve a Class I rail carrier. Therefore, the proposed transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

[1] HHG filed its verified notice of exemption on April 6, 2022, and on April 22, 2022, HHG filed a supplement clarifying the specific authority that HNW is seeking in Docket No. FD 36607. In light of the supplement, April 22, 2022, is deemed the filing date of the verified notice.

HHG has also filed a petition for waiver of 49 CFR 1180.4(g)(1), which states that a notice of exemption must be filed at least 30 days before a transaction is consummated. HHG asks the Board to waive that provision and allow this notice to become effective by May 6, 2022, to minimize the risk of disruption of rail service on the Line. HHG's request will be addressed in a separate decision, in which the Board will establish the effective date of the exemption.

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. However, 49 U.S.C. 11326(c) does not provide for labor protection for transactions under 49 U.S.C. 11324 and 11325 that involve only Class III rail carriers. Because this transaction involves Class III rail carriers only, the Board, under the statute, may not impose labor protective conditions for this transaction.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than May 13, 2022 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36608, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on HHG's representative, Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606–3208.

According to HHG, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: May 3, 2022.

By the Board, Valerie O. Quinn, Acting Director, Office of Proceedings.

Regena Smith-Bernard,

Clearance Clerk.

[FR Doc. 2022–09774 Filed 5–5–22; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2022–0559; Notice of Availability Docket No. 22–ANE–6]

Notice of Availability of the Final Environmental Assessment (Final EA)/ Finding of No Significant Impact (FONSI) and Record of Decision (ROD) for a New Instrument Approach Procedure (IAP), Referred to as the Area Navigation (RNAV) Global Positioning System (GPS) Runway 4 Left (4L) Procedure, to Runway 4L at Boston Logan International Airport (BOS)

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

ACTION: Notice of availability.

SUMMARY: The FAA, Eastern Service Center, is issuing this notice to advise the public of the availability of the Final Environmental Assessment (Final EA) and FAA's Finding of No Significant Impact (FONSI)/Record of Decision (ROD) to implement a new RNAV GPS arrival procedure to Runway 4L at BOS. The FAA issued its Final EA and FONSI/ROD on May 4, 2022.

FOR FURTHER INFORMATION CONTACT: Veronda Johnson, Federal Aviation Administration, Operations Support Group, Eastern Service Center, 1701 Columbia Avenue, College Park, Georgia 30337, (404) 305–5598. Additional information about the FAA's actions and environmental review of this project is available at the following website: *FAABostonWorkshops.com.*

SUPPLEMENTARY INFORMATION: The Final EA responds to agency and public comments received by the FAA and it updates the Draft EA, issued on September 21, 2020. The Final EA and FONSI/ROD documents that the Proposed Action is consistent with FAA Order 1050.1F, *Environmental Impacts: Policies and Procedures* and with existing national environmental policies and objectives set forth in Section 101 of the *National Environmental Policy Act of 1969,* 42 U.S.C. 4321 *et seq.* (NEPA), Council on Environmental Quality regulations, 40 CFR parts 1500–1508, the requirements of Section 106 of the *National Historic Preservation Act,* and all other applicable special purpose laws. The Proposed Action will not significantly affect the quality of the human environment or otherwise include any condition requiring consultation pursuant to Section 102(2)(C) of NEPA, and that an Environmental Impact Statement (EIS) is therefore not necessary. The FONSI/ROD documents the FAA's decision to implement the Proposed Action alternative as detailed in and supported by the Final EA. The proposed instrument approach procedure will enhance public aviation safety by providing pilots with lateral and vertical electronic guidance to ensure a stabilized approach to landing, particularly during marginal and poor weather conditions. The proposed instrument approach procedure will also reduce delays at the Airport by reducing the number of flights that must be canceled during times of poor weather, resulting in an increase in efficiency at the airport as well as the National Airspace System (NAS) as a whole.

Availability: The Final EA and FONSI/ROD are available for review at the following locations:

(1) Online at *FAABostonWorkshops.com.*

(2) Electronic Versions of the Final EA and FONSI/ROD have been sent to twelve libraries in the vicinity of BOS with a request to make the digital document available to patrons. A list of these libraries is available online at the website above and is shown below. The FAA recognizes that libraries may be closed due to the COVID–19 public health emergency and, therefore, availability through these libraries may be impacted.

Boston Public Library, Central Library, 700 Boylston St., Boston, MA
Boston Public Library, Codman Square, 690 Washington St., Boston, MA
Boston Public Library, Fields Corner, 1520 Dorchester Avenue, Dorchester, MA
Boston Public Library, Grove Hall, 41 Geneva Avenue, Boston, MA
Boston Public Library, Lower Mills, 27 Richmond St., Boston, MA
Boston Public Library, Mattapan, 1350 Blue Hill Avenue, Boston, MA
Boston Public Library, Roxbury, 149 Dudley St. Roxbury, MA
Boston Public Library, South Boston, 646 E Broadway, South Boston, MA
Boston Public Library, South End, 685 Tremont St., Boston, MA
Milton Public Library 476 Canton Avenue, Milton, MA
Thomas Crane Public Library, 40 Washington St., Quincy, MA
Hyde Park Branch of the Boston Public Library, 35 Harvard Avenue, Hyde Park, MA

(3) Further information about the FAA's actions and environmental review of this project is also available at the following website: *https://www.faa.gov/air_traffic/community_engagement/bos/.*

If you are unable to access the documentation through one of these means, email *Veronda.Johnson@faa.gov* to request a copy of the document.

The FAA previously published notice of this decision in the **Federal Register** on May 2, 2022 (87 FR 25691). The timing of that notice was made in error and is superseded by this notice.

Veronda Johnson,

EPS, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2022–09718 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 2022–0612]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Bipartisan Infrastructure Law Airport Terminal and Tower Project Information

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves soliciting project information for the Bipartisan Infrastructure Law (BIL) Airport Terminal and Tower Programs. The information to be collected will be used to determine projects to be awarded BIL competitive discretionary grants.

DATES: Written comments should be submitted by July 5, 2022.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Robin K. Hunt, Federal Aviation Administration, ATTN: Airports Financial Assistance Division (APP–500), 800 Independence Avenue SW, Suite 619, Washington DC 20591.

By fax: 202–267–5302.

FOR FURTHER INFORMATION CONTACT: Robin K. Hunt, Manager, BIL Implementation Team, by email at: *9-ARP-BILAirports@faa.gov;* phone: (202) 267–3831.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0806.

Title: Bipartisan Infrastructure Law Airport Terminal and Tower Project Information.

Form Numbers: 5100–144.

Type of Review: Renewal of an information collection.

Background: The FAA uses this collection to solicit the information necessary to evaluate and select airport terminal and tower projects for funding under the Bipartisan Infrastructure Law (BIL), signed on November 15, 2021. The BIL provides about $1,020,000,000 annually, for five years, to award competitive discretionary grants for airport terminal and tower development. Of this amount, about $1,000,000,000 annually, for five years, is for the Airport Terminal Program, and $20,000,000 annually, for five years, is for an Airport-owned Contract Tower Program (referred to collectively as ''Airport Terminal and Towers Programs''). The information collected is based on grant considerations and priorities outlined in the BIL. Project consideration areas include increasing terminal capacity and passenger access; replacing aging infrastructure; achieving compliance with the Americans with Disabilities Act (42 U.S.C. 12101, *et seq.*) and expanding accessibility for persons with disabilities; improving airport access for historically disadvantaged populations; improving energy efficiency, including upgrading environmental systems, upgrading plant facilities, and achieving Leadership in Energy and Environmental Design (LEED) accreditation standards; improving airfield safety through terminal relocation; encouraging actual and potential competition; and creating good paying jobs. The information FAA is collecting will include general airport information, a project overview, and narratives on project consideration areas as outlined in the BIL. Airport owners and managers who want to pursue funding and obtain benefits from the BIL Airport Terminal and Tower Programs will submit information via FAA Form 5100–144 to compete for grants. Approximately 3,075 airports are eligible to compete for this funding, but FAA expects only a small subset of eligible airports to submit project information through this competitive discretionary grant process.

Respondents: Approximately 655 airports.

Frequency: Annually.

Estimated Average Burden per Response: 6 Hours.

Estimated Total Annual Burden: 3,930 Hours for all respondents.

Issued in Washington, DC, on May 3, 2022.

Robin K. Hunt,

Manager, BIL Implementation Team, Office of Airports.

[FR Doc. 2022–09803 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2021–0002]

New Car Assessment Program; Request for Comments; Extension of Comment Period

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Extension of comment period.

SUMMARY: NHTSA received two petitions to extend the comment period for a Request for comments (RFC) notice on significant updates to the New Car Assessment Program (NCAP). Pursuant to fulfilling the FAST Act directive and the Bipartisan Infrastructure Law, NHTSA published an RFC notice announcing its current and future plans for updating NCAP on March 9, 2022. The comment period for the RFC notice was scheduled to end on May 9, 2022. NHTSA is extending the comment period for the March 9, 2022 RFC notice by 30 days.

DATES: The comment period for the RFC notice published on March 9, 2022 is extended to June 8, 2022.

ADDRESSES: You may submit comments to the docket number identified in the heading of this document by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, M–30, U.S. Department of Transportation, West Building, Ground Floor, Rm. W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE,

between 9 a.m. and 5 p.m. Eastern Time, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9332 before coming.

• *Fax:* 202–493–2251.

Regardless of how you submit your comments, please mention the docket number identified in the heading of this document.

Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its decision-making process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.* In order to facilitate comment tracking and response, the Agency encourages commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered.

Docket: For access to the docket to read background documents or comments received, go to *www.regulations.gov,* or the street address listed above. To be sure someone is there to help you, please call (202) 366–9332 before coming. Follow the online instructions for accessing the dockets.

FOR FURTHER INFORMATION CONTACT: For technical issues, you may contact Ms. Jennifer N. Dang, Division Chief, New Car Assessment Program, Office of Crashworthiness Standards (telephone: 202–366–1810). For legal issues, you may call Mr. Daniel Koblenz, Office of Chief Counsel (telephone: 202–366–2992). Address: National Highway Traffic Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Washington, DC 20590.

SUPPLEMENTARY INFORMATION: On March 9, 2022, pursuant to fulfilling the FAST Act directive and section 24213 of the Bipartisan Infrastructure Law, NHTSA published an RFC notice announcing its current and future plans for updating NCAP (87 FR 13452). The RFC notice included significant upgrades to NCAP, including (1) proposing to add four new advanced driver assistance system (ADAS) technologies, (2) proposing to strengthen the current test procedures for certain existing ADAS technologies, (3) proposing a near- and long-term roadmap for future NCAP updates, (4) discussing various approaches on the development of a new rating system for ADAS technologies, (5) discussing the rulemaking process to update the NCAP safety information on the Monroney label that includes a comprehensive consumer research, and (6) seeking comment on emerging technologies to help people make safe driving choices. The comment period for the RFC notice is scheduled to end on May 9, 2022.

Comment Period Extension Requests

The Alliance for Automotive Innovation and the Motor & Equipment Manufacturers Association submitted a joint letter on March 25, 2022, requesting a 30-day extension of the comment period. The requestors state that the RFC notice addresses several complex topics that would require conducting in-depth review and analysis to develop informed feedback. They suggest the additional time would allow them to conduct the detailed review of the notice and develop responses to the more than 100 questions and issues included in the notice. The requestors state that the additional time would allow for more fully developed feedback to support the agency's next steps.

In a joint letter submitted to the Agency on April 15, 2022, Advocates for Highway and Auto Safety, Center for Auto Safety, Public Citizen, National Association of Mutual Insurance Companies, Kids & Cars Safety, Vision Zero Network, Insurance Institute for Highway Safety, Society for the Advancement of Violence and Industry Research, and Families for Safe Streets, request a 60-day extension of the comment period. The requestors state that the RFC notice raises numerous complex technical and policy issues that requires significant analysis. They note that extending the comment period is in the public interest as it would permit the public with sufficient time to provide specific and thorough feedback on the many substantial questions raised in the notice, and provide the requesters with time to consult with a variety of experts and stakeholders.

Agency Decision

Pursuant to 49 CFR 553.19 and after thorough consideration of the requests with various extension periods, NHTSA determined that the requestors have provided sufficient justification for an extension, and that the extension is consistent with the public interest (49 CFR 553.19). NHTSA agrees that allowing additional time for the public and its stakeholders to provide comments to the many questions raised in the RFC notice would better inform NHTSA on its final decision on the various program areas and topics discussed in the RFC notice. Therefore, NHTSA is granting the aforementioned requests to extend the comment period; however, NHTSA is extending it only for 30 days. Section 24213 of the November 2021 Bipartisan Infrastructure Law, enacted as the Infrastructure Investment and Jobs Act, requires NHTSA to publish its final decision on the NCAP upgrade by November 15, 2022. A 30-day extension appropriately balances NHTSA's interest in providing the public with sufficient time to comment on the numerous questions raised in the RFC notice, with its interest to issue a final decision on the NCAP upgrade in a timely manner.

Authority: 49 U.S.C. 322, 30111, 30115, 30117, and 30166; delegation of authority at 49 CFR 1.95 and 49 CFR 501.8.

Issued in Washington, DC, under authority delegated in 49 CFR 1.95 and 501.8.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2022–09831 Filed 5–5–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Interagency Appraisal Complaint Form

AGENCY: Office of the Comptroller of the Currency, Treasury (OCC).

ACTION: Notice and request for comment.

SUMMARY: The Office of the Comptroller of the Currency (OCC) as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on an information collection renewal as required by the Paperwork Reduction Act of 1995. An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number. The OCC is soliciting comment concerning the renewal of its information collection titled ''Interagency Appraisal Complaint Form.'' The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be received by June 6, 2022.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, 1557–0314, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0314'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Written comments and recommendations for the proposed information collection should also 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.

On February 17, 2022, the OCC published a 60-day notice for this information collection, 87 FR 9103. You may review comments and other related materials that pertain to this information collection following the close of the 30-day comment period for this notice by the method set forth in the next bullet.

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Hover over the ''Information Collection Review'' tab and click on ''Information Collection Review'' drop-down menu. From the ''Currently under Review'' drop-down menu, select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0314'' or ''Interagency Appraisal Complaint Form.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The OCC asks that OMB extend its approval of the collection in this document.

Abstract: Section 1473(p) of the Dodd-Frank Wall Street Reform and Consumer Protection Act [1] provides that if the Appraisal Subcommittee (ASC) of the Federal Financial Institutions Examination Council (FFIEC) determines, six months after enactment of that section (*i.e.,* January 21, 2011), that no national hotline exists to receive complaints of non-compliance with appraisal independence standards and Uniform Standards of Professional Appraisal Practice (USPAP), then the ASC shall establish and operate such a hotline (ASC Hotline). The ASC Hotline shall include a toll-free telephone number and an email address. Section 1473(p) further directs the ASC to refer complaints received through the ASC Hotline to the appropriate government bodies for further action, which may include referrals to OCC, the Board of Governors of the Federal Reserve (Board), the Federal Deposit Insurance Corporation (FDIC), the National Credit Union Administration (NCUA), the Bureau of Consumer Financial Protection (CFPB), and state agencies. The ASC determined that a national appraisal hotline did not exist at a meeting held on January 12, 2011, and a notice of that determination was published in the **Federal Register** on January 28, 2011, (76 FR 5161). As a result, the ASC established a hotline to refer complaints to appropriate state and Federal regulators.

Representatives from the OCC, the Board, the FDIC, the NCUA (Agencies), and the CFPB met and established a process to facilitate the referral of complaints received through the ASC Hotline to the appropriate Federal financial institution regulatory agency or agencies. The Agencies developed the Interagency Appraisal Complaint Form to collect information necessary to take further action on the complaint. The CFPB incorporated the process into one of their existing systems.

The Interagency Appraisal Complaint Form was developed for use by those who wish to file a formal, written complaint that an entity subject to the jurisdiction of one or more of the Agencies has failed to comply with the appraisal independence standards or USPAP. The Interagency Appraisal Complaint Form is designed to collect information necessary for the Agencies to take further action on a complaint from an appraiser, other individual, financial institution, or other entities. The Agencies use the information to take further action on the complaint to the extent the complaint relates to an issue within their jurisdiction.

OMB Control No.: 1557–0314.

Estimated Number of Respondents: 100.

Estimated Burden per Response: 0.5 hours.

Estimated Total Annual Burden: 50 hours.

On February 17, 2022, the OCC published a 60-day notice for this information collection, 87 FR 9103. No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimates of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2022–09723 Filed 5–5–22; 8:45 am]

BILLING CODE 4810–33–P

[1] Dodd-Frank Wall Street Reform and Consumer Protection Act section 1473, Public Law 111–203, 124 Stat. 1376, July 21, 2010; 12 U.S.C. 3351(i).

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Taxpayer Assistance Center Improvements Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will still be held via teleconference.

DATES: The meeting will be held Thursday, June 9, 2022.

FOR FURTHER INFORMATION CONTACT: Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Taxpayer Assistance Center Improvements Project Committee will be held Thursday, June 9, 2022, at 3:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Matthew O'Sullivan. For more information please contact Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274, or write TAP Office, 1301 Clay Street, Oakland, CA 94612–5217 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: May 3, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–09825 Filed 5–5–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Special Projects Committee

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Special Projects Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will still be held via teleconference.

DATES: The meeting will be held Wednesday, June 8, 2022.

FOR FURTHER INFORMATION CONTACT: Antoinette Ross at 1–888–912–1227 or 202–317–4110.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Special Projects Committee will be held Wednesday, June 8, 2022, at 11:00 a.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Antoinette Ross. For more information please contact Antoinette Ross at 1–888–912–1227 or 202–317–4110, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: May 3, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–09823 Filed 5–5–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, June 23, 2022.

FOR FURTHER INFORMATION CONTACT: Gilbert Martinez at 1–888–912–1227 or (737) 800–4060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Thursday, June 23, 2022, at 1:30 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. For more information, please contact Gilbert Martinez at 1–888–912–1227 or (737–800–4060), or write TAP Office 3651 S IH–35, STOP 1005 AUSC, Austin, TX 78741, or post comments to the website: *http://www.improveirs.org.*

The agenda will include various committee issues for submission to the IRS and other TAP related topics. Public input is welcomed.

Dated: May 3, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–09828 Filed 5–5–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Lines Project Committee

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Lines Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will be held via teleconference.

DATES: The meeting will be held Tuesday, June 14, 2022.

FOR FURTHER INFORMATION CONTACT: Rosalind Matherne at 1–888–912–1227 or 202–317–4115.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Lines Project Committee will be held Tuesday, June 14, 2022, at 3:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Rosalind Matherne. For more information, please contact Rosalind Matherne at 1–888–912–1227 or 202–317–4115, or write TAP Office, 1111

Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: May 3, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–09826 Filed 5–5–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Taxpayer Communications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will be held via teleconference.

DATES: The meeting will be held Wednesday, June 8, 2022.

FOR FURTHER INFORMATION CONTACT: Conchata Holloway at 1–888–912–1227 or 214–413–6550.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be held Wednesday, June 8, 2022, at 12:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Conchata Holloway. For more information, please contact Conchata Holloway at 1–888–912–1227 or 214–413–6550, or write TAP Office, 1114 Commerce St. MC 1005, Dallas, TX 75242 or contact us at the website: *https://www.improveirs.org.* The agenda will include various IRS issues.

Dated: May 3, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–09821 Filed 5–5–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will be held via teleconference.

DATES: The meeting will be held Tuesday, June 14, 2022.

FOR FURTHER INFORMATION CONTACT: Fred Smith at 1–888–912–1227 or (202) 317–3087.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be held Tuesday, June 14, 2022, at 1:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Fred Smith. For more information, please contact Fred Smith at 1–888–912–1227 or (202) 317–3087, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.*

Dated: May 3, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–09824 Filed 5–5–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Credit for Renewable Electricity Production and Publication of Inflation Adjustment Factor and Reference Price for Calendar Year 2022; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction notice.

SUMMARY: This document contains corrections to a publication of the inflation adjustment factor and reference price for calendar year 2022 as required by section 45(e)(2)(A) of the Internal Revenue Code that was published in the **Federal Register** on April 14, 2022. The 2022 inflation adjustment factor and reference price are used in determining the availability of the credit for renewable electricity production.

FOR FURTHER INFORMATION CONTACT: Charles Hyde, CC:PSI:6, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224, (202) 317–6853 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The publication of the inflation adjustment factor and reference price for calendar year 2022 as required by section 45(e)(2)(A) of the Internal Revenue Code (26 U.S.C. 45(e)(2)(A)) that is the subject of this correction is under section 45 of the Internal Revenue Code.

Need for Correction

As published, the notice of the publication of the inflation adjustment factor and reference price for calendar year 2022 as required by section 45(e)(2)(A) of the Internal Revenue Code (26 U.S.C. 45(e)(2)(A)) contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the inflation adjustment factor and reference price for calendar year 2022 as required by section 45(e)(2)(A) of the Internal Revenue Code (26 U.S.C. 45(e)(2)(A)), that is the subject of FR Doc. 2022–07967, is corrected as follows:

On Page 22286, column 1, under the title ''Inflation Adjustment Factor'', the last line of the paragraph, the language ''is 1.8012.'' is corrected to read ''is 1.7593.''.

On Page 22286, column 2, line 6 from the top of the page, the language ''factor (1.8012), the phaseout of the'' is corrected to read ''factor (1.7593), the phaseout of the''.

On Page 22286, column 2, under the title ''Credit Amount by Qualified Energy Resource and Facility'', line 11 from the bottom of the paragraph, the language ''is 2.7 cents per kilowatt hour on the sale'' is corrected to read ''is 2.6 cents per kilowatt hour on the sale''.

On Page 22286, column 2, under the title ''Credit Amount by Qualified Energy Resource and Facility'', line 7 from the bottom of the paragraph, the language ''energy, and 1.4 cents per

kilowatt hour'' is corrected to read ''energy, and 1.3 cents per kilowatt hour''.

Oluwafunmilayo A. Taylor,

Branch Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2022–09695 Filed 5–5–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service. This meeting will be held via teleconference.

DATES: The meeting will be held Tuesday, June 14, 2022.

FOR FURTHER INFORMATION CONTACT: Robert Rosalia at 1–888–912–1227 or (718) 834–2203.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee will be held Tuesday, June 14, 2022, at 12:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Robert Rosalia. For more information, please contact Robert Rosalia at 1–888–912–1227 or (718) 834–2203, or write TAP Office, 2 Metrotech Center, 100 Myrtle Avenue, Brooklyn, NY 11201 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: May 3, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–09822 Filed 5–5–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, May 26, 2022.

FOR FURTHER INFORMATION CONTACT: Gilbert Martinez at 1–888–912–1227 or (737) 800–4060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Thursday, May 26, 2022, at 1:30 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. For more information, please contact Gilbert Martinez at 1–888–912–1227 or (737–800–4060), or write TAP Office 3651 S IH–35, STOP 1005 AUSC, Austin, TX 78741, or post comments to the website: *http://www.improveirs.org.*

The agenda will include various committee issues for submission to the IRS and other TAP related topics. Public input is welcomed.

Dated: May 3, 2022.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2022–09827 Filed 5–5–22; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

45 CFR Parts 144, 147, 153, et al.

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144, 147, 153, 155, 156, and 158

[CMS–9911–F]

RIN 0938–AU65

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule includes payment parameters and provisions related to the risk adjustment and risk adjustment data validation programs, as well as 2023 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 final rule also includes requirements related to guaranteed availability; the offering of QHP standardized plan options through Exchanges on the Federal platform; requirements for agents, brokers, and web-brokers; verification standards related to employer sponsored coverage; Exchange eligibility determinations during a benefit year; special enrollment period verification; cost-sharing requirements; Essential Health Benefits (EHBs); Actuarial Value (AV); QHP issuer quality improvement strategies; accounting for quality improvement activity (QIA) expenses and provider incentives for medical loss ratio (MLR) reporting and rebate calculation purposes; and re-enrollment. This final rule also responds to comments on how the Department of Health and Human Services (HHS) can advance health equity through QHP certification standards and otherwise in the individual and group health insurance markets, and how HHS might address plan choice overload in the Exchanges.

DATES: These regulations are effective July 1, 2022.

FOR FURTHER INFORMATION CONTACT:

Cam Moultrie Clemmons, (206) 615–2338, or Anthony Galace, (301) 492–4400, for matters related to past-due premiums.

Allison Yadsko, (410) 786–1740, John Barfield, (301) 492–4433, Jacqueline Wilson, (301) 492–4286, or Leanne Klock, (410) 786–1045, for matters related to risk adjustment or risk adjustment data validation.

Aaron Franz, (410) 786–8027, or John Barfield, (301) 492–4433, for matters related to Federally-facilitated Exchange and State-based Exchange on the Federal platform user fees.

Nora Simmons, (410) 786–1981, for matters related to advance payment of the premium tax credit proration.

Aaron Franz, (410) 786–8027, or Hi'ilei Haru, (301) 492–4363, for matters related to cost-sharing reduction reconciliation.

Josh Van Drei, (410) 786–1659, for matters related to actuarial value.

Becca Bucchieri, (301) 492–4341, Agata Pelka, (301) 492–4400, or Leigha Basini, (301) 492–4380, for matters related to nondiscrimination based on sexual orientation and gender identity, essential health benefit benchmark plans, and defrayal of State-required benefits.

Marisa Beatley, (301) 492–4307, for matters related to employer sponsored coverage verification.

Susan Kalmus, (301) 492–4275, for matters related to agent, broker, and web-broker guidelines.

Dena Nelson, (240) 401–3535, or Carly Rhyne, (301) 492–4188, for matters related to eligibility standards.

Katherine Bentley, (301) 492–5209, or Ariel Kennedy, (301) 492–4306, for matters related to special enrollment period verification.

Christina Whitefield, (301) 492–4172, for matters related to the medical loss ratio program.

Nidhi Singh Shah, (301) 492–5110, for matters related to quality improvement strategy standards for Exchanges.

Dan Brown, (301) 492–5146 for matters related to downstream and delegated entities.

Nikolas Berkobien, (301) 492–4400, or Leigha Basini, (301) 492–4380 for matters related to standardized plan options.

Erika Melman, (301) 492–4348, Deborah Hunter, (443) 386–3651, Whitney Allen, (667) 290–8748, or Emily Martin, (301) 492–4423, for matters related to network adequacy and essential community providers.

Linus Bicker, (803) 931–6185, for matters related to State Exchange improper payment measurement.

Phuong Van, (202) 570–5594, for matters related to advancing health equity through qualified health plans.

Angelica Torres-Reid, (410) 786–1721, and Robert Yates, (301) 492–5151, for matters related to State Exchange general program integrity and oversight requirements.

Zarah Ghiasuddin, (301) 492–4308, for matters related to re-enrollment in the Exchanges.

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Background

In the proposed rule, ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023'' (87 FR 584), published in the January 5, 2022 edition of the **Federal Register** (2023 Payment Notice proposed rule), HHS proposed amendments to certain regulations prohibiting discrimination in health insurance coverage, including discrimination in the design and implementation of health plans, under §§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) under title 45 of the Code of Federal Regulations (CFR). HHS proposed to amend these regulations to explicitly identify and recognize discrimination on the basis of sexual orientation and gender identity as prohibited forms of discrimination based on sex consistent with the Supreme Court's decision in *Bostock* v. *Clayton County,* 140 S. Ct. 1731 (2020), and HHS nondiscrimination policy that existed prior to the 2020 regulatory amendments HHS made in conformance with the ''Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority'' final rule (85 FR 37160), published in the June 19, 2020 edition of the **Federal Register**.[1] In connection with discriminatory benefit designs prohibited under § 156.125, HHS also included in the proposed rule an example related to gender-affirming care that was intended to illustrate a health plan design that presumptively discriminates against enrollees based on gender identity.

Currently, HHS is developing a proposed rule[2] that also will address prohibited discrimination based on sex in health coverage under section 1557 of the Patient Protection and Affordable Care Act (ACA)[3] (42 U.S.C. 18116). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the ACA or its amendments. Because HHS' proposed rule implementing section 1557 of the ACA will also address issues related to prohibited discrimination based on sex, HHS is of the view that it would be most prudent to address the nondiscrimination proposals related to sexual orientation and gender identity in the 2023 Payment Notice proposed rule at a later time, to ensure that they are consistent with the policies and requirements that will be included in the section 1557 rulemaking. Therefore, HHS will not address in this final rule the nondiscrimination proposals related to sexual orientation and gender identity included in the 2023 Payment Notice proposed rule or the comments submitted in response to those proposals.

HHS is committed to robust civil rights protections in health care for all consumers, including protections to combat discrimination on the basis of gender identity or sexual orientation.[4] Moreover, to the extent that entities subject to the relevant regulations prohibiting discrimination in health insurance coverage are also covered by section 1557, they are already under the statutory obligation not to discriminate on the basis of sex.[5] Consistent with the Supreme Court's decision in *Bostock* v. *Clayton County,* 140 S. Ct. 1731 (2020), and the HHS Notice of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972 (86 FR 27984), published in the May 25, 2021 edition of the **Federal Register**, HHS will continue to interpret and enforce section 1557 of the ACA and its protections against sex discrimination to prohibit discrimination on the basis of sexual orientation and gender identity in all aspects of health insurance coverage governed by section 1557.[6] Thus, notwithstanding that the Department will address in future rulemaking the proposals related to sexual orientation and gender identity and the example related to gender-affirming care, HHS will continue to scrutinize the activities of covered health plans to root out practices that unlawfully discriminate on the basis of sexual orientation or gender identity. HHS' interpretation of section 1557 will guide HHS in processing complaints and conducting investigations, but does not itself determine the outcome in any particular case or set of facts. In enforcing Section 1557, HHS will comply with the Religious Freedom Restoration Act, 42 U.S.C. 2000bb *et seq.,* and all other legal requirements.[7]

I. Executive Summary

American Health Benefit Exchanges, or ''Exchanges,'' are entities established under the ACA through which qualified individuals and qualified employers can purchase health insurance coverage in qualified health plans (QHPs). Many individuals who enroll in QHPs through individual market Exchanges are eligible to receive a premium tax credit (PTC) to reduce their costs for health insurance premiums and to receive reductions in required cost-sharing payments to reduce out-of-pocket expenses for health care services. The ACA also established the risk adjustment program, which transfers funds from issuers that attract lower-than-average risk populations to issuers that attract higher-than-average risk populations to reduce incentives for issuers to avoid higher-risk enrollees.

In previous rulemakings, we established provisions and parameters to implement many ACA requirements and programs. In this final rule, we amend some of these provisions and parameters, with a focus on maintaining a stable regulatory environment. These changes are intended to provide issuers with greater predictability for upcoming plan years (PYs), while simultaneously enhancing the role of States in these programs. They will also provide States

[1] See also 85 FR 37160, 37218 through 21 (the 2020 final rule implementing section 1557 of the ACA revised the following CMS regulations: 45 CFR 147.104, 155.120, 155.220, 156.200, 156.1230).

[2] HHS submitted a draft notice of proposed rulemaking addressing section 1557 of the Patient Protection and Affordable Care Act and its implementing regulations to the Office of Management and Budget on or around March, 22, 2022. See *https://www.reginfo.gov/public/do/eoDetails?rrid=234566.*

[3] 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.''

[4] HHS' proposals related to sexual orientation and gender identity in the 2023 Payment Notice proposed rule resulted, in part, from reviews HHS conducted as directed in President Biden's January 20, 2021, Executive Order 13988 (86 FR 7023), which stated the Administration's policy on preventing and combating discrimination on the basis of gender identity and sexual orientation and the President's conclusion that ''[u]nder *Bostock*'s reasoning, laws that prohibit sex discrimination . . . , along with their respective implementing regulations—prohibit discrimination on the basis of gender identity or sexual orientation, so long as the laws do not contain sufficient indications to the contrary.'' This Executive Order instructed the Secretary of Health and Human Services (Secretary of HHS, or HHS Secretary) to review all existing regulations, guidance documents, and other agency actions to determine whether they are consistent with the aforementioned policy and construction of the laws, and to consider whether to suspend, revise, or rescind any agency actions that are inconsistent with that policy and construction.

[5] See 85 FR 37219 (explaining that section 1557 governs entities established under Title I of the ACA, including Exchanges).

[6] See also *Hammons* v. *Univ. of Maryland Med. Sys. Corp.,* No. 20–cv–2009, 2021WL 3190492, at *17 (D. Md. July 28, 2021) (stating *Bostock* ''made clear that the position stated in HHS's [Bostock Notice] was already binding law'').

[7] 86 FR 27985.

with additional flexibilities, reduce unnecessary regulatory burdens on stakeholders, empower consumers, ensure program integrity, and improve affordability.

Risk adjustment continues to be a core program in the individual, small group, and merged markets both on and off Exchanges. We published a technical paper, the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes [8] in October 2021 (2021 RA Technical Paper), and sought comment on three potential updates to the risk adjustment models. We are finalizing two of the three proposed updates to the HHS risk adjustment models beginning with the 2023 benefit year. Specifically, beginning with the 2023 benefit year, we are finalizing the removal of the current severity illness factors from the adult models and the addition of an interacted hierarchical condition category (HCC) count model specification to the adult and child models. We also are finalizing the replacement of the current enrollment duration factors in the adult models with HCC-contingent enrollment duration factors. We are not finalizing the proposed model specification change to add a two-stage weighted approach to the adult and child models. We are finalizing the use of the 2017, 2018, and 2019 enrollee-level External Data Gathering Environment (EDGE) data to recalibrate the 2023 benefit year risk adjustment models. For 2023, we are also finalizing the continued application of a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the risk adjustment models, consistent with the approach adopted beginning with the 2020 models.

In addition, we are finalizing the targeted removal of the mapping of hydroxychloroquine sulfate to Immune Suppressants and Immunomodulators (RXC 09) in the 2018 and 2019 benefit year enrollee-level EDGE data used for the 2023 benefit year model recalibration.[9] We are also finalizing, for the 2024 benefit year and beyond, the proposal to recalibrate the adult models using the final, fourth quarter (Q4) RXC mapping document that was applicable for each benefit year of data that is included in the current year's model recalibration. We will begin to use this approach for recalibration of the 2023 adult risk adjustment models, with the exception of the 2017 enrollee-level EDGE data year, for which we will use the most recent RXC mapping document that was available when we first processed the 2017 enrollee-level EDGE data (that is, Q2 2018).

Additionally, we are finalizing the proposal to repeal the ability of States, other than prior participants, to request a reduction in risk adjustment State transfers starting with the 2024 benefit year. We are also finalizing the changes that limit a prior participant's ability to request a reduction in risk adjustment transfers under § 153.320(d) to only those that meet the *de minimis* threshold criteria. In future rulemaking, HHS intends to propose to eliminate the prior participant exception starting with the 2025 benefit year. For the 2023 benefit year, we are announcing approval of Alabama's request to reduce risk adjustment State transfers for its individual and small group markets, but at lower percentages than requested. We approve a 25 percent reduction in Alabama's individual market transfers (including the catastrophic and non-catastrophic risk pools) and a 10 percent reduction in Alabama's small group market transfers for the 2023 benefit year.

We are finalizing the 2023 benefit year risk adjustment user fee for States where HHS operates the risk adjustment program of $0.22 per member per month (PMPM). We are also finalizing the proposal to collect and extract five new data elements as part of the enrollee-level EDGE data beginning with the 2023 benefit year. We are also finalizing the proposal to extract three data elements issuers already report to their EDGE servers—plan ID, rating area, and subscriber indicator—as part of the required risk adjustment data. Plan ID and rating area will be extracted beginning with the 2021 benefit year, and subscriber indicator will be extracted beginning with the 2022 benefit year.

Finally, we are finalizing that whenever HHS recoups high-cost risk pool funds as a result of audits of risk adjustment covered plans, actionable discrepancies, or successful appeals, the recouped funds will be used to reduce high-cost risk pool charges for that national high-cost risk pool for the next applicable benefit year for which high-cost risk pool payments have not already been calculated.

We are finalizing as proposed the refinements to the HHS risk adjustment data validation (HHS–RADV) error estimation methodology beginning with the 2021 benefit year to: (1) Extend the application of Super HCCs [10] (which are currently based on the coefficient estimation groups defined in the applicable benefit year's ''Additional Adult Variables'' Table of the ''Do It Yourself (DIY)'' software (Table 6 in the 2021 Benefit Year DIY Software), which is published on the CCIIO website [11]) from their current application only in the sorting step that assigns HCCs to failure rate groups to broader application throughout the HHS–RADV error rate calculation process; (2) specify that Super HCCs will be defined separately according to the age group model to which an enrollee is subject, except when the child and adult coefficient estimation groups have identical definitions; and (3) constrain to zero any failure rate group outlier with a negative failure rate, regardless of whether the outlier issuer has a negative or positive error rate.

As we do every year in the HHS Notice of Benefit and Payment Parameters, we are finalizing updated parameters for the individual and small group markets. For the PY 2023, we are maintaining FFE and SBE–FP user fees at the current PY 2022 rates, 2.75 and 2.25 percent of total monthly premiums, respectively. On December 28, 2021, we released the Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage for the 2023 Benefit Year guidance setting forth these parameters for PY 2023.[12]

We are not finalizing the proposal to require all Exchanges to prorate premiums and advance payments of the premium tax credit (APTC). After considering the comments received, we are finalizing the policy to clarify the APTC proration methodology which Exchanges on the Federal platform will be subject to under HHS' authority to administer APTC, but we are not finalizing the requirement for State Exchanges to prorate premium or APTC amounts as described in the proposed rule. Rather, beginning in PY 2024, State

[8] *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[9] The same concern was not present for the 2016 or 2017 enrollee-level EDGE data because hydroxychloroquine was not included in the crosswalk until 2018.

[10] As finalized in this rule, beginning with the 2021 benefit year of HHS–RADV, a Super HCC will be defined as the aggregate de-duplicated frequencies of EDGE HCCs that share an HCC coefficient estimation group determined based on the enrollees' risk adjustment model.

[11] *Regulations and Guidance.* (2022). CMS. *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance.* The January 7, 2022 version of the DIY software is available at *2021 Benefit Year Risk Adjustment Updated HHS-Developed Risk Adjustment Model Algorithm* ''*Do It Yourself (DIY)*'' *Software.* (2022). CMS.

[12] *Premium Adjustment Percentage.* (2021, December 28). CMS. *https://www.cms.gov/files/document/2023-papi-parameters-guidance-v4-final-12-27-21-508.pdf.*

Exchanges must report to HHS through existing State Exchange oversight mechanisms the methodology the State Exchange will use that does not cause total monthly APTC amounts to exceed an enrollee's monthly PTC eligibility. This will ensure compliance with HHS and Internal Revenue Service (IRS) regulations particularly when an enrollee is enrolled in a policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month.

We are finalizing changes to clarify that the cost-sharing reduction (CSR) data submission process is mandatory only for those issuers that received CSR payments from HHS for any part of the benefit year and voluntary for other issuers that did not. We also finalize a technical correction to the definition of large group market in § 144.103 to delete the concluding phrase ''unless otherwise provided under State law.''

We are finalizing new display requirements for web-broker non-Exchange websites, including requirements related to QHP comparative information and standardized disclaimer language; a prohibition on displaying QHP advertisements or otherwise providing favored or preferred display of QHPs based on compensation agents, brokers, or web-brokers receive from QHP issuers; and a requirement to prominently display a clear explanation of the rationale for explicit QHP recommendations and the methodology for the default display of QHPs on web-broker non-Exchange websites to better inform and protect consumers using such websites.

We also finalize policies to address certain agent, broker, and web-broker practices. These policies will be added as part of the FFE standards of conduct codified at § 155.220(j)(2), improving CMS' ability to enforce existing responsibilities and requirements applicable to agents, brokers, and web-brokers participating in the FFEs and SBE–FPs, while also providing more detail about specific business practices that are prohibited.

We are finalizing 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.

We are finalizing flexibility under which Exchanges may conduct risk-based employer sponsored coverage verification in connection with eligibility determinations for APTC. This policy will help States more effectively balance the need to prevent improper APTC payments with the costs of verification.

We are finalizing amendments to implementing regulations to codify existing MLR policy that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes. We are also updating the MLR regulations to specify that only expenses directly related to activities that improve health care quality may be included as QIA expenses for MLR reporting and rebate calculation purposes. In addition, we are finalizing a technical amendment to the MLR provisions to remove a reference to a provision that was vacated by the United States District Court for the District of Maryland in *City of Columbus, et al.* v. *Cochran,* 523 F. Supp. 3d 731 (D. Md. 2021), and thus rescinded the provision in a final rule published in the **Federal Register** on May 5, 2021 (86 FR 24140) (part 2 of the 2022 Payment Notice final rule).

With regard to the EHBs, we are finalizing a permanent annual deadline in early-May for EHB-benchmark plan applications by States, as well as the repeal of the ability for States to permit issuers to substitute benefits between EHB categories. In addition, we are finalizing changes to the *de minimis* thresholds for the AV for plans subject to EHB requirements, as well as narrower *de minimis* thresholds for individual market silver QHPs and income-based CSR plan variations. We also finalize the proposal to remove the State annual reporting requirement to report State-required benefits in addition to the EHB to HHS.

We are finalizing policies to strengthen and clarify our network adequacy standards, including expanding the provider specialty list for time and distance standards and adding appointment wait time standards. We will begin implementation of appointment wait time standards in PY 2024. We are also finalizing the requirement for issuers to submit information about whether providers offer telehealth services. For plans with tiered networks, we are finalizing that, to count toward the issuer's satisfaction of the essential community provider (ECP) standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. This rule finalizes that the ECP threshold will increase from 20 percent to 35 percent.

We are finalizing the proposed amendments to the current HHS regulation that establishes standards for QHP issuer downstream and delegated entities. These changes will hold QHP issuers in all models of Exchange responsible for their downstream and delegated entities' adherence to applicable Federal standards, and make their oversight obligations, and the obligations of their downstream and delegated entities, explicit.

We solicited comments on incorporating the net premium, maximum out-of-pocket (MOOP), deductible, and annual out-of-pocket costs (OOPC) of a plan into the Exchange re-enrollment hierarchy, as well as additional criteria or mechanisms HHS could consider to ensure the Exchange hierarchy for re-enrollment aligns with plan generosity and consumer needs, such as re-enrolling a current bronze QHP enrollee into an available silver QHP with a lower net premium and higher plan generosity offered by the same QHP issuer. We also finalize the proposal to update the quality improvement strategy (QIS) standards to require QHP issuers to address health and health care disparities as a specific topic area within their QIS beginning in 2023.

We also proposed and are finalizing policies related to requirements that issuers of QHPs in FFEs and SBE–FPs offer standardized QHP options through the Exchange beginning in PY 2023.

Finally, we solicited comments regarding additional ways HHS could incentivize QHP issuers to design plans that improve health equity and health conditions in enrollees' environments, as well as how QHP issuers could address other social determinants of health (SDOH) outside of the QHP certification process and provide responses to the public comments received.

II. Background

A. Legislative and Regulatory Overview

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new title XXVII to the Public Health Service Act (PHS Act) to establish various reforms to the group and individual health insurance markets.

These provisions of the PHS Act were later augmented by other laws, including the 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.[13]

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 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.

Section 2791 of the PHS Act defines several terms, including ''large group market''.

Section 1301(a)(1)(B) of the ACA directs all issuers of QHPs to cover the 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 sections 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 establishes 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 establishes special enrollment periods and section 1311(c)(6)(D) of the ACA establishes the monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act.[14]

Section 1311(c)(1)(E) of the ACA specifies that to be certified as a QHP, each health plan must implement a QIS, which is described in section 1311(g)(1) of the ACA. Section 1311(g)(1) of the ACA describes this strategy as a payment structure that provides increased reimbursement or other incentives to improve health outcomes of plan enrollees, to prevent hospital readmissions, improve patient safety and reduce medical errors, promote wellness and health, and reduce health and health care disparities.

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 PTC and 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[15] 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

[13] The term ''group health plan'' is used in title XXVII of the PHS Act and is distinct from the term ''health plan'' as used in other provisions of title I of ACA. The term ''health plan'' does not include self-insured group health plans.

[14] The Indian Health Care Improvement Act (IHCIA), the cornerstone legal authority for the provision of health care to American Indians and Alaska Natives, was made permanent when President Obama signed the bill on March 23, 2010, as part of the Patient Protection and Affordable Care Act.

[15] Office of Management and Budget. (2004). *Circular A–25 Revised. https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf.*

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 1401(a) of the ACA amended the Internal Revenue Code (the Code) to add section 36B, 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) 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 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 1557 of the ACA applies certain long-standing civil rights nondiscrimination requirements to ''any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive agency, or any entity established under'' Title I of the ACA (or amendments). It did so by referencing statutes that specify prohibited grounds of discrimination, namely, race, color, national origin, sex, age, or disability, in an array of federally funded and administered programs or activities.[16] In addition, HHS has previously finalized rules unrelated to section 1557 of the ACA to address populations that have historically been subject to discrimination.

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.[17] 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.[18] 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 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 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

[16] 42 U.S.C. 18116.

[17] Public Law 115–97, 131 Stat. 2054 (2017).

[18] See 42 U.S.C. 18061, 18062, and 18063.

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.[19]

• 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.[20]

• 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 released 2021 Benefit Year Final HHS Risk Adjustment Model Coefficients to the CCIIO website.[21]

• 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' 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 containing policy and regulatory revisions related to the risk adjustment program, including 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.[22]

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 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

[19] *Updated 2019 Benefit Year Final HHS Risk Adjustment Model Coefficients.* (2018, July 27). CMS. *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Updtd-Final-HHS-RA-Model-Coefficients.pdf.*

[20] *Update on the HHS-operated Risk Adjustment Program for the 2017 Benefit Year.* (2018, July 27). *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2017-RA-Final-Rule-Resumption-RAOps.pdf.*

[21] *Final 2021 Benefit Year Final HHS Risk Adjustment Model Coefficients.* (2020, May 12). CMS. *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf.*

[22] *Updated 2022 Benefit Year Final HHS Risk Adjustment Model Coefficients.* (2021, July 19). CMS *https://www.cms.gov/files/document/updated-2022-benefit-year-final-hhs-risk-adjustment-model-coefficients-clean-version-508.pdf.*

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.

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 components of the Exchanges and set forth 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 January 5, 2022 **Federal Register** (87 FR 584), we published a proposed rule that outlined proposals 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 proposed various policies to address certain agent, broker, and web broker practices and conduct. We also proposed updates to the requirement that all 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.[23] 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 PYs 2020 and beyond.

6. Medical Loss Ratio (MLR)

We published a request for comment on section 2718 of the PHS Act in the April 14, 2010 **Federal Register** (75 FR 19297), and published an interim final rule with a 60-day comment period relating to the MLR program on December 1, 2010 (75 FR 74863). A final rule with a 30-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76573). An interim final rule with a 60-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76595). A final rule was published in the **Federal Register** on May 16, 2012 (77 FR 28790). The MLR program requirements were amended in final rules published in the March 11, 2014 **Federal Register** (79 FR 13743), the May 27, 2014 **Federal Register** (79 FR 30339), the February 27, 2015 **Federal Register** (80 FR 10749), the March 8, 2016 **Federal Register** (81 FR 12203), the December 22, 2016 **Federal Register** (81 FR 94183), the April 17, 2018 **Federal Register** (83 FR 16930), the May 14, 2020 **Federal Register** (85 FR 29164), an interim final rule that was published in the September 2, 2020 **Federal Register** (85 FR 54820), and the May 5, 2021 **Federal Register** (86 FR 24140).

7. Quality Improvement Strategy

We promulgated regulations in 45 CFR 155.200(d) to direct Exchanges to evaluate quality improvement strategies, and 45 CFR 156.200(b) that direct QHP issuers to implement and report on a quality improvement strategy or strategies consistent with section 1311(g) standards as QHP certification criteria for participation in an Exchange. In the 2016 Payment Notice, published in the February 27, 2015 **Federal Register** (80 FR 10749), we finalized regulations at § 156.1130 to establish standards and the associated timeframe for QHP issuers to submit the necessary information to implement QIS standards for QHPs offered through an Exchange.

8. Nondiscrimination

Section 1302 of the ACA provides for the establishment of an EHB package that includes coverage of EHB and AV requirements. In the February 25, 2013 **Federal Register** (78 FR 12834), HHS published the ''Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial

[23] *Essential Health Benefits Bulletin.* (2011, December 16). CMS. *https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.*

Value, and Accreditation'' final rule, which included nondiscrimination protections.

In the 2020 section 1557 final rule on section 1557 of the ACA, published in the June 19, 2020 **Federal Register** (85 FR 37160), HHS removed nondiscrimination protections on the basis of gender identity and sexual orientation from various CMS nondiscrimination regulations. In the HHS Notice of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, published in the May 25, 2021 **Federal Register** (86 FR 27984), HHS informed the public that HHS will interpret and enforce section 1557's and Title IX's prohibition on discrimination on the basis of sex to include discrimination based on sexual orientation and gender identity.

B. Stakeholder Consultation and Input

HHS consulted with stakeholders on policies related to the PHS Act and ACA Federal market reform requirements, including the operation of Exchanges and the risk adjustment program (including HHS–RADV). For example, related to risk adjustment, HHS released the 2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes [24] and the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations.[25] We also held a number of meetings with consumers, providers, employers, health plans, advocacy groups, and the actuarial community to gather public input. We solicited input from State representatives on numerous topics, particularly EHBs, State mandates, and risk adjustment. We consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with States through the Exchange Blueprint approval and general Exchange oversight processes, and meetings with Tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We considered all public input and written comments we received in response to the proposed rulemaking as we developed the policies in this final rule.

C. Structure of Final Rule

The regulations outlined in this final rule will be codified in 45 CFR parts 144, 147, 153, 155, 156, and 158.

The changes to 45 CFR part 144 will remove superfluous language from the definition of a large group market.

The changes to 45 CFR part 147 will ensure that issuers cannot refuse to effectuate new coverage based on the failure of an individual or employer to pay premiums owed for prior coverage.

The policies relating to 45 CFR part 153 involve recalibration of the 2023 benefit year risk adjustment models using the 2017, 2018, and 2019 enrollee-level EDGE data. We also finalize updates to the adult and child risk adjustment models for 2023 and beyond to better predict plan liability for certain subpopulations. Specifically, beginning with the 2023 benefit year, we will update the adult risk adjustment models by removing the current severity illness factors and replacing the current enrollment duration factors with enrollment duration factors contingent on the enrollee having at least one HCC. In addition, we will add an interacted HCC count model specification for 2023 and beyond to the adult and child models. We are not finalizing the proposal to add a two-stage weighted approach to model recalibrations.

We are finalizing a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the risk adjustment models, consistent with the approach adopted beginning with the 2020 models. We are finalizing removing the mapping of hydroxychloroquine sulfate to RXC 09 (Immune Suppressants and Immunomodulators) in the 2018 and 2019 benefit year enrollee-level EDGE data used for the annual recalibration of the HHS risk adjustment models.[26] For the 2024 benefit year and beyond, we will recalibrate the models using the final, fourth quarter (Q4) RXC mapping document that was applicable for each benefit year of data that is included in the current year's model recalibration. We are finalizing using this approach for recalibration of the 2023 adult risk adjustment models with the exception of the 2017 enrollee-level EDGE data year, for which we will use the most recent RXC mapping document that was available when we first processed the 2017 enrollee-level EDGE data (that is, Q2 2018).

We are finalizing the proposal to collect and extract five new data elements as part of the enrollee-level EDGE data. Beginning with the 2023 benefit year, issuers will be required to populate the ZIP Code and subsidy indicator fields as part of their EDGE data submissions. Issuers will also be required to populate the race, ethnicity, and Individual Coverage Health Reimbursement Arrangement (ICHRA) indicator fields. For the 2023 and 2024 benefit years, we are adopting a transitional period for the race, ethnicity, and ICHRA indicator fields during which time issuers will be required to populate these fields using available data sources. Then, beginning with the 2025 benefit year, issuers that do not have an existing source to populate these fields for particular enrollees will also be required to make a good faith effort to collect and submit race, ethnicity, and ICHRA indicator data elements for these enrollees. We are also finalizing the proposal to extract three data elements—plan ID, rating area, and subscriber indicator—issuers already report to their EDGE servers as part of the required risk adjustment data. We are finalizing the extraction of plan ID and rating area beginning with the 2021 benefit year, and subscriber indicator will be extracted beginning with the 2022 benefit year. Additionally, we finalize the proposal to amend § 153.730 to address situations when April 30 does not fall on a business day and to provide that when this occurs, the deadline for issuers to submit the required risk adjustment data in States where HHS operates the program would be the next applicable business day.

In part 153, we are finalizing policies related to risk adjustment State flexibility requests. We are finalizing the repeal of the ability of States to request a reduction in risk adjustment State transfers starting with the 2024 benefit year, with an exception for prior participants. We further limit a prior participant's ability to request a reduction in risk adjustment transfers starting with the 2024 benefit year to only those that meet the *de minimis* threshold criteria. In future rulemaking, HHS intends to propose to eliminate the prior participant exception starting with the 2025 benefit year. For the 2023 benefit year, we approve Alabama's requests to reduce risk adjustment State transfers, but at lower percentages, than the State requested. We approve for the 2023 benefit year a 25 percent reduction in Alabama's individual market (including the catastrophic and non-

[24] *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[25] *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations.* (2021, December 28). CMS. *https://www.cms.gov/files/document/report-summary-results-transfer-simulations.pdf.*

[26] The same concern was not present for the 2017 enrollee-level EDGE data because hydroxychloroquine sulfate was not included in the RXC crosswalk until 2018.

catastrophic risk pools) transfers and a 10 percent reduction in Alabama's small group market transfers.

In part 153, we also finalize the risk adjustment user fee for the 2023 benefit year at $0.22 PMPM. We also finalize the proposed update to the HHS–RADV error estimation process to extend the application of Super HCCs beyond the sorting step that assigns HCCs to failure rate groups, to also apply throughout the HHS–RADV error rate calculation processes. We further specify that Super HCCs will be defined separately according to the model (infant, child, adult) to which an enrollee is subject, except for where child and adult coefficient estimation groups have identical definitions. We also finalize the proposal to constrain to zero any failure rate group outlier negative failure rate, regardless of whether the outlier issuer has a negative or positive error rate. These refinements to the HHS–RADV error rate methodology and processes will apply beginning with the 2021 benefit year. Finally, we adopt the policy that whenever HHS recoups high-cost risk pool funds as a result of audits of risk adjustment covered plans, an actionable discrepancy, or a successful administrative appeal, the recouped high-cost risk pool funds will be used to reduce high-cost risk pool charges for that national high-cost risk pool beginning for the next benefit year for which a high-cost risk pool payment has not already been calculated.

In addition, we are finalizing the part 153 proposals related to MLR reporting requirements and how issuers should report certain ACA program amounts that could be subject to reconsideration. More specifically, we add references to HHS–RADV adjustments to § 153.710(h) to make clear that HHS expects issuers to report HHS–RADV adjustments as part of their MLR reports in the same manner as they report risk adjustment payment and charge amounts.

We finalize changes to 45 CFR part 155 to allow Exchanges to implement a verification process for enrollment in or eligibility for an eligible employer sponsored plan based on the Exchange's assessment of risk for inappropriate payments of APTC/CSR. We are codifying the proposed APTC proration methodology as the methodology Exchanges on the Federal platform will continue to use, but we are not finalizing the requirement for State Exchanges to prorate premium or APTC amounts using the methodology described in the proposed rule. Rather, we are finalizing that beginning in PY 2024, State Exchanges will be required to report to HHS their methodology that ensures the amount of APTC applied to an enrollee's monthly premium does not exceed their total monthly APTC.

We are also finalizing new requirements in part 155 related to the QHP comparative information and standardized disclaimer required to be displayed on web-broker non-Exchange websites; a prohibition on displaying QHP advertisements or otherwise providing favored or preferred placement in the display of QHPs on web-broker non-Exchange websites based on compensation agents, brokers, or web-brokers receive from QHP issuers; and the prominent display of a clear explanation of the rationale for explicit QHP recommendations and the methodology for the default display of QHPs on web-broker non-Exchange websites to better inform and protect consumers using such websites. After consideration and review of the comments, we will not finalize § 155.220(j)(2)(ii)(A)(*1*), which would prohibit agents from entering consumer email addresses with domains that remove email from an inbox after a set period of time. We encourage agents, brokers, and web-broker entities to remain aware of, and avoid using, such temporary email accounts when assisting consumers in obtaining coverage as a best practice and will likely issue future guidance on the matter. Otherwise, we are generally finalizing the changes to the remainder of § 155.220(j)(2)(ii) to clarify the FFE standards of conduct for agents, brokers, and web-brokers, and what it means to provide the Exchange with correct information under section 1411(b) of the ACA. We also finalize the changes to § 155.220(j)(2)(vi) through (viii) to expand the FFE standards of conduct and codify more detail about specific business practices that are prohibited.

In 45 CFR part 156, we are finalizing the user fee rates for the 2023 benefit year for all issuers participating on Exchanges that use the Federal platform. We also finalize technical amendments to § 156.50 to conform with the repeal of the Exchange Direct Enrollment (DE) option finalized in part 3 of the 2022 Payment Notice (86 FR 53412 at 53424 through 53429 and 53445). Also, we finalize changes to § 156.430 to clarify that the CSR data submission process is mandatory only for those issuers that receive CSR payments from HHS for any part of the benefit year as a result of HHS possessing an appropriation to make CSR payments and voluntary for other issuers.

In part 156, we are also finalizing a refinement to the EHB nondiscrimination policy to provide that a nondiscriminatory health plan design that provides EHB is one that is clinically based; a permanent annual deadline in early May for EHB-benchmark plan applications by States, a repeal of States' ability to permit issuers to substitute benefits between EHB categories; changes to the *de minimis* thresholds for the AV of plans subject to the AV requirements, as well as narrower *de minimis* thresholds for individual market silver QHPs and income-based CSR plan variations; and a repeal of the annual requirement for States to report to HHS State-required benefits in addition to the EHB.

In part 156, we are also finalizing a requirement that issuers of QHPs in FFEs and SBE–FPs offer through the Exchange standardized QHP options beginning in PY 2023. We are also finalizing an update to the QIS standards to require QHP issuers to address health and health care disparities as a specific topic area within their QIS beginning in 2023.

The changes to 45 CFR part 158 codify that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes. The changes to part 158 also specify that only expenses directly related to activities that improve health care quality may be included as QIA expenses for MLR reporting and rebate calculation purposes. In addition, we finalize a technical amendment to § 158.170(b) to correct an oversight and remove the reference to the percentage of premium QIA reporting option described in § 158.221(b)(8), a provision that was vacated by the United States District Court for the District of Maryland in *City of Columbus,*[27] and thus deleted in part 2 of the 2022 Payment Notice final rule.

III. Provisions of the Final HHS Notice of Benefit and Payment Parameters for 2023

A. Part 144—Requirements Relating to Health Insurance Coverage

1. Definitions (§ 144.103)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 594), we proposed to remove the phrase ''unless otherwise provided under State law'' from the definition of large group market at § 144.103. As discussed in the proposed rule, the phrase has no meaning or application and does not appear in the

[27] *City of Columbus, et al.* v. *Cochran,* 523 F. Supp. 3d 731 (D. Md. 2021).

statutory definition of large group market in section 2791(e)(3) of the PHS Act. That phrase was initially included in the PHS Act regulatory definitions of large group market, large employer, and small employer adopted by HHS under HIPAA.[28] However, in the final rules published on October 30, 2013 (78 FR 65045), we amended the definitions of large employer and small employer to make them consistent with section 2791(e) of the PHS Act, as amended by the ACA, and in so doing, removed that phrase from the definitions. At that time, we inadvertently neglected to delete the phrase from the regulatory definition of large group market, and we proposed to do so in the proposed rule, to align these definitions and make the regulatory definition for large group market consistent with the definition under the ACA.

We sought comment on this proposal.

After reviewing public comments, we are finalizing this provision as proposed. The removal of the phrase ''unless otherwise provided under State law,'' will add clarity to the regulatory definition of ''large group market,'' and align with the current definition under section 2791(e) of the PHS Act.

We summarize and respond to public comments received on the definition of large group market below.

Comment: We received two comments related to the definition of a large group market. One commenter did not see any adverse consequences to the revision. Another expressed concern that State law definitions of ''large group'' would be adversely affected by the change in Federal law because each State passes laws tailored to the market in their respective State.

Response: As discussed in the proposed rule, we proposed this change to align the regulation with the underlying statutory definition of ''large group market,'' which does not include the phrase ''unless otherwise provided under State law.'' In addition, removing this language will not affect State law definitions of large group market to the extent that they do not prevent the application of Federal law.

B. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Guaranteed Availability of Coverage (§ 147.104)

a. Past-Due Premiums

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 594 through 595), we proposed to re-interpret the guaranteed availability requirement at section 2702 of the PHS Act and its implementing regulation at § 147.104 to require issuers to accept individuals and employers who apply for coverage, even when the individual or employer owes past-due premiums for coverage from the same issuer or another issuer in the same controlled group. Under the current interpretation of the guaranteed availability requirement, to the extent permitted by applicable State law, an issuer does not violate the guaranteed availability requirements under § 147.104 when the issuer attributes a premium payment made for new coverage to any past-due premiums owed for coverage from the same issuer or another issuer in the same controlled group within the prior 12-month period before effectuating enrollment in the new coverage.[29]

On January 28, 2021, President Biden issued Executive Order 14009, ''Strengthening Medicaid and the Affordable Care Act'' (E.O. 14009).[30] 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, to include protecting and strengthening the ACA and making high-quality health care accessible and affordable for all individuals. On April 5, 2022, President Biden issued Executive Order 14070, ''Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage'' (E.O. 14070).[31] Section 2 of E.O. 14070 directs agencies with responsibilities related to Americans' access to health coverage, in addition to taking the actions directed pursuant to E.O. 14009, to review agency actions to identify ways to continue to expand the availability of affordable health coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health coverage. Consistent with section 3(iv) of E.O. 14009 and section 2(a) of E.O. 14070, the re-interpretation of the guaranteed availability requirement is intended to remove an unnecessary barrier and make it easier for consumers to enroll in coverage.

In the proposed rule (87 FR 594), we proposed to re-designate § 147.104(i) as § 147.104(j) and add a new § 147.104(i) to specify that a health insurance issuer that denies coverage to an individual or employer due to the individual's or employer's failure to pay premium owed under a prior policy, certificate, or contract of insurance, including by attributing payment of premium for a new policy, certificate, or contract of insurance to the prior policy, certificate, or contract of insurance, violates § 147.104(a). Based on our experience, we believe that the currently effective interpretation of guaranteed availability has the unintended consequence of creating barriers to health coverage that disproportionately affect low-income individuals.

After reviewing the public comments, we are finalizing this provision as proposed. We summarize and respond to public comments received on the proposed re-interpretation of guaranteed availability requirements for the group and individual health insurance markets below.

Comment: Many commenters supported the proposal, stating that the current interpretation of the guaranteed availability requirement is inconsistent with the ACA and creates barriers to accessing health care that disproportionately harm persons with low incomes and those experiencing economic hardship. Other commenters in favor of the proposal stated that the current interpretation of the guaranteed availability requirement is a barrier to enrollment that disproportionately impacts people of color, especially women of color, persons with disabilities, lesbian, gay, bisexual, transgender, queer, and intersex (LGBTQI+) people, and immigrants.

Some commenters stated that non-payment of past-due premiums is typically not an intentional decision to avoid financial responsibility, and may be the result of a mistake or catastrophic events such as financial hardship, environmental disaster, hospitalization, or lack of awareness of past-due premium debt. Some commenters expressed concern that the current interpretation of the guaranteed availability requirement permits issuers to adopt punitive measures against consumers who, without malice, are unable to satisfy past-due premium debt.

Some commenters stated that the current interpretation of the guaranteed availability requirement compounds barriers to enrollment by requiring consumers with past-due premium debt

[28] 62 FR 16894 and 69 FR 78720.

[29] 82 FR 18346, 18349 through 18353.

[30] Executive Order 14009 on Strengthening Medicaid and the Affordable Care Act. (2021, February 2). See 86 FR 7793.

[31] Executive Order 14070 on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage, April 5, 2022; see 87 FR 20689.

to pay multiple months of premiums on top of a binder payment in order to effectuate coverage. A commenter noted that there is no evidence that individuals are attempting to ''game the system'' by enrolling in coverage and paying premiums only when care is needed. Other commenters stated that the current interpretation poses a steep barrier to enrollment for consumers responding to catastrophic life events, particularly given that the amount of past-due premiums owed to payors is nominal compared to issuer profits.

Other commenters opposed the proposed policy and stated that more research is necessary to determine why individuals and employers fail to pay past-due premiums and questioned whether other coverage options could be made more accessible.

Response: We believe finalizing the proposed re-interpretation of the guaranteed availability requirement will alleviate a barrier to enrollment for individuals struggling to access health coverage, which disproportionately affects historically marginalized populations and individuals facing financial hardship. The current interpretation of this policy disincentivizes enrollment by conditioning coverage on the repayment of the past-due premium debt, which may deter individuals who have accrued past-due premium debt from seeking coverage altogether. Conversely, permitting individuals to enroll in coverage, regardless of past-due premium debt, will help ensure continuous access to health care, especially for individuals facing dire economic circumstances. We agree with commenters that enrollees fail to pay premiums for numerous, valid reasons that have nothing to do with exploiting grace periods or special enrollment periods to avoid paying for health coverage. Additionally, many consumers and small businesses face financial challenges. As such, we believe it is prudent to remove barriers to accessing health coverage to ease the enrollment process.

While the exact cause of premium non-payment and past-due premium accrual may not be clear in all cases, we are of the view that this should not be a reason to deny individuals coverage. We agree with commenters suggesting that more research is needed to determine why individuals and employers fail to pay past-due premiums, and believe that such research could inform future policies to better support consumers in staying enrolled in coverage.[32]

Comment: Some commenters recommended limiting the re-interpretation of the guaranteed availability requirement to the individual market and not making it applicable to the group market. One commenter stated that the proposed change could have significant impacts on issuer management of enrollment and billing for group market accounts.

Response: Under section 2702 of the PHS Act and § 147.104, the guaranteed availability requirement applies to both the individual and group markets. We believe the same principles underlying this policy should apply equally to both markets, and therefore, decline to adopt this recommendation.

Comment: Commenters stated that this proposal restricts issuers' ability to collect past-due premiums or requires them to forgive such debt. Some commenters expressed concern that finalizing the proposal will remove a disincentive that guards against enrollees ceasing to pay premiums during the last 3 months of the plan year, and will leave issuers without adequate redress when faced with non-payment. Some commenters stated that permitting individuals with past-due premium debt to enroll in coverage before repaying past-due premiums will ultimately result in fewer choices and higher premiums, harming consumers with low incomes. One commenter requested that HHS specify other options for issuers besides collections.

In contrast, another commenter noted that issuers have largely chosen not to use the flexibility provided under the current interpretation of the guaranteed availability requirement because the implementation of a policy that attributes payments made for new coverage to past-due premiums before effectuating new enrollment would cost more than the past-due premiums the issuer would recoup through such a policy. Other commenters agreed that issuers have other tools for recouping unpaid premiums. Some commenters suggested that issuers should be prohibited from acting to collect past-due premiums.

Response: We disagree that this proposal restricts issuers from collecting past-due premiums. Issuers are generally not permitted to forgive the past-due premium debt and have alternative methods to collect past-due premiums (such as pursuing debt collection). We believe this mitigates the risk that some enrollees may take advantage of the guaranteed availability rules. We also believe that the low adoption among issuers of policies that rely on the current interpretation of guaranteed availability demonstrates that there are sufficient avenues for issuers to collect past-due premium debt without having to condition enrollment into new coverage on the payment of past-due premium debt. However, we acknowledge that issuers that implemented a policy of attributing payment made for new coverage to past-due premiums before effectuating enrollment will need to make operational changes as a result of this re-interpretation of the guaranteed availability requirement. Finally, in response to the commenter's suggestion that issuers should be prohibited from acting to collect on debt for past-due premiums, we reiterate that an issuer's forgiveness of premium debt is generally not permissible under our rules.

b. Nondiscrimination Based on Sexual Orientation and Gender Identity

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 595 through 597), we proposed to amend 45 CFR 147.104(e) to explicitly prohibit discrimination based on sexual orientation and gender identity. As we explain in the Supplemental Information section earlier in the preamble, HHS will address this policy, as well as the public comments submitted in response to this proposal, in a future rulemaking.

C. 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. 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.[33] HHS did not receive any requests from States to operate risk adjustment for the 2023 benefit year. Therefore, HHS will operate risk adjustment in every State and the District of Columbia for the 2023 benefit year.

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2022, the permanent risk adjustment program is subject to the fiscal year 2022

[32] Cunningham, P.J., Green, T.L., & Braun, R.T. (2018, February 26). Income Disparities in the Prevalence, Severity, and Costs of Co-Occurring Chronic and Behavioral Health Conditions. *Medical Care.*

[33] See also 42 U.S.C. 18041(c)(1).

sequestration.[34] Therefore, the risk adjustment program will be sequestered at a rate of 5.7 percent for payments made from fiscal year 2022 resources (that is, funds collected during the 2022 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 (Pub. L. 99–177, enacted December 12, 1985), as amended, and the underlying authority for the risk adjustment program, the funds that are sequestered in the fiscal year 2022 from the risk adjustment program will become available for payment to issuers in the fiscal year 2023 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 Coronavirus Aid, Relief, and Economic Security (CARES) Act amended section 251A(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 and extended sequestration for the risk adjustment program through the fiscal year 2030 at a rate of 5.7 percent per fiscal year.[35]

We received no comments on the FY2022 sequestration rate for risk adjustment.

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 diagnosis is added together to produce an individual risk score. Additionally, to calculate enrollee risk scores in the adult models, we added enrollment duration factors beginning with the 2017 benefit year, and prescription drug categories (RXCs) beginning with the 2018 benefit year.[36] Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of diagnoses. If applicable, the risk score for adults, children, or infants is multiplied by a CSR 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 or PLRS) within a geographic rating area is one of the inputs into the risk adjustment State payment transfer formula, which determines the State transfer payment or charge that an issuer will receive or be required to pay for that plan for the applicable State market risk pool. Thus, the HHS risk adjustment models predict average group costs to account for risk across plans, in keeping with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

a. Data for Risk Adjustment Model Recalibration for 2023 Benefit Year and Beyond

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 598), we proposed to recalibrate the 2023 benefit year risk adjustment models with 2017, 2018, and 2019 enrollee-level EDGE data. We sought comment on this proposal.

In the proposed rule, we also sought comments on the future use of the 2020 enrollee-level EDGE data due to the COVID–19 PHE. Under current policy, 2020 enrollee-level EDGE data would be used in the recalibration of the HHS risk adjustment models for the 2024 benefit year, and that data would continue to be used for the 2025 and 2026 benefit years models.[37] Although HHS has not analyzed the 2020 enrollee-level EDGE data yet, we solicited comment on the future use of the 2020 enrollee-level EDGE data for the annual recalibration of the HHS risk adjustment models.

After reviewing the public comments, we are finalizing, as proposed, the use of the 2017, 2018, and 2019 enrollee-level EDGE data to recalibrate the 2023 benefit year risk adjustment models. We were unable to finalize coefficients in time to publish them in this final rule. Therefore, consistent with § 153.320(b)(1)(i), we will publish the final coefficients for the 2023 benefit year in guidance soon after the publication of this final rule.

Additionally, we appreciate comments on the future use of the 2020 enrollee-level EDGE data due to the COVID–19 PHE. We continue to consider how to handle 2020 enrollee-level EDGE data for recalibration of the 2024, 2025, and 2026 benefit year models and will work with stakeholders as we analyze the data. Changes to the established policies for recalibration of the risk adjustment models, including proposals related to the use of 2020 enrollee-level EDGE data for such purposes, would be pursued through notice-and-comment rulemaking.

We summarize and respond to public comments received on data for risk adjustment model recalibration for the 2023 benefit year and beyond below.

Comment: Many commenters supported the use of the 2017, 2018, and 2019 enrollee-level EDGE data to recalibrate the 2023 risk adjustment models. One commenter noted that the 2017, 2018, and 2019 enrollee-level EDGE data reflect the most recently available health outcomes and recent treatment patterns in the enrollee population. Another commenter supported using the most recent 3 years of EDGE data available in time for publication of the draft coefficients in the proposed rule in order to give the industry the earliest opportunity to model premium rates for the next benefit year.

Response: We are finalizing the use of the 2017, 2018, and 2019 enrollee-level EDGE data to recalibrate the 2023 risk adjustment models as proposed. The 2017, 2018, and 2019 enrollee-level EDGE data were the 3 most recent consecutive years of enrollee-level EDGE data that were available at the time we incorporated the data in the draft recalibrated coefficients published in the proposed rule. As discussed in the 2022 Payment Notice, the purpose of using the 3 most recent consecutive years of enrollee-level EDGE data that were available at the time we incorporated the data in the draft recalibrated coefficients published in the proposed rule was to respond to stakeholders' request to provide the draft coefficients in the proposed rule (86 FR 24152). We believe that this approach promotes stability and avoids the delays in publication of the coefficients while continuing to develop blended, or averaged, coefficients from the 3 years of separately solved models for model recalibration.

Comment: We received several comments on the use of 2020 enrollee-level EDGE data for recalibration of the

[34] *OMB Report to the Congress on the BBEDCA 251A Sequestration for Fiscal Year 2022.* (2021, May 28). White House. *https://www.whitehouse.gov/wp-content/uploads/2021/05/BBEDCA_251A_Sequestration_Report_FY2022.pdf.*

[35] CARES Act, S.3548. (2020).

[36] 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.

[37] Consistent with the approach finalized in the 2022 Payment Notice, use of the 3 most recent consecutive years of enrollee-level EDGE data would result in the use of 2018, 2019, and 2020 enrollee-level EDGE data for the recalibration of the 2024 benefit year models; the use of 2019, 2020, and 2021 enrollee-level EDGE data for recalibration of the 2025 benefit year models; and the use of 2020, 2021, and 2022 enrollee-level EDGE data for recalibration of the 2026 benefit year models.

2024, 2025, and 2026 benefit years. Some of these commenters supported the inclusion of 2020 enrollee-level EDGE data in these future benefit year model recalibrations, stating that 2020 data would accurately reflect utilization patterns that can be expected in 2021 and beyond and that the inclusion of 3 years of enrollee-level EDGE data in recalibration would dampen the impact of 2020 data. Another commenter noted that failure to include 2020 data would result in an outdated picture of medical spending.

One commenter opposed the inclusion of 2020 enrollee-level EDGE data in model recalibration altogether. Another commenter noted that not relying on 2020 experience to develop risk adjustment coefficients is consistent with industry practice, asserting that the majority of Medicare Advantage and ACA issuers used 2019 data in lieu of 2020 data for 2022 pricing.

Several commenters requested HHS develop a technical paper on using 2020 enrollee-level EDGE data in future model recalibrations, with several commenters suggesting that 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. One commenter requested that HHS release 2020-related statistics and solicit further comment on how to best proceed with 2020 data, including whether to instead use 2017, 2018, and 2019 EGDE data for the 2024 benefit year recalibration of the HHS risk adjustment models.

One commenter recommended either assigning 2020 enrollee-level EDGE data lower weight if used to recalibrate the models in the 2024, 2025, and 2026 benefit years, or using four years of enrollee-level EDGE data in the annual model recalibration until 2020 data is no longer included in recalibration. Another commenter recommended that HHS evaluate if it would be better to use 1 or 2 years of data for recalibration of the models in the 2024, 2025, and 2026 benefit years on a transitional basis until only post-2020 data would be used.

Response: We appreciate comments on the future use of the 2020 enrollee-level EDGE data for risk adjustment model recalibration and will consider this feedback as we analyze the 2020 enrollee-level EDGE data and consider options for its use for recalibration of the risk adjustment models.

b. Risk Adjustment Model Updates

In the proposed rule (87 FR 598 through 605), we proposed three modeling updates to the risk adjustment models beginning with the 2023 benefit year. Consistent with the potential model updates discussed in the 2021 RA Technical Paper, we proposed the following model updates, which are the same as those proposed but not finalized in the 2022 Payment Notice:[38] (1) Adding a two-stage weighted model specification to the adult and child models; (2) removing the severity illness factors in the adult models and replacing them with new severity and transplant indicators interacted with HCC count factors in the adult and child models; and (3) replacing the current enrollment duration factors in the adult models with HCC-contingent enrollment duration factors in the adult models.

After a review of public comments, we are finalizing two of the three proposed model specification updates. We are not finalizing the proposed addition of a two-stage weighted model specification to the adult and child models. We are finalizing, as proposed, removing the current severity illness factors in the adult models and replacing them with new severity and transplant indicators that interacted with HCC count factors in the adult and child models. We are also finalizing, as proposed, replacing the current enrollment duration factors in the adult models with HCC-contingent enrollment duration factors in the adult models. In the following sections, we describe the proposed model specification changes, as well as summarize and respond to the comments received on each of these proposals.

i. Two-Stage Weighted Model Specification

We proposed to use a two-stage weighted model specification to recalibrate the adult and child risk adjustment models starting with the 2023 benefit year to improve the underprediction of plan liability for the lowest-risk enrollees (that is, enrollees in low-risk deciles and enrollees without HCCs [39]). For a full description of the proposed two-stage weighted model specification see the proposed rule (87 FR 599 through 601). We sought comment on the two-stage weighted model specification proposal.

After reviewing the public comments, we are not finalizing the adoption of the two-stage weighted model specification.

We summarize and respond to public comments received on the proposed two-stage model specification below.

Comment: Several commenters supported the implementation of the proposed two-stage weighted model specification. Some of these commenters generally supported all of the proposed model specification changes, while others specifically noted that the proposed two-stage model improved prediction for the lowest-risk enrollees.

Conversely, several other commenters opposed the implementation of the proposed two-stage weighted model specification. Several commenters were concerned that the proposed two-stage weighted model specification would have anti-competitive effects, leading to fewer choices for consumers. These commenters stated that the two-stage weighted model specification would increase premiums on more generous health insurance coverage, incentivize issuers to adopt narrow networks and lower-quality plans, encourage issuers to avoid enrolling consumers with chronic illnesses, and contribute to the creation and use of discriminatory benefit designs.

Other commenters did not support a model change that improved risk predictions for certain subpopulations at the expense of the risk adjustment program's ability to mitigate adverse selection for high-cost enrollees. Some commenters stated that the proposed two-stage weighted model specification ignores current market dynamics in which plans are already incentivized to attract the healthiest enrollees. Additionally, some commenters recommended additional analysis of the two-stage weighted model specification, specifically geographic and market-specific considerations, before its adoption. One commenter suggested that if HHS finalizes the two-stage weighted model specification, HHS should pilot or phase-in the implementation based on an analysis of localized market conditions.

Response: After consideration of the comments on this proposal, we are not finalizing the proposed two-stage

[38] In the 2022 Payment Notice Proposed Rule, we proposed three model specification changes, see 85 FR 78572 at 78583 through 78586. In the 2022 Payment Notice Final Rule, in response to comments, we did not finalize the proposed updates and announced that we would publish a technical paper on the proposed model changes; see 86 FR 24140 at 24151 through 24162. See also HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf* and HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations. (2021, December 28). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[39] When we refer to the enrollees without HCCs, we are referring to enrollees without payment HCCs.

weighted model specification. We pursued the proposed model specification updates to improve the prediction of certain subpopulations in response to feedback from stakeholders and internal analysis where we had observed underprediction in the current models. As we previously reported in the 2018 Payment Notice, our initial analysis found that, based on the commercial MarketScan® data, the HHS risk adjustment models slightly underpredicted risk for the lowest-risk enrollees (81 FR 61472 through 61473 and 81 FR 94082 through 94083). Our subsequent analysis of enrollee-level EDGE data confirmed this preliminary finding.[40] In addition, stakeholders have consistently encouraged HHS to adjust the models to address this underprediction of risk, which affects the PLRSs of plans that enroll more healthy individuals. HHS has therefore been examining these issues, considering different options, and soliciting comments on ways to modify the risk adjustment models to improve prediction for certain subpopulations, including the lowest-risk enrollees, over several years (81 FR 61473 and 85 FR 7101 through 7104). Throughout this process, we consistently emphasized the need to carefully evaluate the impact on and consider the trade-offs that would need to be made in model predictive power among subgroups of enrollees.

The proposed two-stage weighted model specification was targeted at improving model prediction for lowest-risk enrollees. As previously explained, we believed that by addressing the underprediction of costs associated with lowest-risk enrollees in the adult and child models, we could encourage the offering and retention of plans that enroll a higher proportion of this subpopulation of enrollees.[41] We also recognized that issuers offering these types of plans were at greater risk of exiting the market if transfers calculated under the State payment transfer formula under-compensated for the true plan liability of the lowest-risk enrollees. These concerns, along with stakeholder comments on these issues, prompted the design of the two-stage weighted model specification two years ago. However, we acknowledged that there are trade-offs associated with the adoption of the proposed two-stage weighted model, including that while it would improve prediction for the lowest-risk enrollees it would worsen model prediction along other dimensions, such as reduced R-squared values, less accurate prediction of plan liability by age-sex factor (especially for younger and older women), as well as a less accurate prediction of costs for certain HCCs.[42] Additionally, since developing the proposed two-stage weighted model specification, there have been key shifts in the individual market, including increased enrollment and increased availability of subsidies,[43] that have made the market more attractive to issuers. However, these market shifts have also shown the pressing need to update the adult model enrollment duration factors, which we are also finalizing as part of this rule.

While the interacted HCC count model specification and the enrollment duration factor updates finalized in this rule do not improve predictive accuracy for the lowest-risk enrollees as much as they would have if they were combined with the proposed two-stage weighted model specification, we believe the finalized model specifications will still make significant gains in improved predictive accuracy for our target subpopulations, including the lowest-risk enrollees, highest-risk enrollees, and partial-year enrollees.[44] As demonstrated in Chapter 4 of the 2021 RA Technical Paper, our analysis found the proposed interacted HCC counts model specification and the proposed HCC-contingent enrollment duration factors improved prediction for the lowest-risk enrollees, compared with the current adult models, even without accounting for the proposed two-stage weighted model specification.[45] Using 2018 enrollee-level EDGE data, the proposed interacted HCC counts model specification combined with the proposed HCC-contingent enrollment duration factors improves the PR for adult silver-plan enrollees in risk decile 1 from 0.52 to 0.81.[46] This approach of incremental improvements in predictive accuracy aligns with our commitment to continuously analyze and refine the risk adjustment models. After consideration of comments and further evaluation of the trade-offs, we are finalizing the interacted HCC count model specification and enrollment duration factor updates but are not finalizing the proposed two-stage weighted model specification.

Since we are not finalizing the proposed two-stage weighted model specification, we do not intend to pursue or otherwise consider pilot or phase-in implementation strategies. Similarly, we do not intend to engage in additional analysis of alternative implementations of the two-stage weighted model specification, including but not limited to an analysis of implementation by geographic or market-specific conditions, at this time.

Comment: One commenter that supported the proposed two-stage weighted model specification also encouraged HHS to recalibrate the State payment transfer formula to further ensure that plans do not face excessive risk adjustment charges when enrolling a high proportion of young and healthy enrollees. Another commenter supported the finalization of the two-stage weighted model specification, but noted that it is unclear to what extent these model changes address situations in which risk adjustment charges for some issuers exceed the premium collected for some lower-risk enrollees.

Response: We did not propose and are not finalizing changes to the State payment transfer formula. However, we intend to continue analysis of the risk adjustment State payment transfer formula to consider whether changes are needed to it. For example, in Appendix A of the 2021 RA Technical Paper, we discussed options to potentially update the risk adjustment State payment transfer formula to improve prediction for CSR enrollees' plan liability. More specifically, we identified several potential options to update the risk term and one option to update the rating term to more precisely account for CSR plan liability in the State payment transfer formula.[47] We familiarized stakeholders with these options and accepted public comments on the considerations in the 2021 RA Technical Paper. We continue

[40] Section 2. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[41] Section 2.1. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[42] Section 2.3. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.* See also 87 FR 600 through 601.

[43] *Biden-Harris Administration Announces 14.5 Million Americans Signed Up for Affordable Health Care During Historic Open Enrollment Period.* (2022, January 27). CMS. *https://www.hhs.gov/about/news/2022/01/27/biden-harris-administration-announces-14-5-million-americans-signed-affordable-health-care-during-historic-open-enrollment-period.html#:~:text=Today%2C%20the%20Biden%2DHarris%20Administration, people%20who%20have%20newly%20gained.*

[44] Figures 4.2, 4.3, and 4.4. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[45] Ibid.

[46] Section 4. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[47] Appendix A. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

to conduct analyses of these options and will propose any changes in future notice-and-comment rulemaking.

As part of future analyses, we also intend to assess the impact of the State payment transfer formula on risk adjustment covered plans with lowest-risk enrollees to the extent that our data allows. However, in response to commenters' concerns that risk adjustment charges exceed premiums collected for some of the lowest-risk enrollees, we do not believe that this concern falls within the scope of the proposed two-stage weighted model specification, and we reiterate that we do not believe that adjusting the State payment transfer formula to limit charges to the level of premiums for enrollees is appropriate (86 FR 24140 at 24186). Also, as previously described, we proposed the two-stage weighted model specification to address the underprediction of the lowest risk enrollees, not to address the situation described by the commenter in which risk adjustment charges may exceed premiums collected for some enrollees. As described in the most recent ''Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year,'' risk adjustment is working as intended to transfer payments from plans with lower than average actuarial risk to plans with higher than average actuarial risk.[48] Furthermore, we do not believe that limiting risk adjustment charges to the level of enrollee premiums is consistent with the framework set forth in section 1343 of the ACA, which requires the establishment of a risk adjustment program focused on risk differentials at the plan level, not the enrollee level.[49] Risk adjustment transfers under the State payment transfer formula are therefore calculated based on the PLRS and the Statewide average premium, not based on individual enrollees' premiums.

Comment: Some commenters requested that if HHS finalizes the proposed two-stage weighted model specification, then HHS should reassess the 14 percent administrative adjustment, which they argue may already address some of the underprediction seen in predictive ratios.

Response: We did not propose and are not finalizing changes to the 14 percent administrative cost reduction to the Statewide average premium used in the State payment transfer formula. While HHS is not finalizing the proposed two-stage weighted model specification, we reiterate that the proposed two-stage weighted model specification and administrative cost adjustment to Statewide average premium address separate considerations. Specifically, the 14 percent administrative cost reduction is used in the State payment transfer formula to adjust the Statewide average premium and does not address the predictive accuracy of the risk adjustment models, as described in the 2021 RA Technical Paper. As detailed in the 2018 Payment Notice, the purpose of the administrative cost adjustment to the Statewide average premium is to exclude fixed administrative costs that are not dependent on enrollee risk, such as taxes (81 FR 61488 through 61489 and 81 FR 94099 through 94100). In contrast, and as previously described elsewhere,[50] the proposed two-stage weighted model specification was a targeted refinement aimed at improving the current adult and child models' prediction for the lowest-risk enrollees. Therefore, we do not agree with commenters' assertions that the administrative cost adjustment addresses the same issue as the two-stage weighted model specification, specifically the underprediction of costs in the lowest-risk enrollee subpopulation.

Comment: Some commenters that opposed the proposed two-stage weighted model specification were concerned it may be resulting in overfitting of the models and may not predict future costs accurately. They also noted that the two-stage weighted model specification is not a standard procedure for risk adjustment and worsens fit in some areas, such as the reduced R-squared values,[51] although the effect is small.

Response: As previously described, we acknowledged that there are trade-offs associated with adoption of the proposed two-stage weighted model, including that it would worsen model prediction along some dimensions, such as reduced R-squared values. We also recognize that the two-stage weighted model specification is not a standard procedure for risk adjustment. After consideration of comments and further evaluation of the trade-offs, we are not finalizing the proposed two-stage weighted model specification update to the adult and child models. In response to commenters' concerns about overfitting, we note that we do not have concerns with respect to overfitting the models for a variety of reasons. First, we estimate the models using 3 years of data and the final model parameters are an average of coefficients across the 3 years. By using 3 years of data, the potential for one unusual year to skew the coefficients is limited. Second, for each model year, the overall sample size is quite large in each adult model, particularly relative to the number of model predictors used in the risk adjustment models.[52] For example, the 2019 recalibration sample alone has 18.7 million adult enrollees whose data are used to fit adult models consisting of 181 predictors for the 2023 benefit year. Additionally, we ensure sample sizes for each coefficient are reasonable through the application of hierarchies, constraints, and similar model design choices.[53] We also note that although the models perfectly predict past experience, this does not guarantee the models will perfectly predict when applied to future payment years, as that will depend, in part, on what happens between the calibration and payment years. However, this does not reflect overfitting. To the extent the calibration years are representative of future payment years, the models are positioned to perform well when used

[48] *Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year.* (2021, June 30). CMS. *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf.*

[49] Compare 42 U.S.C. 18063 (establishing the permanent risk adjustment program, which involves an assessment and comparison of the actuarial risk in each issuer's plans in a State market risk pool with the average actuarial risk of all plans in the applicable State market risk pool) and 42 U.S.C. 18061 (establishing the transitional reinsurance program, which involves an assessment of actuarial risk of individual enrollees to identify those that qualify as ''high risk.'')

[50] Section 2.2. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.* See also 85 FR 78667 and 86 FR 24283.

[51] We acknowledge three areas where the two-stage weighed model specification worsens fit of the risk adjustment models along other dimensions in Section 2.3 in the *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[52] Kautter, J., Pope, G., Ingber, M. J., Freeman, S. E., Patterson, L. J., Cohen, M. A., & Keenan, D. P. (2014). The HHS–HCC risk adjustment model for individual and small group markets under the Affordable Care Act. *Medicare & Medicaid Research Review, 4*(3), E1–E46. doi:10.5600/mmrr.004.03.a03. Kautter, J., Pope, G., & Keenan, D. P. (2014). Affordable Care Act risk adjustment: Overview, context, and challenges. *Medicare & Medicaid Research Review, 4*(3), E1–E11. doi:10.5600/mmrr.004.03.a02.

[53] For information on the use of hierarchies and constraints, see Sections 2.1, 3.7 and 3.8 of the March 2016 Risk Adjustment Methodology White Paper. (2016, March 24). *https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.* See also the June 2019 *Potential Updates to HHS–HCCs for the HHS-operated Risk Adjustment Program* Technical Paper (2019, June 17). CMS. *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Potential-Updates-to-HHS-HCCs-HHS-operated-Risk-Adjustment-Program.pdf.*

for payment.[54] For all of these reasons, we are not concerned about the proposed two-stage weighted model specification change resulting in overfitting of the models; however, as previously described, we are not finalizing the proposed two-stage weighted model specification.

ii. Interacted HCC Counts Model Specification

In addition to the two-stage weighted model specification, we proposed to add an interacted HCC counts model specification to the adult and child risk adjustment models starting with the 2023 benefit year to address the current models' underprediction of plan liability for the very highest-risk enrollees (that is, those in the top 0.1 percentile and those enrollees with the most HCCs). While this highest-risk subpopulation represents a small number of enrollees, it represents a large portion of expenditures.[55]

Therefore, to address the underprediction of the highest-risk enrollees, we explored the addition of severity and transplant factors interacted with HCC counts in the adult and child models, wherein a factor flagging the presence of at least one severe or transplant payment HCC is interacted with counts of the enrollee's payment HCCs. The purpose of adding severity and transplant factors interacted with HCC count factors to the adult and child models is to address the underprediction of the highest-risk enrollees by accounting for the fact that costs of certain HCCs rise significantly when they occur with multiple other HCCs.

In developing this interacted HCC counts model specification, we tested different types of severity and transplant indicators interacted with HCC counts with the goal of improving prediction for enrollees with the highest costs and multiple HCCs to counterbalance the reciprocal prediction weights that relatively underpredicted costs for these enrollees. For this approach, we assessed the HCCs for enrollees with extremely high costs, and HCCs that were being underpredicted in the current risk adjustment models. We found that many of the HCCs that were flagged as being underpredicted were those HCCs that indicated severe illness, such as the transplant HCCs, and other HCCs related to severity of disease; therefore, we proposed dropping the current severity illness indicators in the adult models and replacing them with severity and transplant indicators interacted with HCC counts factors in the adult and child models.

We proposed the inclusion of the factors in Tables 1 and 2 of the proposed rule as the severity and transplant interaction factors in the adult and child models starting with the 2023 benefit year. We separated out severity and transplant HCCs into two sets of interaction factors, as expressed in Tables 1 and 2 of the proposed rule, because we found that this approach improved prediction for the highest-risk enrollees better than an approach that included a single set of factors.

If an enrollee has at least one severity HCC in Table 3 of the proposed rule (shown in Table 1 of this rule as the Final HCCs Selected for the HCC Interacted Counts), the enrollee will receive an interacted HCC count factor toward their risk score, and the severity HCC count factor selected would be based on the enrollee's total payment HCC count.[56] If an adult or child enrollee has at least one transplant HCC in Table 1 of this rule, the enrollee will receive an interacted HCC count factor for both a severity HCC interacted factor and, if the enrollee has four or more HCCs, a transplant HCC interacted factor towards their risk score, and both of those count factors would be based on the enrollee's total payment HCC count.

To further explain, as seen in Table 2 of this rule, the severity-HCC-count-interaction factors were calculated as 10 separate factors for the adult models, and seven separate factors for the child models. In the adult models, the first nine factors specified the presence of (1) an HCC in the severity list in Table 1 of this rule and (2) exactly one payment HCC in the enrollee's data, exactly two, exactly three, and so on, up to exactly nine payment HCCs. The tenth factor specified the presence of (1) an HCC in the severity list in Table 1 of this rule and (2) 10 or more payment HCCs in the enrollee's data. For the child models, the first five factors represent the presence of (1) an HCC in the severity list in Table 1 of this rule and (2) exactly one payment HCC in the enrollee's data, exactly two, exactly three, and so on, but the sixth factor represents the presence of (1) an HCC in the severity list in Table 1 and (2) six to seven payment HCCs, and the seventh factor represents the presence of (1) an HCC in the severity list in Table 1 and (2) eight or more payment HCCs in the enrollee's data.

[54] Section 1.4. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[55] Section 4.1. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[56] For additional information on how the interacted HCC counts model specification works, see Section 4.3 of the *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.* See also 87 FR at 601 through 603.

TABLE 1: Final HCCs Selected for the HCC Interacted Counts Variables for the Adult and Child Models Beginning with the 2023 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 18 Pancreas Transplant Status	X	X
HCC 23 Protein-Calorie Malnutrition	X	
HCC 34 Liver Transplant Status/Complications	X	X
HCC 41 Intestine Transplant Status/Complications	X	X
HCC 42 Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	X	
HCC 96 Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	X	
HCC 121 Hydrocephalus	X	
HCC 122 Coma, Brain Compression/Anoxic Damage	X	
HCC 125 Respirator Dependence/Tracheostomy Status	X	
HCC 135 Heart Infection/Inflammation, Except Rheumatic	X	
HCC 145 Intracranial Hemorrhage	X	
HCC 156 Pulmonary Embolism and Deep Vein Thrombosis	X	
HCC 158 Lung Transplant Status/Complications	X	X
HCC 163 Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	X	
HCC 183 Kidney Transplant Status/Complications	X	X
HCC 218 Extensive Third -Degree Burns	X	
HCC 223 Severe Head Injury	X	
HCC 251 Stem Cell, Including Bone Marrow, Transplant Status/Complications	X	X
G13 (Includes HCC 126 Respiratory Arrest and HCC 127 Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes)	X	
G14 (Includes HCC 128 Heart Assistive Device/Artificial Heart and HCC 129 Heart Transplant Status/Complications)	X	X

TABLE 2: Structure of the Severity HCC Count Indicators

	Severity HCC Count Indicators
Adult Model Factors	1, 2, 3, 4, 5, 6, 7, 8, 9, 10+
Child Model Factors	1, 2, 3, 4, 5, 6 or 7, 8+

As seen in Table 3 of this rule, the transplant-HCC-count-interaction factors are calculated similarly. However, the transplant factors are calculated using a different range of HCC counts. In the adult models, five separate transplant interaction factors were created, representing the presence of (1) an HCC in the transplant list in Table 1 and (2) payment HCC counts of exactly four, exactly five, exactly six, exactly seven, and eight or more payment HCCs in the enrollee's data. For the child models, we created only one transplant interaction factor indicating the presence of (1) an HCC in the transplant list in Table 1 of this rule and (2) a total of four or more payment HCCs in the enrollee's data. Using only one transplant-HCC-count-interaction factor stabilized the child model estimates by increasing the sample size used to estimate the factor coefficients.[57]

TABLE 3: Structure of the Transplant HCC Count Indicators

	Transplant HCC Count Indicators
Adult Model Factors	4, 5, 6, 7, 8+
Child Model Factors	4+

To implement the severity- and transplant-HCC-count-interaction factors in the regression model and estimate the value of their factor coefficients, we proposed to remove the current severity illness factors in the adult models and add severity- and transplant-HCC-count-interaction factors for the adult and child models beginning with the 2023 benefit year.

We sought comment on this proposal.

We are finalizing the removal of the current adult model severity illness factors and adding an interacted HCC count model specification to the adult and child risk adjustment models starting with the 2023 benefit year, as proposed.

We summarize and respond to public comments received on the interacted HCC counts model specification updates below.

Comment: Several commenters supported the proposal to add an interacted HCC counts model specification to the adult and child risk adjustment models noting that the interacted HCC counts model specification will improve model prediction and more accurately quantify risk. Some commenters expressed general agreement with HHS that the current models may be underpredicting plan liability of the highest-risk enrollees, but did not otherwise comment on the interacted HCC count model specification proposals. One commenter suggested that the proposed refinement will mitigate issuers' concerns about adverse selection and lead to a more competitive market, while another agreed that it would address the current models' underestimate of plan liability for the very highest-risk enrollees.

However, several other commenters opposed the proposed interacted HCC counts model policy, stating that this change would add undue complexity to the models and would increase coding and issuer gaming. Some commenters requested clarification on how the interacted HCC counts variable would be accommodated in the HHS–RADV process. These commenters requested that HHS increase program integrity measures and adopt additional safeguards against upcoding, such as targeted sampling to test for upcoding in the HHS–RADV process, as an additional measure to protect against gaming if this model specification change is finalized. One commenter generally noted they only supported the interacted HCC counts model specification if the two-stage weighted model specification was also finalized.

Response: We agree with the commenters that the interacted HCC counts model specification will improve model prediction, more accurately quantify risk, and address the underprediction of plan liability of the highest-risk enrollees that we have observed in the current adult and child models. The current adult models incorporate a severe illness adjustment that accounts for combinations of selected HCCs. However, the total count of an enrollee's HCCs does not currently independently affect the risk score and, while the current severity illness indicator helps predict costs accurately among most adult enrollees with qualifying severe illnesses, it does not fully address the underprediction for the very highest-risk enrollees. The current severity of illness indicators also do not extend to the child models. The proposed interacted HCC counts model specification was targeted at addressing these concerns and more accurately predicting risks and capturing costs for the highest-risk enrollees.

We understand that there are concerns about the increased complexity that the interacted HCC counts model specification may introduce. However, we see the interacted HCC counts model specification as an advancement of our current severe illness indicators, which have been in place since the beginning of the risk adjustment models, so we believe the interacted HCC counts model specification change only slightly increases complexity. As described in our analysis of 2018 enrollee-level EDGE data in the 2021 RA Technical Paper, the interacted HCC counts model specification, along with the HCC-contingent enrollment duration factors, significantly improved prediction for the very highest-risk enrollees, which we believe outweighs the disadvantages of slightly increasing model complexity.[58]

Additionally, we acknowledge concerns over the potential for upcoding and issuer gaming and further note that incorporating safeguards to protect against the potential for gaming was a major consideration in our investigation of various interacted HCC counts model specifications. When developing the proposed interacted HCC counts model specification we were specifically concerned that the presence of counts across all HCCs, without requiring a

[57] For an illustration of how the proposed severity- (or transplant-) HCC-count-interaction factors would be assigned to an enrollee, see 87 FR 601 through 602.

[58] Section 4.4. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

severe illness or transplant HCC, would further incentivize issuers to code for more HCCs, thus increasing their payment or reducing their charge under the State payment transfer formula. This would be inconsistent with the risk adjustment principle not to encourage coding proliferation.[59] However, we believe that implementing the interacted HCC counts model specification updates, as proposed, which restricts the incremental risk score adjustment to enrollees with at least one severe illness or transplant HCC, reduces concerns of issuers inflating HCC counts to increase their transfers under the State payment transfer formula. More specifically, our analysis of 2016, 2017, and 2018 enrollee-level EDGE data revealed that severe illness HCCs are relatively uncommon; less than 2 percent of the adult enrollee-level EDGE data population across these 3 benefit years had at least one severe illness HCC, as opposed to about 20 percent of adult enrollees with any payment HCC. Therefore, opportunities to inflate HCC counts would be limited to a small fraction of total enrollees.

Although we believe this approach appropriately balances the different trade-offs by improving prediction for highest-risk enrollees while mitigating the potential for gaming or upcoding, we generally intend to monitor implementation of the model specification updates finalized in this rule. Specifically, we will look for any notable changes in HCC failure rates for the interacted severity and transplant HCCs in HHS–RADV beginning with the 2023 benefit year that could be the result of implementation of the interacted HCC counts model specification updates.

Lastly, we note the interacted HCC counts model specification update finalized in this rule is effective beginning with 2023 risk adjustment. The HHS–RADV process for the 2023 benefit year would not begin until spring 2024. Therefore, we intend to consider whether changes are needed beginning with the 2023 benefit year HHS–RADV error estimation methodology or processes in recognition of the interacted HCC counts model specification and would propose any such changes in future notice-and-comment rulemaking. HHS will also consider whether targeted sampling, or other approaches, in HHS–RADV are necessary to detect and address upcoding or coding proliferation as a result of the implementation of the interacted HCC counts model specification.

Comment: Some commenters questioned whether the exclusion of capitated claims biases the analysis of the proposed interacted HCC counts model specification change.

Response: As previously explained,[60] we have historically excluded enrollees with capitated claims from the recalibration sample due to concerns that methods for computing and reporting derived amounts from capitated claims would not result in reliable data for recalibration or analysis.[61] However, in response to comments submitted to the 2021 RA Technical Paper and the proposed rule, we conducted additional analyses to investigate how enrollees with capitated claims could have impacted our assessment of the underpredicted subpopulations described in the 2021 RA Technical Paper. This additional analysis did not show that the exclusion of enrollees with capitated claims biased the analysis or results in the 2021 RA Technical Paper.

To conduct this additional analysis, we compared the recalibration sample, which excluded enrollees with any capitated claims,[62] with the capitation sample, which included only enrollees with capitated claims. Overall, for the 2023 risk adjustment models, the capitation exclusion resulted in 15–17 percent of enrollees being dropped from the recalibration sample. As described in the 2021 RA Technical Paper, where we utilized the recalibration sample to analyze the proposed model changes, we observed underpredicted plan liability for the lowest-risk enrollees (enrollees in low-risk deciles and without HCCs) and underpredicted plan liability for the highest-risk enrollees (enrollees in the top 0.1 percent decile and with many HCCs).[63] In our additional analysis of the capitation sample, we also observed the same general trends of underprediction of the lowest-risk and highest-risk enrollees. Further, we evaluated whether the proposed 2023 model specification changes produced similar improvements in addressing the underprediction of these subpopulations in the capitation sample as the recalibration sample and found that the proposed 2023 model specification changes resulted in similar prediction improvements for both samples. Therefore, we do not believe that the exclusion of enrollees with capitated claims biased the analysis or results, and we do not believe that their inclusion would have meaningfully impacted our findings.

Comment: Some commenters recommended additional information and analysis on the proposed interacted HCC counts model change specification, such as its effect on calculations under the State payment transfer formula for issuers that tend to attract healthier enrollees, whether small sample sizes were an issue, and an evaluation of whether removing the interacted severity HCCs would improve PLRS PRs more than attaching counts to those HCCs. One of the commenters suggested that it is difficult to assess the net effect of the interacted HCC count proposals on risk adjustment State transfers selection incentives. This commenter further noted they would oppose the proposal if this proposed change reduced State transfers paid by issuers with lower than average risk scores.

Response: We provided extensive information on the interacted HCC counts model specification changes and the estimated impact on State transfers in rulemakings,[64] the 2021 RA Technical Paper,[65] and the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations.[66] In the transfer simulation report, we provided summary-level information on the estimated combined

[59] For information on the principles that guide the HHS risk adjustment models' diagnostic classification system, see Section 1.1.2 of the *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf* (see, in particular, Principle 6: The diagnostic classification should not reward coding proliferation.)

[60] March 2016 Risk Adjustment Methodology White Paper. (2016, March 24). *https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.* See also 87 FR 602 through 603.

[61] Enrollees with at least one capitated claim in EDGE are excluded from recalibration, as the risk adjustment models are used to evaluate enrollees' expenditures, and capitated claims do not provide meaningful and comparable cost (allowed charges) data in comparison to non-capitated claims. We are also concerned that methods for computing and reporting derived amounts from capitated claims could be inconsistent across issuers and would not provide reliable or comparable data.

[62] The calibration sample is the same sample used for the analysis in the 2021 RA Technical Paper, which excludes capitated enrollees.

[63] Figures 1.2 and 1.3. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[64] 85 FR 78583 through 78586 and 87 FR 598 through 605.

[65] *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[66] HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations. (December 28, 2021). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

impact of the proposed model specification changes on the calculation of plan-level risk scores and State transfers. Issuers that participated in the simulation also received detailed issuer-specific data, including risk score and transfer estimates for the simulated results.

While we acknowledge stakeholders' requests for additional analysis, such as the effect of the interacted HCC counts model specification updates on transfer calculations for issuers who tend to attract healthier enrollees, operational and technological limitations within both HHS and the issuer community limited capacity to conduct additional simulations. Despite these limitations in being able to conduct additional simulations, we were able to produce and share evidence and detailed analyses in support of the proposed interacted HCC counts model specification.[67] For example, as described in the 2021 RA Technical Paper, the interacted HCC counts model specification improved prediction for the highest-risk enrollees.[68]

We also acknowledge the request to evaluate the impact of removing the current severity and transplant indicators against the proposed interacted HCC counts model specification. However, we do not believe this approach warrants further evaluation because we did not propose to entirely remove the indicators without replacing them. Additionally, the current severity illness indicators improve the current adult models' prediction of high-risk enrollees, so we do not believe we should consider completely removing the severity illness terms from the models. We reiterate that the proposed interacted HCC counts model specification further improves the adult and child models' predictive power beyond the adult models' current severity illness indicators. Therefore, we do not believe that we should further consider removing the severity illness indicators and not replacing them.

We recognized that one potential concern with this model specification change was that the severity- and transplant-HCC-count-interaction factor coefficients might be based on small sample sizes. Therefore, we considered sample sizes of the various interacted HCC count factors when developing this proposal and the proposed factor coefficients. We explored alternative methods of interacting HCC counts with severity and transplant HCCs, including interacting the HCC counts with individually selected severity and transplant HCCs, but found that interacting the HCC counts with a factor indicating the presence of at least one of the selected HCCs in each group produced PR improvements and sufficient sample sizes for reasonably stable factor coefficient estimates. To that end, we analyzed 2016, 2017, and 2018 enrollee-level EDGE data and chose the model specifications that grouped the HCC counts interacted with individual severity and transplant HCCs into two sets of aggregated factors to maximize sample size, reduce concerns of overfitting the model, and reduce the number of factors being added to the models. More specifically, in the adult models, we found that starting with 4+ HCCs for the transplant interacted factors improved predictions of enrollees at the very high end in terms of risk and cost and ending at 8+ HCCs for the transplant interacted factors, instead of 10+ HCCs, addressed the small sample sizes of enrollees with a transplant and 9+ HCCs. For the child models, we found having one transplant interacted factor for 4+ HCCs provided more stable estimates given the smaller sample sizes for children than those for adults. With the proposed structure for transplant and severity interacted factors in place, the resulting sample sizes are comparable to the sample sizes used for individual HCCs in the adult and child risk adjustment models.

iii. Changes to the Adult Model Enrollment Duration Factors [69]

In the proposed rule, we proposed to change the enrollment duration factors in the adult risk adjustment models to improve prediction for partial-year adult enrollees with and without HCCs (87 FR 603 through 604). Although the values for the factors change from year to year as part of the annual recalibration of the adult models, we have not made changes to the structure of the enrollment duration factors since they were first adopted for the 2017 benefit year in the 2018 Payment Notice (81 FR 94071 through 94074).

As described in prior rules and the 2021 RA Technical Paper, we found that the current adult model enrollment duration factors underpredicted plan liability for partial-year adult enrollees with HCCs and overpredicted plan liability for partial-year adult enrollees without HCCs.[70] [71]

Therefore, beginning with the 2023 benefit year, we proposed to eliminate the current monthly enrollment duration factors of up to 11 months for all enrollees in the adult models, and replace them with new monthly enrollment duration factors of up to 6 months that would apply only to adult enrollees with HCCs. We explained that under this proposal there would be no enrollment duration factors for adult enrollees without HCCs starting with the 2023 benefit year, nor would there be enrollment duration factors for adult enrollees with HCCs and more than 6 months of enrollment.

We solicited comments on the proposed changes to the enrollment duration factors for the adult models.

After reviewing the public comments, we are finalizing the proposal to replace the current enrollment duration factors in the adult models with HCC-contingent enrollment duration factors as proposed. As such, beginning with the 2023 benefit year, there will no longer be enrollment duration factors for adult enrollees without HCCs starting with the 2023 benefit year, nor will there be enrollment duration factors for adult enrollees with HCCs and more than 6 months of enrollment.

We summarize and respond to public comments received on proposed changes to the adult model enrollment duration factors below.

Comment: Most commenters supported the proposed changes to the enrollment duration factors for the adult models. Many of these commenters asserted that the proposed changes would improve model prediction. One commenter noted that the HCC-contingent enrollment duration factors would solve the majority of model prediction issues even in the absence of

[67] Figures 4.2, 4.3, and 4.4 in the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes demonstrate the improvements in PRs of the interacted HCC counts and HCC-contingent EDFs. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[68] Section 4.4. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[69] As explained in the 2021 Payment Notice proposed rule, we found that partial-year enrollees in the child models did not have the same risk differences as partial-year enrollees in the adult models, and they tended to have similar risk to full-year enrollees in the child models. See 85 FR 7103 through 7104. In the infant models, we found that partial-year infants had higher expenditures on average compared to their full-year counterparts; however, the incorporation of enrollment duration factors created interaction issues with the current severity and maturity factors and did not have a meaningful impact on the general predictive accuracy of the infant models. Ibid. Therefore, we proposed to continue to apply enrollment duration factors to the adult models only.

[70] 85 FR 29164 at 29188 through 29190.; 86 FR 24140 at 24151 through 24162; and the HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[71] When we refer to the enrollees with and without HCCs, we are referring to enrollees without payment HCCs.

the adoption of the proposed two-stage weighted model and interacted HCC counts model specification updates. Several commenters also stated that the proposed HCC-contingent enrollment duration factors would reduce issuers' incentives for risk selection.

Response: We are finalizing the replacement of the current monthly enrollment duration factors of up to 11 months for all enrollees in the adult models with new monthly enrollment duration factors of up to 6 months that would apply only to enrollees in the adult models with HCCs. As previously explained, our analysis of the current adult model enrollment duration factors found that plan liability was underpredicted for partial-year adult enrollees with HCCs and overpredicted for partial-year adult enrollees without HCCs.[72] This targeted refinement was developed in response to this finding and will improve prediction for partial-year adult enrollees with and without HCCs. Additionally, HHS agrees that the enrollment duration factor changes will reduce issuers' incentives for risk selection by improving model prediction.

Comment: Several commenters focused on the intersection of special enrollment periods (SEP) and these proposed changes. Some commenters suggested that the proposed enrollment duration factor updates would mitigate the impact of the recent access to SEPs enhanced during the 2020 and 2021 benefit years due to the COVID–19 PHE and ARP,[73] which changed the SEP enrollee pool and increased opportunities for adverse selection. One of these commenters noted the importance of predictive accuracy for 1 to 6-month enrollees as Exchanges on the Federal platform and State Exchanges expand plan selection options during SEP enrollments. Another commenter noted HHS' analysis of the proposed HCC-contingent duration factors is not representative of the current SEP landscape and recommended additional analysis before the proposed enrollment duration factor updates are implemented.

Response: We appreciate the comments on the intersection of SEP opportunities and the proposed updates to the adult model enrollment duration factors. We agree with commenters that the proposed updates would mitigate the impact of the recent SEPs enhanced during the 2020 and 2021 benefit years due to the COVID–19 PHE and ARP on potential opportunities for adverse selection, but note that these updates to the enrollment duration factors will not be implemented until the 2023 benefit year. We also agree with the commenter on the importance of predictive accuracy for partial-year enrollees and believe that these changes will improve the current models' predictive accuracy for partial-year adult enrollees with and without HCCs.

As noted above, we are finalizing the changes to the adult model enrollment duration factors as proposed and will implement the new factors beginning with the 2023 benefit year adult models. To develop the 2023 benefit year risk adjustment models, we used the 2017, 2018, and 2019 enrollee-level EDGE data, as these datasets were the 3 most recent consecutive years of enrollee-level EDGE data that were available at the time we incorporated the data in the draft recalibrated coefficients published in the proposed rule. Therefore, we believe that the data years that we used to develop the HCC-contingent enrollment duration factors are the most appropriate data years available at this time for purposes of analyzing the proposal to adopt these changes beginning with the 2023 benefit year and that further analysis is not required at this time. As discussed elsewhere in this rule, we are still assessing whether to use the 2020 enrollee-level EDGE for model recalibration in the future, and we do not have 2021 benefit year enrollee-level EDGE yet.[74] As such, we have not yet been able to analyze the impact of the most recent SEP changes. However, HHS remains committed to ongoing analysis of these issues and intends to study the impact of the new factors once implemented.

Comment: A few commenters expressed concerns that the proposed HCC-contingent enrollment duration factors would negatively impact the small group market or that the changes would not align with small group market enrollment renewal patterns (for example, non-calendar year coverage). One commenter that opposed the adoption of the proposed changes stated that eliminating enrollment duration factors for non-HCC enrollees would disincentivize issuers from taking on new small group employers in the fourth quarter. Other commenters that supported the proposed enrollment duration factors changes noted general concerns that the proposed updates to the enrollment duration factors may negatively impact the small group market.

Response: We explored partial-year enrollment patterns between the individual[75] and small group markets as part of the consideration of updates to the enrollment duration factors for the risk adjustment adult models. In the 2021 Payment Notice (85 FR 29189), we shared our preliminary analysis of the 2017 enrollee-level EDGE dataset found separate enrollment duration factors by market in the adult models could be warranted; therefore, we continued to study these issues as additional enrollee-level EDGE data became available. Our analysis of partial-year enrollment using the 2018 enrollee-level EDGE dataset, which occurred alongside our development of the proposed HCC-contingent enrollment duration factors in the proposed 2022 Payment Notice, did not find a meaningful distinction in relative costs between markets on average once the proposed enrollment duration factors of up to 6 months for adult enrollees with HCCs were implemented.[76] Even though reasons for and patterns of partial-year enrollment differ by market, we concluded that the patterns most relevant for predicting cost (for example, how enrollment duration relates to cost conditional on the presence of HCCs) were the same for both markets.[77] Therefore, we determined it would not be necessary to introduce market-specific factors if the proposed HCC-contingent enrollment duration factors were adopted in place of the existing enrollment duration factors. We also explained that if the HCC-contingent factors were to vary by market, the factors for both markets would generally be very similar, which would add little value to the models while adding additional complexity.[78] Therefore, we proposed the adoption of

[72] HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[73] See, for example, HHS Announces Marketplace Special Enrollment Period for COVID–19 Public Health Emergency. (2021, January 28). CMS. *https://www.hhs.gov/about/news/2021/01/28/hhs-announces-marketplace-special-enrollment-period-for-covid-19-public-health-emergency.html.*

[74] See 45 CFR 153.730. Since April 30, 2022, falls on a weekend, CMS will exercise enforcement discretion to shift the deadline for submission of final 2021 benefit year risk adjustment data to May 2, 2022.

[75] Section 3. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.* In the enrollee-level EDGE dataset, merged market enrollees are assigned to the individual or small group market indicator based on their plan.

[76] Section 3.3.2. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.* See also 86 FR 24161.

[77] Ibid.

[78] Section 3.3.2. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

the same HCC-contingent factors for both markets.

In response to comments, we again considered whether the HCC-contingent enrollment duration factors could have negative impacts on small group market issuers, such as on those that offer non-calendar year coverage and take on new business later in the year. Our continued consideration of these issues did not find evidence of such negative impacts.[79] More specifically, while we recognize there are likely some cases where a partial-year enrollee only receives risk adjustment ineligible services, our analysis found no evidence that it is associated with meaningful underpayment in either the individual or small group market. In other words, on average, costs are sufficiently low for partial-year enrollees with no HCCs that even a risk score based only on demographic factors would generally overpredict plan liability.[80] Commenters did not provide data or other information in support of the general assertions or concerns about potential impacts on the small group market and have not otherwise refuted the conclusions drawn from our analysis of available enrollee-level EDGE data. Therefore, we continue to believe it is appropriate to finalize and apply the proposed changes to the adult model enrollment duration factors to both the individual and small group (including merged) markets and to not pursue factors that vary by market. For the reasons outlined above, we also believe that the presumed negative impact on new business in the small group market would be limited, and the guaranteed availability provisions, which require health insurance issuers offering non-grandfathered coverage in the individual or small group market to accept every individual and employer in the State that applies for such coverage unless an exception applies, further protects against issuers declining to take on new small group employers.

Comment: One commenter stated that they were against limiting enrollment duration factors to up to 6-month enrollees and would support the proposed changes if the upper limit for the factors was extended to 9 months. The commenter noted this change to the upper limit would better account for renewal patterns in the small group market.

Response: While we considered other enrollment duration factor structures, we proposed and are finalizing a 6-month limit to the enrollment duration factors because we found that the monthly average cost variation by the number of months enrolled is meaningfully reduced after 6 months for adult enrollees with HCCs, and enrollment duration factors beyond 6 months did not meaningfully improve prediction for the adult models.[81] Specifically, we found that these coefficients would have been close to 0 (and in some cases negative), which means they would not have contributed much to the overall risk score for enrollees or would have had to be constrained to 0 in the risk adjustment adult models. Given this analysis and in an effort to limit the number of factors in the models, we are finalizing the HCC-contingent enrollment duration factors for up to 6 months as proposed.

Additionally, as explained above, we continue to believe it is appropriate to finalize and apply the proposed changes to the adult model enrollment duration factors to the small group market and to not pursue factors that vary by market.

iv. Combined Impact of the Model Changes

As discussed in detail above, after reviewing the public comments on the proposed risk adjustment model changes, we are finalizing the addition of the interacted HCC counts factors in the adult and child models, the removal of the current adult model severity illness factors, and the replacement of the existing enrollment duration factors with the HCC-contingent enrollment duration factors in the adult models, as proposed. Our analysis of the proposed interacted HCC counts factors combined with the proposed HCC-contingent enrollment duration factors in the adult models significantly improves predictions across most deciles and HCC counts for the very highest-risk enrollees, as well as the lowest-risk enrollees without HCCs.[82] However, we are not finalizing the proposal to add a two-stage weighted model specification to model recalibrations.

We summarized and responded to public comments received on proposed model specifications updates in the above sections.

c. Pricing Adjustment for the Hepatitis C Drugs

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 605), for the 2023 benefit year, we proposed to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the risk adjustment models.[83]

We sought comment on this proposal.

After reviewing the public comments, we are finalizing this proposal to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the risk adjustment models, consistent with the approach adopted beginning with the 2020 models.

We summarize and respond to public comments received on the pricing adjustment for Hepatitis C drugs below.

Comment: Most commenters supported the Hepatitis C pricing adjustment. One commenter noted that the pricing adjustment ensures HHS is applying the most accurate data, while protecting against issuers that might seek to influence provider prescribing patterns to the issuers' benefit. Another commenter noted that without the Hepatitis C pricing adjustment, issuers would be incentivized to focus on only a subset of enrollees needing treatment if they can trigger an increase in an enrollee's risk score that is higher than the actual plan liability of the drug claim.

Conversely, a few commenters expressed concerns about the Hepatitis C drugs pricing adjustment. These commenters asserted that the professional independence and ethical standards of providers would prevent them from prescribing drugs that they did not believe were medically necessary and appropriate, reducing the potential for issuers to game the model. These commenters were concerned about undercompensating issuers for enrollees with serious chronic conditions, which would incentivize issuers to avoid these enrollees. They encouraged HHS to evaluate the models continually to ensure they fully capture the cost of the current standard of care for conditions in the models. Additionally, one commenter cautioned against reducing the coefficient more than the expected decrease, which the commenter explained would incentivize issuers to reduce the availability of the treatment. This commenter also recommended that HHS clarify the data source and approach it is using to constrain the Hepatitis C RXC

[79] Section 3.4. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[80] Ibid.

[81] Section 3.2. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[82] Figure 4.2. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[83] 84 FR 17463 through 17466.

coefficient. Finally, one commenter expressed concern that constraining the Hepatitis C RXC coefficient would undermine recent progress to treat Hepatitis C infections.

Response: We continue to believe that the Hepatitis C pricing adjustment is appropriate at this time, will help avoid perverse incentives, and will lead to Hepatitis C RXC coefficients that better reflect anticipated actual 2023 benefit year plan liability associated with Hepatitis C drugs. Specifically, the purpose of the Hepatitis C pricing adjustment is to address 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 that present a risk of creating perverse incentives by overcompensating issuers. We reassessed the pricing adjustment for the Hepatitis C RXC for the 2023 benefit year model recalibration and found that the data used for the 2023 benefit year risk adjustment model recalibration (that is, 2017, 2018, and 2019 enrollee-level EDGE data) still does not account for the significant pricing changes that we have observed for the Hepatitis C drugs due to the introduction of newer and cheaper Hepatitis C drugs. Therefore, the data that will be used to recalibrate the models needs to be adjusted because it does not precisely reflect the average cost of Hepatitis C treatments expected in the 2023 benefit year.

In making this determination, we consulted our clinical and actuarial experts, and analyzed the most recent enrollee-level EDGE data available to further assess the changing costs associated with Hepatitis C enrollees. Due to the high cost of these drugs reflected in the 2017, 2018, and 2019 enrollee-level EDGE data, without a pricing adjustment to plan liability, issuers would be overcompensated for the Hepatitis C RXC in the 2023 benefit year, and they could be incentivized to encourage overprescribing practices and game risk adjustment such that the issuer's risk adjustment payment is increased or risk adjustment charge is decreased. We also recognize concerns that applying a pricing adjustment that would reduce the coefficient for the Hepatitis C RXC by more than the expected decrease in costs could incentivize issuers to reduce the availability of the treatment. However, we believe that the Hepatitis C pricing adjustment accurately captures the costs of Hepatitis C drugs for the applicable risk adjustment benefit year using the most recently available data, balances the need to deter gaming practices with the need to ensure that issuers are adequately compensated, and does not undermine recent progress in the treatment of Hepatitis C.

Additionally, we recognize the important role that the ethical standards of providers play in preventing overprescribing of drugs that they do not believe are medically necessary and appropriate, but we believe that the Hepatitis C pricing adjustment is the most effective way to protect against perverse incentives that could affect prescribing patterns. Furthermore, while we appreciate commenters' concerns about undercompensating issuers for enrollees with serious chronic conditions, HHS is adopting several proposals in this rulemaking to address the adult and child models' underprediction for enrollees with many HCCs.[84] Specifically, we finalized the interacted HCC counts and HCC-contingent enrollment duration factors model specifications to improve model prediction for the higher risk enrollees and ensure that issuers are being accurately compensated for these enrollees.[85] We intend to continue to reassess this pricing adjustment as part of future benefit years' model recalibrations using additional years of available enrollee-level EDGE data.

d. Risk Adjustment RXC Mapping for Recalibration

i. Inclusion and Exclusion Criteria for Drugs in RXC Mapping and Recalibration

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 605), we provided an overview of the inclusion and exclusion criteria HHS uses to identify drugs for mapping to RXCs in the adult risk adjustment models, reviewed what version of the RXC mapping document HHS uses when processing the enrollee-level EDGE data for a benefit year for recalibration of the adult risk adjustment models, and outlined the criteria that warrant consideration for changes to the incorporation (or exclusion) of particular drugs from the RXC mappings in future benefit year recalibrations. We also proposed a change to the approach for identifying the version of the RXC mapping document HHS would use to process a given benefit year's enrollee-level EDGE data for recalibration of the adult risk adjustment 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 on the annual recalibration of the adult risk adjustment models' RXC coefficients using data from the applicable prior benefit years trended forwarded to reflect the applicable benefit year of risk adjustment. Drugs that appear on claims data, either through National Drug Codes (NDCs) or Healthcare Common Procedural Coding System (HCPCS), are cross walked to RxNorm Concept Unique Identifiers (RXCUIs).[86] RXCUI mappings are always matched to the NDCs and HCPCS applicable to the particular EDGE data year as the NDC and HCPCS reflect the drugs that were available in the market during the benefit year.[87] As explained in the proposed rule, we had been using the most recent RXC mappings (RXCUIs that map to RXCs) that were available when we first processed the enrollee-level EDGE data for a benefit year for recalibration of the adult risk adjustment models.[88] For example, for the 2022 benefit year, we recalibrated the adult risk adjustment models using 2016, 2017, and 2018 enrollee-level EDGE data, and applied the second quarter (Q2) 2018 RXC mapping document for both 2016 and 2017[89] and the Q2 2019 mapping document for 2018 for recalibration of the adult risk adjustment models' RXC factors.

As noted in the 2022 Payment Notice (86 FR 26164), we also continuously

[84] Figure 1.3. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[85] The Interacted HCC Counts and HCC-contingent enrollment duration factors also improve the models' predictive accuracy for the lower risk deciles. See, for example, Figure 4.2. *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[86] See, for example, 81 FR 94074 through 94080.

[87] See, for example, Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXCs) Crosswalk Memorandum. (2017, September 18). CMS. *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf.*

[88] RXCUIs differ by chemical (drug ingredient), strength, and dose form, but not by manufacturer or package size. This means that RXCUIs describe the same drugs year-over-year, even as the underlying NDCs and HCPCs change due to changes in labelers, which is why it is possible to apply different mappings to different years. For further information, see *RxNorm Overview.* (2022, January 3). NIH. *https://www.nlm.nih.gov/research/umls/rxnorm/overview.html.*

[89] RXCs were not added to the risk adjustment models until 2018 benefit year; therefore, we used 2018 RXC mappings for both 2016 and 2017 enrollee-level EDGE data as there were no 2016 and 2017 RXC mapping documents. Note that, even though 2018 RXC mappings were applied to these earlier years, they were cross walked to the NDCs and HCPCS that describe the applicable drugs during those earlier years.

assess the availability of drugs in the market and the associated mapping of those drugs to RXCs in the adult risk adjustment models. More specifically, during a benefit year, HHS conducts quarterly reviews of RXCUIs that map to RXCs in the adult risk adjustment models for that benefit year. During our annual review of enrollee-level EDGE data for recalibration purposes, and to a certain extent during quarterly reviews of RXCUIs that map to RXCs in the adult risk adjustment models, HHS evaluates the inclusion and exclusion of RXCUIs based on criteria such as: (1) Whether costs for an individual drug are comparable to the costs of other drugs in the same class, (2) whether a drug is a good predictor of the presence of the diseases that map to the HCCs that an RXC indicates (which can be evaluated through clinical expert review in the absence of data), (3) whether the pharmacological properties and prescribing patterns are consistent with treatment of a particular condition (also evaluated through clinical expert review), and (4) stakeholder feedback.[90] As a result of this ongoing assessment, we make quarterly updates to the RXC Crosswalk, which identifies the list of NDCs and HCPCS indicating the presence of an RXC in the current benefit year ''Do It Yourself'' (DIY) software and EDGE reference data, to ensure drugs are appropriately mapped to RXCs. This can include the addition or removal of drugs based on market availability and the other criteria identified above. As such, the risk adjustment mapping of RXCUIs to RXCs, along with the list of NDCs and HCPCS that crosswalk to each RXCUI, may be updated throughout a particular benefit year of risk adjustment. HHS provides information to issuers on these updates through the DIY software, which is published on the CCIIO website,[91] as well as through the EDGE global reference updates, which are published on the Distributed Data Collection program page on the Registration for Technical Assistance Portal (REGTAP).[92]

This ongoing updating process occurs on a different timeline than the annual model recalibration activities for a given benefit year.

In the proposed rule, we proposed to change the approach for identifying the version of the RXC mapping document HHS would use to process a given benefit year's enrollee-level EDGE data for the annual recalibration of the adult risk adjustment models. More specifically, we proposed to recalibrate the adult risk adjustment models using each final, fourth quarter (Q4) RXC mapping document that was applicable for each benefit year of data that is included in the applicable benefit year's model recalibration, while continuing to engage in annual and quarterly review processes using the inclusion and exclusion criteria described above. For example, if we recalibrate the 2024 benefit year adult risk adjustment models using 2018, 2019, and 2020 benefit year enrollee-level EDGE data, we would use the Q4 RXC mapping document for each of those benefit years (that is, Q4 2018, Q4 2019, and Q4 2020, respectively) for recalibration purposes. We would also use the criteria described above to evaluate the inclusion and exclusion of RXCUIs and may make other updates to the 2024 benefit year RXC Crosswalk to ensure drugs are appropriately mapped to RXCs.

We proposed to begin to use this approach for recalibration of the 2023 adult risk adjustment models with the exception of the 2017 enrollee-level EDGE data year, for which we proposed to use the most recent RXC mapping document that was available when we first processed the 2017 enrollee-level EDGE data (that is, Q2 2018). We proposed to use the applicable benefit year's Q4 RXC mapping documents for both the 2018 and 2019 benefit years of enrollee-level EDGE data for the recalibration of the adult risk adjustment models for the 2023 benefit year. Under this proposal, we would generally hold those mappings constant when using the 2018 and 2019 enrollee-level EDGE data years in future benefit year model recalibrations (except under the extenuating circumstances that are described in the next section that can result in targeted changes to RXC mappings)—meaning that we would use the applicable benefit year's Q4 RXC mapping documents when the 2018 or 2019 benefit year of enrollee-level EDGE data is used for future benefit year model recalibrations.[93] The purpose of maintaining a specific version of the same RXC mapping document for future recalibrations is to limit the volatility of some coefficients from year-to-year and to ensure that we are capturing the utilization and costs observed for the underlying drugs in use in that year for the condition. Because the final DIY software update contains the Q4 list, this approach would also have the added benefit of providing issuers the opportunity to see the mappings/crosswalk that are likely to be applied to that data year in the final DIY software release before it is used for recalibration.

For purposes of the 2023 benefit year recalibration, we proposed an exception for the 2017 benefit year enrollee-level EDGE data and would instead use the most recent RXC mapping document that was available when we first processed the benefit year's enrollee-level EDGE data for recalibration purposes (that is, Q2 2018). We proposed this approach for the 2017 benefit year enrollee-level EDGE data because the RXCs were still under development in 2017, and were not included in the adult risk adjustment models until 2018;[94] therefore, no RXC mappings existed for the 2017 benefit year. Thus, we proposed to use the Q2 2018 RXC mapping document for the 2017 benefit year enrollee-level EDGE data for 2023 model recalibration, consistent with the mapping used for processing the 2017 data for recalibration of the 2021 and 2022 adult models. We sought comment on this proposal.

We summarize and respond to public comments received on the proposals related to the RXC mapping document used for the annual recalibration of the adult models, along with the comments and responses on the other risk adjustment RXC mapping proposals.

ii. Targeted Changes to RXC Mappings for Recalibration

Regardless of the version of the RXC mapping document we use during the annual adult risk adjustment model recalibration, there may be a relatively small number of drugs that still require additional analysis and consideration given the changes that can occur in the market between the data year and the applicable benefit year of risk adjustment. The targeted changes to particular drugs' mappings typically occur when performing recalibration for future benefit years. Based on our experience since the incorporation of RXCs into risk adjustment models in the 2018 benefit year, we do not believe that the removal or addition of an RXCUI

[90] See, for example, Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXCs) Crosswalk *Memorandum*. (2017, September 18). CMS. *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf*.

[91] The January 7, 2022 version of the DIY software is available at *2021 Benefit Year Risk Adjustment Updated HHS-Developed Risk Adjustment Model Algorithm ''Do It Yourself (DIY)'' Software*. (2022). CMS.

[92] Available at *Distributed Data Collection*. REGTAP.

[93] Consistent with the approach finalized in the 2022 Payment Notice, the 2018 and 2019 enrollee-level EDGE data would be used for the recalibration of the 2024 benefit year models and the 2019 enrollee-level EDGE data would be used for the recalibration of the 2025 benefit year models.

[94] See 81 FR 94075.

from the RXC mappings (and the associated removal of the NDCs and HCPCS associated with that RXCUI) are typically material to recalibration because most drug removals are not associated with utilization and cost levels that would have a meaningful impact on model coefficients.[95] However, in extenuating circumstances where HHS believes there will be a significant impact from a change in an RXCUI to RXC mapping, such as: (1) Evidence of significant off-label prescribing (as was the case with hydroxychloroquine sulfate[96]); (2) abnormally large changes in clinical indications or practice patterns associated with drug usage; or (3) certain situations in which the cost of a drug (or biosimilars) become much higher or lower than the typical cost of drugs in the same prescription drug category, HHS will consider whether changes to the RXCUI to RXC mapping from the applicable data year crosswalk are needed for future benefit year recalibrations. In the proposed rule (87 FR 608 through 609), we illustrated cases where we believe extenuating circumstances existed and how we evaluated whether to make targeted changes to RXC mappings due to those extenuating circumstances as part of the annual recalibration process for the 2023 benefit year adult models. In particular, we considered the cases of RXCUI to RXC mapping of Descovy® and hydroxychloroquine sulfate. For Descovy®, we did not propose to make an exception to remove Descovy® from mapping to RXC 01 in 2017, 2018 or 2019 benefit year enrollee-level EDGE datasets used for the 2023 benefit year recalibration of the adult models. For hydroxychloroquine sulfate, we proposed that the targeted removal of this drug from mapping to RXC 09 was again appropriate, but to effectuate the targeted removal of this drug for purposes of the 2023 benefit year recalibration of the adult models, we would adopt a different approach than the one used for the 2022 benefit year risk adjustment model recalibration and would instead remove the RXCUI to RXC mapping in the 2018 and 2019 enrollee-level EDGE data for 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 09 x HCC048, 041). We explained that we would adopt a similar approach for any future year that uses the enrollee-level EDGE data for the 2018 and 2019 benefit years for purposes of the annual model recalibration.[97] For a full discussion of these examples, see the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 608 through 609).

After reviewing the public comments on the various risk adjustment RXC proposals, we are finalizing using the Q4 RXC mapping document for each benefit year of recalibration data, as proposed. Additionally, as proposed, we will remove hydroxychloroquine sulfate in the 2023 benefit year model recalibration and will not remove Descovy® from mapping to RXC 01 in 2017, 2018, and 2019 benefit year enrollee-level EDGE datasets used for the 2023 benefit year recalibration of the adult models.

We summarize and respond to public comments received on all of the risk adjustment recalibration RXC mapping proposals below.

Comment: Several commenters supported our RXC mapping proposal to recalibrate the 2023 benefit year models and future model years using the final, Q4 RXC Crosswalk associated with the applicable EDGE data year, with the exception of the 2017 enrollee-level EDGE data year, for which we would use the most recent RXC mapping document that was available when we first processed the 2017 enrollee-level EDGE data (Q2 2018). Those supporting comments noted that the changes improve the risk adjustment models and will align condition identification experienced in the data year with concurrent relevance of particular drugs for each RXC. These commenters appreciated the increased transparency into the approach HHS takes to RXC mapping noting it would allow stakeholders to plan for downstream implications of changes to RXC mapping.

A few commenters requested that HHS provide a technical paper on the impact of the different approaches outlined in the RXC mapping proposal. One commenter requested that HHS provide a technical paper with analysis on the impact of the different approaches for identifying the RXC mapping document to use for the annual recalibration of the adult models, but stated that in lieu of that analysis, the commenter would support the adoption of the alternative approach to use the latest RXC mapping available at the time of recalibration as it would most closely aligns costs between recalibration data and current benefit year data.

Response: We appreciate the support for the proposal to recalibrate the adult risk adjustment model using the final, Q4 RXC Crosswalk associated with the applicable EDGE data year. Recalibrating the adult risk adjustment models using the final, Q4 RXC mapping document that was applicable for each benefit year of data that is included in the applicable benefit year's model recalibration will ensure that we are capturing the utilization and costs observed for the underlying drugs in use in that year for the condition. We are finalizing, as proposed, implementation of this approach beginning with the 2023 benefit year recalibration of the adult models, with an exception for the 2017 enrollee-level EDGE data year, for which we will use the most recent RXC mapping document that was available when we first processed the 2017 enrollee-level EDGE data (that is, Q2 2018). We will generally hold these mappings constant when using the 2018 and 2019 enrollee-level EDGE data years in future benefit year model recalibrations (except under the extenuating circumstances that are described previously in this section that can result in targeted changes to RXC mappings)—meaning that we would use the applicable benefit year's Q4 RXC mapping documents when the 2018 or 2019 benefit year of enrollee-level EDGE data is used for future benefit year model recalibrations.

We also agree that this approach will improve issuers' ability to plan for downstream implications of changes to RXC mapping as it will provide issuers the opportunity to see the mappings/crosswalk that will be applied to that data year in the final DIY software release before it is used for recalibration. We believe that the benefits of limiting the volatility of some coefficients from year-to-year, ensuring that we are capturing the utilization and costs observed for the underlying drugs in use during the data year, and improving issuers' ability to plan for downstream implications of changes to RXC mapping outweigh the benefits of the alternative approach of using the latest RXC mapping available at the time of recalibration. Based on the detailed

[95] For example, in reviewing drugs removed in Q1 2020, the average effect of the removal of a single therapeutic drug ingredient was an approximate decrease of 0.14 percent in total pharmacy claims spending among RXC drugs. In reviewing drugs removed in Q1 2021, the average effect of the removal of a single non-hydroxychloroquine therapeutic drug ingredient was an approximate decrease of 0.68 percent in total pharmacy claims spending among RXC drugs.

[96] See, for example, 86 FR 24180.

[97] Consistent with the approach finalized in the 2022 Payment Notice, the 2018 and 2019 benefit year enrollee-level EDGE datasets would continue to be used for recalibration of the 2024 benefit year models; and the 2019 benefit year enrollee-level EDGE dataset would also be used for recalibration of the 2025 benefit year models. See 85 FR 78582 through 78583.

comments received in response to the proposals for identifying the version of the RXC mapping document used for the annual recalibration of the adult models, we do not believe that additional analysis or a technical paper of the approaches to identifying the RXC mapping document for recalibration purposes is needed at this time.

Comment: Several commenters inquired about the timing of RXC Crosswalk changes that occur outside of the model recalibration process. Some requested notification of RXC Crosswalk changes for drugs that could have large impacts on risk adjustment transfers in the spring prior to the applicable benefit year. Others requested HHS finalize and announce the RXC Crosswalk changes that occur outside of the model recalibration process for an applicable benefit year no later than the December preceding the applicable benefit year, examine opportunities to identify and release such changes ahead of applicable State Exchange pricing deadlines, and communicate the final mappings prior to the end of the applicable benefit year. For changes to the RXC mappings that occur during the risk adjustment benefit year, one commenter suggested that HHS consider the relative benefit of removing an RXC at a late stage (that is, the fourth quarter of data submission) relative to potential impact on market stability and financial outcomes for issuers. Another commenter asserted that the timely inclusion of new drugs in the model will help ensure the incentives created by risk adjustment do not contribute to delays in the coverage of new treatments and recommended HHS monitor trends in drug coverage on risk adjustment plans to ensure that specific RXC mapping updates are not negatively impacting patient access to needed medications.

Response: We acknowledge commenters' desire to receive RXC Crosswalk updates as early as possible in order to fit rating timetables and reduce uncertainty. We clarify that, as part of our regular Crosswalk review process, we make regular changes that do not typically meaningfully impact coefficients and we release this information at its earliest availability through DIY software updates posted on the CCIIO website and EDGE global reference updates published through REGTAP.[98] However, we have found that there may be a relatively small number of drugs that require additional consideration given changes that can occur between the data year and the applicable benefit year of risk adjustment. As such, we continue to believe that it is appropriate to update the risk adjustment mapping of RXCUIs to RXCs, along with the list of NDCs and HCPCS that Crosswalk to each RXCUI, throughout a benefit year of risk adjustment, while also retaining the flexibility to make targeted removals of drugs from the RXC Crosswalk and mapping document during the annual recalibration process.

Based on our experience since the incorporation of RXCs into adult risk adjustment models in the 2018 benefit year, the removal of an RXCUI from the RXC mappings (and the associated removal of the NDCs and HCPCS associated with that RXCUI) has not typically been material to recalibration because most drug removals are not associated with utilization and cost levels that would have a meaningful impact on model coefficients. However, in extenuating circumstances where HHS believes there will be a significant impact, we will consider whether targeted RXC mapping changes for recalibration are necessary or appropriate, using the criteria outlined above.

As far as our regular crosswalk review process, we acknowledge commenter concerns over the relative benefit of late stage changes to RXC mappings relative to potential impact on market stability and financial outcomes for issuers, but we continue to believe that it is appropriate to update the risk adjustment mapping of RXCUIs to RXCs throughout a benefit year of risk adjustment. We also note that we rarely remove entire RXC categories from the risk adjustment models. Since the RXCs were introduced in 2018, only two RXC categories have been removed altogether and that type of structural change to the RXC factors was pursued through notice-and-comment rulemaking (83 FR 16941).

Comment: Some commenters requested clarification on how drugs with multiple indications are treated in considering changes to RXC mapping changes that occur outside the annual recalibration process and more clear criteria for these types of drug changes.

Response: We provided an explanation of the criteria used to develop the RXCUI to RXC Crosswalk in the 2017 Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Adult Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXCs) Crosswalk Memorandum.[99] In short, drugs with multiple indications are evaluated by clinical experts to determine if they have reliable specificity to the RXC-associated diagnoses. New drugs with multiple indications that are all associated with diagnoses in the drug-diagnosis pairs that a particular RXC represents are included in that RXC. Drugs associated with the drug-diagnosis pairs of multiple RXCs, or with diagnoses both paired and unpaired with an RXC, can be evaluated against existing drugs with the same active ingredients. Alternatively, these drugs need clinical evidence that the RXC-associated diagnosis is the primary intended clinical application. In the absence of evidence, such drugs with multiple indications would not be mapped to an RXC.

Comment: Some commenters requested a separate RXC for pre-exposure prophylaxis (PrEP).

[98] CMS Registration for Technical Assistance Portal (REGTAP), available at *https://regtap.cms.gov/index.php.*

[99] *Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Adult Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXCs) Crosswalk.* (2017, September 18). CMS. *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf.*

Response: We did not propose and are not finalizing the addition of PrEP as an RXC to the adult risk adjustment models. As explained in the 2021 Payment Notice (85 FR 29187), we chose not to propose incorporating PrEP as an RXC because, as a general principle, RXCs are incorporated into the HHS risk adjustment adult models to impute a missing diagnosis or indicate severity of a diagnosis.[100] Since the use of PrEP is currently recommended as a preventive service for persons who are not infected with HIV and are at high risk of HIV infection, the use of PrEP does not adequately represent risk due to an active condition, and would be inconsistent with this principle to add it as an RXC at this time. However, we incorporate 100 percent of the PrEP costs for enrollees without HIV diagnosis or treatment in the simulation of plan liability for purposes of recalibrating the adult and child models. We further note that enrollees in risk adjustment covered plans that use PrEP drugs in combination with another HIV treatment drug that maps to RXC 01 will still receive credit for RXC 01 in the 2023 benefit year of risk adjustment. We will continue to explore these issues and the potential inclusion of PrEP as an RXC in future benefit years, as may be appropriate.

Comment: One commenter supported the targeted removal of hydroxychloroquine sulfate from the data used for recalibration and supported our decision not to effectuate a targeted removal of Descovy®, one commenter supported the removal of the mapping of hydroxychloroquine sulfate to an RXC, and one commenter generally asserted that Descovy® should not be mapped to RXC 01.

Response: We appreciate comments on our discussion of the treatment of hydroxychloroquine sulfate and Descovy®. For the 2023 benefit year, we are finalizing, as proposed, the removal of the mapping of hydroxychloroquine sulfate to RXC 09 (immune Suppressants and Immunomodulators) in the 2018 and 2019 benefit year enrollee-level EDGE data used for recalibration of the adult risk adjustment models for the 2023 benefit year.[101] In addition, we included Descovy® in the mapping to RXC 01 (Anti-HIV Agents) for 2023 benefit year risk adjustment model recalibration, as the benefits of maintaining this mapping outweigh the benefits of removing it.

e. List of Factors to be Employed in the Risk Adjustment Models

Consistent with our approach in previous benefit years, we will release the final 2023 benefit year coefficients in guidance after publication of the final rule, as we were unable to finalize them in time to publish in this final rule.[102]

f. Cost-Sharing Reduction Adjustments

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 623), we proposed to continue including an adjustment for the receipt of CSRs in the risk adjustment models in all 50 States and the District of Columbia. We explained that while we continue to study and explore ways to update the CSR adjustments to improve prediction for CSR enrollees,[103] for the 2023 benefit year, to maintain stability and certainty for issuers, we proposed to maintain the CSR adjustment factors finalized in the 2019, 2020, 2021, and 2022 Payment Notices.[104] See Table 4. We also proposed to continue to use a CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans in the risk adjustment PLRS calculation, as all of Massachusetts' cost-sharing plan variations have AVs above 94 percent.[105]

We sought comment on these proposals.

TABLE 4: Cost-Sharing Reduction Adjustment Factors

Household Income	Plan AV	Adjustment Factor
Silver Plan Variation Recipients		
100-150% of Federal Poverty Level (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

[100] See 81 FR 94058 at 94075. See also March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting Questions & Answers. (2016, June 8). CMS. *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/RA-OnsiteQA-060816.pdf.*

[101] The same concern was not present for the 2017 enrollee-level EDGE dataset—the other data year that will be used for the 2023 benefit year adult model recalibration—because hydroxychloroquine sulfate was not included in the RXC Crosswalk until 2018.

[102] See 45 CFR 153.320(b)(1)(i).

[103] See Appendix A. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[104] See 83 FR 16930 at 16953; 84 FR 17454 at 17478 through 17479; 85 FR 29164 at 29190; and 86 FR 24140 at 24181.

[105] See 81 FR 12203 at 12228.

After reviewing the public comments, we are finalizing the CSR adjustment factors as proposed. We summarize and respond to public comments received on cost-sharing reduction adjustments below.

Comment: One commenter supported the use of CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans. Another commenter noted that HHS should continue to evaluate the purpose and appropriateness of the current CSR adjustment factors in light of continued non-funding of CSR subsidies and the potential socioeconomic health equity issues associated with the lower-than-anticipated induced utilization level identified in the 2021 RA Technical Paper. Another commenter recommended that HHS use a CSR-specific adult model that uses CSR enrollees' paid claims.

Response: We are finalizing the CSR adjustment factors as proposed. For the 2023 benefit year, we are maintaining the CSR adjustment factors finalized in the 2019, 2020, 2021, and 2022 Payment Notices to maintain stability and certainty for issuers. We did not propose and are not finalizing the addition of a CSR-specific adult model that uses CSR enrollees' paid claims. We agree continued study of the current CSR adjustment factors is warranted. We intend to consider different options for potential changes to the CSR factors for future benefit years, including those outlined in the 2021 RA Technical Paper.[106] We would pursue any changes to the CSR adjustment factors in future notice-and-comment rulemaking.

g. Model Performance Statistics

Each benefit year, to evaluate risk adjustment model performance, we examined each model's R-squared statistic and 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 models is the ratio of the weighted mean predicted plan liability for the model sample population to the weighted mean actual plan liability for the model sample population. The 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 HHS risk adjustment models, the R-squared statistic and the PRs are in the range of published estimates for concurrent risk adjustment models.[107] Because we blend the coefficients from separately solved models based on the 2017, 2018, and 2019 benefit years' enrollee-level EDGE data, we publish the R-squared statistic for each model separately to verify their statistical validity. We will publish the final 2023 benefit year R-squared statistics with the final 2023 benefit year risk adjustment coefficients in guidance.

We did not receive any comments in response to the model performance statistics discussion.

3. Overview of the HHS Risk Adjustment Methodology (§ 153.320)

In part 2 of the 2022 Payment Notice final rule, 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.[108] We explained that under this approach, we will no longer republish these formulas in future annual HHS notices of benefit and payment parameters unless changes are being proposed. We did not propose any changes to the formula in this rule and therefore are not republishing the formulas in this rule. We will continue to apply the formula as finalized in the 2021 Payment Notice in the States where HHS operates the risk adjustment program in the 2023 benefit year.[109]

Additionally, as finalized in the 2020 Payment Notice, we will maintain the high-cost risk pool parameters for the 2020 benefit year and beyond, unless amended through notice-and-comment rulemaking.[110] We did not propose any changes to the high-cost risk pool parameters for the 2023 benefit year; therefore, we will maintain the $1 million threshold and 60 percent coinsurance rate.

We did not receive any comments in response to the overview of the HHS risk adjustment methodology applicable to the 2023 benefit year.

4. Risk Adjustment State Flexibility Requests (§ 153.320(d))

We proposed to repeal the ability of States to request a reduction in risk adjustment State transfers under § 153.320(d) starting with the 2024 benefit year, with an exception for States that have requested such reductions in prior benefit years.[111] We also published and sought comments on requests from Alabama to reduce risk adjustment State transfers for the 2023 benefit year in the individual (including the catastrophic and non-catastrophic risk pools) and small group markets.

a. Requests To Reduce Risk Adjustment Transfers for the 2023 Benefit Year

For the 2023 benefit year, HHS received requests from Alabama to reduce risk adjustment State transfers for its individual and small group markets by 50 percent.[112] Alabama asserts that the State payment transfer formula produces imprecise results in Alabama because of the extremely unbalanced market share in the individual and small group markets. Specifically, Alabama asserts that the presence of a dominant issuer in the individual and small group markets precludes the HHS-operated risk adjustment program from working as precisely as it would with a more balanced distribution of market share. The State asserted that its review of the issuers' financial data suggested that any premium increase resulting from a reduction to risk adjustment payments of 50 percent in the individual market for the 2023 benefit year would not exceed 1 percent, the *de minimis* premium increase threshold set forth in § 153.320(d)(1)(iii) and (d)(4)(i)(B).

In the small group market request, Alabama states that its review of the issuers' financial data from the 2020 benefit year suggests that any premium increase resulting from a reduction to risk adjustment payments of 50 percent in the small group market for the 2023 benefit year would exceed the *de minimis* threshold. However, Alabama asserts that HHS should consider data for years other than 2020 to analyze its small group market request for the 2023 benefit year because the COVID–19 PHE renders an analysis based on 2020 data unreliable. Alabama further notes that there is no regulatory requirement to analyze the request using the most recent available year of data. Alabama

[106] See Section A.3. *HHS-Operated Risk Adjustment* Technical Paper *on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[107] See Hileman, G. & Spenser S. (2016). Accuracy of Claims-Based Risk Scoring Models. Society of Actuaries.

[108] See 86 FR 24183 through 24186.

[109] For an illustration and further details on the State payment transfer formula, see 86 FR 24183 through 24186.

[110] See 84 FR 17466 through 17468.

[111] For the 2020 and 2021 benefit years, the state of Alabama submitted a 50 percent risk adjustment transfer reduction request for its small group market and HHS approved both requests. See 84 FR 17484 through 17485 and 85 FR 29193 through 29194. For the 2022 benefit year, the state of Alabama submitted 50 percent risk adjustment transfer reduction requests for its individual (including catastrophic and non-catastrophic risk pools) and small group markets, and HHS approved both requests. See 86 FR 24187 through 24189.

[112] 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.

further states that the *de minimis* regulatory threshold does not work when a small issuer receives a risk adjustment payment, and that the test should instead be based on what percentage market share the large issuer in Alabama holds compared to the other issuers in the market.

We sought comment on the requests to reduce risk adjustment State transfers in the Alabama individual and small group markets by 50 percent for the 2023 benefit year. The requests and additional documentation submitted by Alabama were posted under the ''State Flexibility Requests'' heading at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html.*

After reviewing the public comments and Alabama's supporting documentation, we are approving a 25 percent reduction in Alabama's individual market transfers and a 10 percent reduction in Alabama's small group market transfers for the 2023 benefit year.

We summarize and respond to the public comments on Alabama's requests for reduced risk adjustment transfers for the 2023 benefit year below.

Comment: A few commenters supported Alabama's requests to reduce risk adjustment transfers in its individual and small group markets for the 2023 benefit year, stating the State is best suited to decide whether an adjustment is needed within the market to maintain competition and program integrity. Some of these commenters reiterated the State's arguments that 2020 data for the small group market may be unreliable due to the COVID–19 PHE. One commenter recommended that HHS not use 2020 data as the sole basis for the determination and analysis of the State's individual and small group market reduction requests. Another commenter suggested that HHS should use other metrics besides the *de minimis* threshold, such as the market share of issuers, to assess the State flexibility requests.

However, other commenters opposed Alabama's 2023 reduction requests, stating that the requested reductions would diminish the effectiveness of the HHS-operated risk adjustment program. One commenter who opposed the State's requests stated that there was no mathematical reason why the presence of one large issuer would preclude HHS-operated risk adjustment from functioning appropriately in Alabama. Many commenters opposed to Alabama's requests expressed more general concern with the transfer reduction request for the individual market than the small group market, stating that the approval of the request in the individual market would result in increased adverse selection.

Some commenters also asserted that the State did not meet its burden to substantiate the requests under the criteria established in § 153.320(d). One of these commenters provided detailed data suggesting the requested individual market transfer reduction would increase premiums for one impacted Alabama issuer by an amount greater than the *de minimis* threshold for the 2023 benefit year. This commenter noted based on their experience from the 2022 benefit year (the first year for which the State requested and HHS approved a 50 percent reduction in risk adjustment transfers in the individual market), their analysis showed a 50 percent reduction in the Alabama individual market for the 2023 benefit year is likely to lead to an approximately 2 percent increase in their premiums.[113]

Response: We continue to believe and recognize that risk adjustment is critical to the proper functioning of the individual and small group (including merged) markets, and we acknowledge commenters' concerns that approving requested reductions in risk adjustment transfers could impact the effectiveness of the risk adjustment program. Therefore, our assessment of the relative benefits of allowing States to request a reduction in risk adjustment transfers has been and continues to be on-going, especially when a State always retains the option to operate its own risk adjustment program if the State believes that the HHS-operated risk adjustment program does not capture its State specific dynamics. As discussed in detail below, we are finalizing amendments to § 153.320(d) and the framework for State reduction requests [114] applicable beginning with the 2024 benefit year; that is, beginning with the 2024 benefit year, only prior participants can make such requests and the requests will only be reviewed and approved under the *de minimis* threshold framework and criteria. In addition, in future rulemaking, we intend to propose to eliminate the prior participant exception and fully repeal the State flexibility framework beginning with the 2025 benefit year.

However, current regulation allows States to request to reduce risk adjustment State transfers, and if the State's reduction request meets the applicable standards under § 153.320(d)(1)(i), HHS will approve the requests, subject to § 153.320(d)(4)(ii). Therefore, HHS' review of and the approval process for the State flexibility requests submitted by Alabama for the 2023 benefit year are guided by the applicable framework and criteria established in regulation under § 153.320(d)(4), which provides that HHS will approve State reduction requests if HHS determines, based on a review of the State's submission, along with relevant public comments and other relevant factors, including the premium impact of the reduction, that (A) the State-specific factors warrant an adjustment to risk adjustment transfers and support the percentage reduction requested, or (B) the State-specific factors warrant an adjustment to risk adjustment transfers and the requested reduction would have a *de minimis* impact on transfers for issuers that would receive reduced transfer payments. Because Alabama's individual and small group market reduction requests included analysis of the premium impacts of the proposed reduction under the *de minimis* framework, HHS' review falls under the criteria established under § 153.320(d)(4)(i)(B); that is, HHS will approve the State's reduction request if HHS determines that State-specific rules warrant an adjustment to more precisely account for relative risk differences in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool and 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. Therefore, so long as this policy remains in place, it would not be appropriate to use other metrics besides the *de minimis* threshold, such as the market share of issuers, to review Alabama's 2023 benefit year reduction requests. Additionally, we do not believe that approving Alabama's 2023 benefit year requests will undermine the efficiency of risk adjustment in the State. We believe the minimal impact on transfers, which is further mitigated by the approval of lower amounts than requested, is outweighed by the benefit of continuing to support the State's efforts to regulate its market risk pools

[113] *BCBSAL Comment Letter.* (2022, January 27). CMS. *https://www.regulations.gov/comment/CMS-2021-0196-0195.*

[114] As detailed further later, we are finalizing, as proposed, the removal of the option for the state to demonstrate the State-specific factors that warrant an adjustment to more precisely account for relative risk differences in the State's individual, small group or merged market. We are also finalizing the amendments that limit this flexibility to prior participants beginning with the 2024 benefit year.

and leverage the flexibility currently available under § 153.320(d).[115]

For the individual market, the State provided information in support of its 50 percent reduction request, including information on the unique State-specific market dynamics that it identified as warranting an adjustment to HHS calculated transfers and its analysis that the reduction requested would have a *de minimis* impact on necessary premium increases. HHS also received public comments in opposition to Alabama's individual market request for the 2023 benefit year. Specifically, an issuer in Alabama shared its data analysis showing a 50 percent reduction would require it to increase its premiums by more than 1 percent.[116] In the comment, the issuer stated that a 50 percent reduction would lead to an approximately 2 percent increase in individual market premiums, which would fail to meet the *de minimis* threshold established for State requests and HHS approval of such requests under § 153.320(d)(1)(iii) and (d)(4)(i)(B), respectively.[117] However, consistent with § 153.320(d)(4)(ii), HHS may approve a reduction amount that is lower than the amount requested in circumstances where the supporting evidence and analysis do not fully support the requested reduction amount.[118] When exercising this flexibility, HHS may assess other relevant factors, including the premium impact of the transfer reduction for the applicable State market risk pool.

Following our consideration of the State's submission and public comments, HHS determined that Alabama provided sufficient information on the unique State-specific market dynamics that it identified as warranting an adjustment to the HHS calculated transfers for the State's individual market, but the supporting evidence and analysis did not fully support the requested reduction amount. Therefore, HHS assessed other relevant factors, including the premium impact of the reduction, as well as relevant factors (for example, detailed stakeholder analysis of the estimated impact of the reduction on price positions [119]). This included consideration and comparison of the data and supporting information submitted by the State and commenters, as well as plan selection and premium data for Alabama. Based on that assessment, HHS has determined that it would be appropriate to approve a reduction amount that is lower than the amount requested, consistent with § 153.320(d)(4)(ii). More specifically, we began our review of the State's individual market reduction request with consideration of available 2020 data [120] and the State's submitted analysis. We also considered detailed stakeholder comments that provided tangible evidence of changing price and market share positions, using 2021 and 2022 data, that raised significant questions about the impact a 50 percent reduction in individual market transfers would have on premiums. These comments estimated a 50 percent reduction in individual market transfers would lead to an approximately 2 percent premium increase based on the stakeholder's experience and the impact of the approval of the State's request to reduce 2022 benefit year individual market transfers by 50 percent. Using open enrollment plan selection and premium data for the individual market in Alabama from the same benefit years as the commenter (2021 and 2022),[121] HHS found the commenter's assumptions regarding the approximately 2 percent increase in premiums to be reasonable. Specifically, HHS' analysis supports the commenters' assertions that a 50 percent reduction in 2023 benefit year individual market transfers would lead to a greater than *de minimis* increase in necessary premiums to cover the reduced payments. HHS is therefore exercising the flexibility under § 153.320(d)(4)(ii) to approve Alabama's requested reduction to individual market transfers, but at an amount lower than requested. To ensure the transfer reduction meets the *de minimis* threshold and does not increase premiums by more than 1 percent, we are approving a 25 percent reduction to 2023 benefit year risk adjustment transfers in Alabama's individual market (including the catastrophic and non-catastrophic risk pools).

For the small group market, the State's reduction request acknowledges that its review of the issuers' financial data from the 2020 benefit year suggests that any premium increase resulting from a reduction to risk adjustment payments of 50 percent in the small group market for the 2023 benefit year would exceed the *de minimis* threshold. However, Alabama asserts that HHS should consider using other prior years of data to analyze its small group market request for the 2023 benefit year, because the COVID–19 PHE renders an analysis based on 2020 data unreliable. HHS also received comments expressing general opposition to the State's small group market request for the 2023 benefit year.

Following our consideration of the State's submission and public comments, HHS determined that Alabama provided sufficient information on the unique State-specific market dynamics that it identified as warranting an adjustment to the HHS calculated transfers for the State's small group market, but the supporting evidence and analysis did not fully support the requested reduction amount. Therefore, HHS assessed other relevant factors, including the premium impact of the transfer reduction for the applicable State market risk pool. This included comparison of the data and supporting information submitted by the State and commenters, as well as EDGE premium and enrollment plan-level data for Alabama's small group market.[122] It also included consideration of the acknowledgement by Alabama in its request that a 50 percent reduction in 2023 benefit year small group market transfers would exceed the applicable *de minimis* threshold.

[115] As detailed elsewhere in this rule, we are finalizing the amendments to the State flexibility to request transfer reduction framework, including the creation of the prior participant exception, as proposed, and intend to propose to fully repeal the framework in a future rulemaking.

[116] *BCBSAL Comment Letter.* (2022, January 28). CMS. *https://www.regulations.gov/comment/CMS-2021-0196-0195.*

[117] As explained in the 2019 Payment Notice, to satisfy the *de minimis* threshold applicable to these requests, the State request must demonstrate the requested reduction in risk adjustment payments would be so small for issuers who would receive risk adjustment payments, that the reduction would have a *de minimis* effect on the necessary premium increase to cover the affected issuer's or issuers' reduced payments. See 83 FR 16955 through 16960.

[118] See 45 CFR 153.320(d)(4)(ii).

[119] Commenter's analysis available at *BCBSAL Comment Letter.* (2022, January 28). CMS. *https://www.regulations.gov/comment/CMS-2021-0196-0195.* Issuer specific BY 2021 and 2022 EDGE enrollment and premium data are not publicly available. However, plan-level QHP rates are available in the *Health Insurance Exchange Public Use Files.* (2021, 2022). CMS. *https://www.cms.gov/CCIIO/Resources/Data-Resources/marketplace-puf.*

[120] Similar to our approach in considering Alabama's reduction requests in previous years, we considered the most recent data available (for example, for the 2022 benefit year, we considered 2019 data as part of the analysis). This included consideration of available EDGE premium and enrollment plan-level data and risk adjustment transfer data.

[121] Commenter's analysis available at *BCBSAL Comment Letter.* (2022, January 28). CMS. *https://www.regulations.gov/comment/CMS-2021-0196-0195.* BY 2021 and 2022 open enrollment plan selection and premium data are not publicly available. However, plan-level QHP rates are available in the *Health Insurance Exchange Public Use Files.* (2021, 2022). CMS. *https://www.cms.gov/CCIIO/Resources/Data-Resources/marketplace-puf.*

[122] HHS does not have the same open enrollment plan selection and premium data on the small group market in Alabama as it does for the individual market in Alabama; therefore, EDGE premium and enrollment plan-level data was used for the small group market assessment.

Based on our review of the unredacted supporting evidence submitted by the State, 2020 benefit year risk adjustment transfer data,[123] and 2020 benefit year EDGE premium and enrollment data available to HHS,[124] we determined it would be appropriate to approve a reduction amount for the small group market that is lower than the amount requested, consistent with § 153.320(d)(4)(ii). Using the most recent 2020 plan-level data available to HHS,[125] HHS estimated transfer calculations as a percent of premiums, which indicated that the risk adjustment payment recipient would have to increase premiums by approximately 5 percent to cover a 50 percent reduction in transfers.[126] Based on this calculation, HHS concluded that a 10 percent reduction in risk adjustment transfers would lead to a *de minimis* (less than 1 percent) premium increase in the small group market and therefore approves a 10 percent reduction in transfers in Alabama's small group market for the 2023 benefit year, exercising our flexibility under § 153.320(d)(4)(ii) to approve an amount lower than requested.

HHS disagrees with assertions that we should not consider 2020 data when considering the 2023 benefit year State flexibility reduction requests. As described in HHS' ''Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year,'' risk adjustment State transfers as a percent of premiums remained relatively steady in 2020 compared to the 2019 benefit year, and the amount of paid claims remained strongly correlated with risk adjustment State payments and charges.[127] Therefore, to assess Alabama's 2023 benefit risk adjustment reduction requests, we considered 2020 data, similar to our approach in considering Alabama's risk adjustment reduction requests in previous years in which we use the most recent data available (for example, for the 2022 benefit year, we considered 2019 data as part of the analysis). Therefore, HHS followed the established precedent for review of these requests. We also considered other data years as part of our analysis of the State's individual market request in response to the detailed comments and analysis using other data years submitted by an impacted stakeholder that called into question whether the requested transfer reduction amount for that market would meet the *de minimis* threshold. Other relevant factors HHS considered were the limited experience with reduction requests in the individual market,[128] the larger magnitude of risk adjustment transfers under the State payment transfer formula in the individual market compared to the small group market,[129] as well as the increased opportunities for adverse selection in the individual market.[130] In addition, the State's individual market request included an analysis that estimated the transfer impact of its requested reduction would meet the *de minimis* threshold, while its request for the small group market acknowledged the requested reduction to transfers would exceed the *de minimis* threshold.

b. Repeal of Risk Adjustment State Flexibility To Request a Reduction in Risk Adjustment State Transfers (§ 153.320(d))

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 625), we proposed numerous amendments to § 153.320(d) to repeal the flexibility for States to request reductions of transfers calculated by HHS under the State payment transfer formula in all State market risk pools starting with the 2024 benefit year, with an exception for States that previously requested a reduction in risk adjustment State transfers under § 153.320(d).

Following our consideration of the State flexibility framework consistent with the instructions in E.O. 14009[131] and prior comments we received on this policy, as well as the general low level of interest States have expressed in the policy, we proposed, beginning for the 2024 benefit year, to repeal the ability for States to request a reduction in risk adjustment State transfers of up to 50 percent in any State market risk pool, with an exception for States that previously requested this flexibility in prior benefit years, namely, Alabama.

For prior participant reduction requests for the 2024 benefit year and beyond, we also proposed to remove the option for the State to demonstrate that State-specific factors warrant an adjustment to more precisely account for relative risk differences in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool. Instead, we proposed prior participants would be required to demonstrate their requests satisfy the *de minimis* impact standard. Under this standard, the requesting State is required to show that the requested transfer reduction would not cause premiums in the relevant market risk pool to increase by more than 1 percent. We proposed conforming amendments to the HHS approval framework under § 153.320(d)(4)(i) and clarified that HHS would retain the flexibility under § 153.320(d)(4)(ii) to approve a lower reduction amount than requested if the State's supporting evidence and analysis do not fully support the requested amount. We also clarified that this proposal to retain this flexibility for prior participants is only intended to permit such States to continue to request risk adjustment State flexibility,

[123] Issuer specific BY 2020 risk adjustment transfers can be found in *Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year.* (2021, June 30). CMS. *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf.*

[124] For BY 2020, issuer specific EDGE premium data have not been made public.

[125] Issuer specific BY 2020 risk adjustment transfers can be found in *Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year.* (2021, June 30). CMS. *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf.* For BY 2020, the issuer specific EDGE premium and enrollment data used for this analysis have not been made public. However, plan-level QHP rates are available in the *Health Insurance Exchange Public Use Files.* (2020). CMS.

[126] Alabama's request acknowledged that reducing the risk transfer by 50 percent in the small group market will result in a more than *de minimis* impact of approximately 4 percent of premium. HHS' analysis indicated that the impact would be approximately 5 percent of premium for the small group market risk payment recipient. HHS and Alabama's estimates slightly differ because we used different data sources in our analysis. HHS used 2020 benefit year data, including risk adjustment transfers and total premiums, to calculate the impact, while Alabama used 2020 benefit year data from the NAIC's Supplemental Health Care Exhibit for 2020. HHS believes our EDGE data most accurately reflects the risk adjustment transfer and premium data necessary to calculate the impact of the reduced transfers. Therefore, we based our approval of a 10 percent reduction in Alabama's small group risk adjustment State transfers based on the analysis showing that a 50 percent reduction would have an approximately 5 percent premium impact on the small group market payment recipient(s).

[127] *Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year.* (2021, June 30). CMS. *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf.*

[128] The 2022 benefit year was the first year Alabama requested, and HHS approved, a reduction request for the individual market under the State flexibility framework. See, for example, 86 FR 24187 through 24189. In contrast, Alabama requested, and HHS approved, reductions to small group market transfers for several years, beginning with the 2020 benefit year and continuing through the approval, in this rule, of an amount lower than requested for the 2023 benefit year.

[129] *Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year.* (2021, June 30). CMS. *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf.*

[130] In the small group market, employers select the plans offered to their employees and often pay a significant portion of employees' premiums to encourage enrollment. Depending on the participation rules and market dynamics in a particular State, risk selection can be significantly less in a State's small group market compared to the individual market.

[131] E.O. 14009; 86 FR 7793 (2021, February 2).

not to automatically apply previously approved transfer reductions to future benefit years. Instead, a prior participant would still be required to submit its request(s) to reduce risk adjustment State transfers each year in the timeframe, form, and manner set forth in § 153.320(d)(1) and (2), and HHS will continue to evaluate risk adjustment State flexibility requests for approval as set forth in § 153.320(d)(4).

We sought comment on this proposal.

After reviewing the public comments, we are finalizing as proposed the amendments to § 153.320(d) that repeal 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. We are also 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 payments does not exceed 1 percent in the relevant State market risk pool.[132] We are finalizing the conforming amendments to the HHS approval framework in § 153.320(d)(4)(i) to reflect the changes to the applicable criteria (that is, only retaining the *de minimis* criterion) beginning with the 2024 benefit year, as well as the proposed definition of ''prior participant'' in § 153.320(d)(5). In future rulemaking, HHS intends to propose to eliminate the prior participant exception beginning with the 2025 benefit year.

We summarize and respond to public comments received on repeal of risk adjustment State flexibility to request a reduction in risk adjustment State transfers § 153.320(d) below.

Comment: Several commenters supported the proposal to repeal the ability for States to request a reduction in risk adjustment State transfers in both the individual and small group markets due to concerns that the reduction in transfers would contribute to adverse selection, increase premiums, and reduce plan options. Commenters stated that reducing the risk adjustment State transfers incentivizes issuers to avoid enrolling chronically ill consumers in the individual market and companies whose workers have above-average costs in the small group market. Commenters supporting the repeal also noted that States can run their own risk adjustment programs if they do not think the HHS-operated risk adjustment program works for their State. Many of the commenters supporting the repeal also opposed the proposal to make an exception for prior participating States and requested that HHS instead repeal this policy in its entirety.

Conversely, several commenters opposed the proposal to repeal the ability for States to request a reduction in risk adjustment State transfers because they support the ability for States to make their own decisions about how best to address the unique circumstances of their insurance markets. Some of these commenters also noted that HHS has the ability to review and reject these requests, indicating that there are appropriate guardrails in place such that States should continue to be offered this flexibility. Additionally, some of these commenters generally opposed the proposed repeal, and in particular opposed limiting the ability to request reductions to prior participants, noting that other States may develop the same market dynamics as the one prior participating State and should have the same ability to request reductions. One of the commenters opposed to the repeal noted concerns with the ability for States to run their own risk adjustment programs, due to the costs to implement such a program within a State.

Response: We are finalizing, as proposed, the repeal of the ability for States to request a reduction in risk adjustment State transfers of up to 50 percent in any State market risk pool, with an exception for prior participants.[133] As detailed in the proposed rule, our further consideration of prior stakeholder feedback, along with consideration of the proposals in light of E.O. 14009,[134] and the very low level of interest from States since the policy was adopted, resulted in an evaluation of whether the policy should be continued and if so, in what manner. After reviewing public comments in response to the proposed amendments to § 153.320(d), including the proposed creation of the prior participant exception, and further consideration of the State flexibility framework under E.O. 14009, we are finalizing this policy as proposed with the intention to propose in future rulemaking to repeal the exception for prior participants beginning with the 2025 benefit year to provide impacted stakeholders additional time to prepare for this change and the potential elimination of this flexibility.

For the 2024 benefit year and beyond, we are also finalizing, as proposed, the removal of the option for States to demonstrate the State-specific factors that warrant an adjustment to more precisely account for relative risk differences in the State individual catastrophic, individual non-catastrophic, small group, or merged market risk pool as the justification for the State's request and the criteria for HHS approval under § 153.320(d)(4)(i). This retains the *de minimis* standard as the only option for prior participants to justify the reduction and for HHS to approve a request and is designed to help ensure that consumers would not experience an increase in premiums greater than 1 percent as the result of a State-requested reduction in transfers, which aligns with the priorities under E.O. 14009 to ensure that health care remains affordable for consumers. Therefore, the only State to have requested risk adjustment transfer reductions from benefit year 2020 to benefit year 2023, Alabama, will be the only State permitted to request reductions in benefit year 2024. However, the *de minimis* standard will be the only option for Alabama to justify the reduction and for HHS review and approval of the requests. We recognize other States may develop the same or similar market dynamics in future benefit years. However, currently, only one State has sought to exercise the flexibility under § 153.320(d) to tailor HHS risk adjustment, which is calibrated using a national dataset, pointing to these unique market dynamics. We therefore believe it is appropriate to provide a transition for this prior participant State, starting with the policies and amendments finalized in this rule that apply beginning with the 2024 benefit year. However, we are concerned about the potential long-term impact of allowing reductions to risk adjustment transfers in any State market risk pool, including the potential negative impacts on the program's ability to mitigate adverse selection and support stability in the individual and small group (including merged) markets. We therefore intend to propose a full repeal of the State flexibility framework (for all States) beginning in the 2025 benefit year in a future rulemaking.

We agree with commenters who noted that States are best able to make their own decisions about how to address the unique circumstances of their insurance markets and remain the primary regulators of their insurance markets. At the same time, however, States have had a low level of interest in this flexibility. Since the 2020 benefit year, all States had the opportunity to submit reduction requests under § 153.320(d), and yet only one State has done so. Similarly,

[132] 83 FR 16957.

[133] This includes finalizing, as proposed, the definition in § 153.320(d)(5) for prior participants.

[134] 86 FR 7793 (Feb. 2, 2021).

since the 2014 benefit year, all States have had the opportunity to operate the risk adjustment program and, to date, only one State has done so—Massachusetts operated a State-based risk adjustment program from the 2014 through 2016 benefit years. Despite a broad range of market conditions across the 50 States and the District of Columbia, only two States have expressed interest in tailoring risk adjustment to address the unique circumstances of their insurance markets, which suggests that States generally do not want to operate their own risk adjustment program and demonstrates that the HHS-operated risk adjustment can work across a broad range of market conditions to mitigate adverse selection in the individual and small group (including merged) markets. Additionally, many commenters had concerns about the potential negative impacts of the transfer reductions on the State's insurance markets. Although, we note these outcomes have not entirely come to bear in Alabama, as new entrants have entered Alabama's individual market and QHP offerings have increased per county in benefit year 2022 [135], other potential negative impacts include reduced plan quality and increased risk selection in the market. We reiterate that a strong risk adjustment program is necessary to support stability and address adverse selection in the individual and small group markets, and under E.O. 14009, we have concerns that this policy could undermine these goals in the long-term and therefore intend to propose a full repeal of the State flexibility framework under § 153.320(d) in a future rulemaking. Finally, we appreciate there are a number of different factors States consider when weighing whether to operate a State-based risk adjustment program, including but not limited to the costs associated with establishing and maintaining such a program. HHS remains committed to working with States and other stakeholders to encourage new market participants, mitigate adverse selection, and promote stable insurance markets through strong risk adjustment programs.

5. Risk Adjustment Issuer Data Requirements (§§ 153.610, 153.700, and 153.710)

In the proposed rule, we proposed that issuers collect and make available for HHS' extraction from issuers' EDGE servers five new data elements—ZIP Code,[136] race, ethnicity, an ICHRA indicator, and a subsidy indicator [137]—as part of the required risk adjustment data that issuers make accessible to HHS in States where HHS operates the risk adjustment program,[138] beginning with the 2023 benefit year. We also proposed that we would extract these five new data elements beginning with the 2023 benefit year. Additionally, beginning with the 2022 benefit year, we proposed HHS would extract from issuers' EDGE servers the following three data elements that issuers already make accessible to HHS as part of the required risk adjustment data—plan ID, rating area, and subscriber indicator. We proposed to exclude plan ID, ZIP Code, and rating area from the limited data set HHS makes available to requestors for research purposes, but include race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator in that limited data set once available. Lastly, we proposed to expand and clarify the scope of permissible HHS uses for the data and the reports extracted from issuer EDGE servers (including summary reports and ad hoc query reports). Related to these proposals, we also considered the burden associated with the collection and extraction of these data elements, and solicited comments on whether there are any policies that HHS could pursue to encourage the consistent use and reporting of ICD–10–CM z codes. The following subsections provide further discussion of these proposals, associated burdens, and accompanying comment solicitation.[139]

a. Collection and Extraction of New Data Elements and Extraction of Current Data Elements

We proposed, beginning with the 2023 benefit year, to collect and extract five new data elements from issuers' EDGE servers through issuers' EDGE Server Enrollment Submission (ESES) files and risk adjustment recalibration enrollment files, specifically: (1) ZIP Code, (2) race, (3) ethnicity, (4) subsidy indicator, and (5) ICHRA indicator. For race and ethnicity data, we proposed to require issuers to report race and ethnicity in accordance with the October 30, 2011 HHS Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status (2011 HHS Data Standards),[140] which is collected at a granular level that would allow HHS to analyze more subpopulations than our current data allows, thereby allowing us to better identify and consider policies to address discrimination in health care and health disparities.[141] [142] In addition to collecting and extracting these new data elements, we also proposed, beginning with the 2022 benefit year, to extract plan ID, rating area, and subscriber indicator from issuers' EDGE servers.[143]

We sought comments on these proposals.

After reviewing the public comments, we are finalizing the proposal to collect and extract ZIP Code, race, ethnicity, an ICHRA indicator, and a subsidy indicator as part of the risk adjustment data issuers of risk adjustment covered plans are required to make accessible to HHS on their EDGE servers in States where HHS operates the risk adjustment program, beginning with the 2023 benefit year. Specifically, we are finalizing that starting with the 2023 benefit year, issuers will be required to populate the ZIP Code and subsidy indicator fields as part of their EDGE data submissions. The ZIP Code field will be formatted at the five-digit level, and the subsidy indicator will indicate whether a particular enrollee is (or is not) receiving APTC. We are also finalizing that starting with the 2023 benefit year, issuers will be required to report race, ethnicity, and ICHRA indicator information as part of their EDGE data submissions. The ICHRA indicator will indicate whether a particular enrollee's health care coverage involves (or does not involve) an ICHRA. Regarding formatting for race and ethnicity data, we are finalizing the collection of these data elements to be consistent with the 2011 HHS Data Standards,[144] which are the standards

[135] *Plan Year 2022 Qualified Health Plan Choice and Premiums in HealthCare.gov States.* (2021, October 15), CMS. *https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/2022QHPPremiumsChoiceReport.pdf.*

[136] ZIP Code™ is a trademark of the United States Postal Service.

[137] The subsidy indicator is intended to indicate whether a particular enrollee is (or is not) receiving APTC.

[138] HHS has been operating the risk adjustment program in all 50 states and the District of Columbia since the 2017 benefit year.

[139] For a full discussion of the background of the HHS-operated risk adjustment program and the required risk adjustment data, as well as the proposals, see the proposed rule (87 FR 627 through 632).

[140] *HHS Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status.* (2011, October 30), CMS. *https://aspe.hhs.gov/reports/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-disability-0.*

[141] As detailed later, we recognize issuers may not have race or ethnicity data for certain enrollees since enrollees are generally not required to provide race and ethnicity data, and we intend to include an option that could be used by issuers in these situations.

[142] See 87 FR 628 through 630.

[143] Ibid.

[144] *HHS Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status.* (2011,

Continued

used by the FFE to collect these data through the Exchange application.[145]

For the 2023 and 2024 benefit years, we are adopting a transitional period during which issuers are required to populate the fields for race and ethnicity using only data they already collect or have accessible regarding their enrollees. For example, for the 2023 and 2024 benefit years, for race and ethnicity data, issuers will be deemed in compliance if they submit these data elements using data they already have or collect through existing means, including, for example, through enrollee data captured and reported to the issuer by the FFE, SBE–FPs, and State Exchanges at the time of enrollment. Then, beginning with the 2025 benefit year, the transitional approach will end, and issuers will be required to populate the fields using available sources and, in the absence of such an existing source for particular enrollees, to make a good faith effort to ensure collection and submission of the race and ethnicity data for these enrollees.

We are also finalizing, with slight modification to the transitional approach, collection of the ICHRA indicator. For the 2023 and 2024 benefit year, similar to the transitional approach for race and ethnicity data, issuers are required to populate the field for the ICHRA indicator using only data they already collect or have accessible regarding their enrollees.[146] Then, beginning with the 2025 benefit year, the transitional approach will end, and issuers will be required to populate the field using available sources (for example, information from Exchanges and small employers, 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 ICHRA indicator for these enrollees.

HHS will provide additional details on what constitutes a good faith effort to ensure collection and submission of the race, ethnicity, and ICHRA indicator data elements in the future. For example, HHS intends to monitor and leverage ongoing work to outline industry-wide standards for collecting health plan demographic data, such as the work by the NAIC's Special Committee on Race & Insurance. As part of this NAIC Committee's efforts to examine and determine which practices or barriers exist in the insurance sector that potentially disadvantage people of color or historically underrepresented groups, it will consider enhanced data reporting and record keeping requirements across product lines to identify race and other sociodemographic factors of insureds, including consideration of legal and privacy concerns.[147] We also intend to seek input from issuers and other stakeholders as we develop this good faith standard and determine the most feasible methods for issuers to ensure collection and submission of these data elements.[148]

Beginning with the 2023 benefit year, HHS will provide additional operational and technical guidance on how issuers should submit these new data elements 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.[149] For example, even though the submission of race and ethnicity data to issuer EDGE servers must conform to the 2011 HHS Data Standards, we intend to provide further instruction to issuers on how to appropriately map information issuers collect to the race and ethnicity EDGE data fields. In addition, we recognize that enrollees are not required to submit race and ethnicity information to the FFE through the eligibility application process, and that SBE–FPs and State Exchanges similarly permit enrollees to decline to provide this information. We anticipate similar practices and flexibility for enrollees to decline to provide this information also currently exists for enrollees seeking coverage off-Exchanges, and that such flexibility will continue to exist in the future for consumers enrolling in coverage on and off-Exchange. As such, we intend to include an option that will allow issuers to indicate that race or ethnicity information is not known in these situations.

Additionally, we are finalizing, as proposed, that any changes to our policies that result from analysis of these data, such as using the data to modify the State payment transfer formula, would generally be subject to notice and comment rulemaking. Furthermore, we would not use the additional data elements or any analysis of them 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.

We are also finalizing the proposals to extract the three data elements issuers already report to their EDGE servers—plan ID, rating area, and subscriber indicator—with a modification to the applicability date for extraction of two of these data elements. As detailed further later, we will begin extraction of plan ID and rating area as part of the enrollee-level EDGE data and reports extracted from issuers' EDGE servers beginning with the 2021 benefit year and will begin extraction of subscriber indicator beginning with the 2022 benefit year. Table 5 provides a summary of the EDGE data collection requirements being finalized in this rule.

October 30) CMS. *https://aspe.hhs.gov/reports/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-disability-0.*

[145] As detailed later, we recognize issuers may not have race and/or ethnicity data for certain enrollees since enrollees are generally not required to provide race and ethnicity data and intend to include a version of ''unknown'' reporting option that could be used by issuers in these situations.

[146] In the proposed rule, we proposed a transitional approach whereby the ICHRA indicator would be optional for the 2023 and 2024 benefit years. See 87 FR at 631. We are finalizing the adoption of a transitional approach for the ICHRA indicator; however, as detailed further later, after consideration of comments, for simplicity and to mitigate burdens, we are adopting the same approach for assessing compliance during the transition for populating the race, ethnicity and ICHRA indicator data fields.

[147] For a full explanation of the work of the NAIC Special (EX) Committee on Race and Insurance, see *https://content.naic.org/cmte_ex_race_and_insurance.htm.*

[148] If the burden estimate for collection of the race, ethnicity, and/or ICHRA indicator data elements changes beginning with the 2025 benefit year, the information collection under OMB control number 0938–1155 would be revised accordingly and stakeholders would be provided the opportunity to comment through that process.

[149] 45 CFR 153.610(a), 153.700(a), and 153.710.

TABLE 5: Summary of EDGE Data Collection Requirements Finalized in this Rule

Summary of EDGE Data Collection Requirements Finalized in this Rule					
Data Element	Submission	Included in Enrollee Level Data	Format Requirements for Data Element	Transitional Approach for 2023 and 2024	Included in Limited Data Set
ZIP Code	2023	2023	5 digits	Not Needed	No
Race	2023	2023	2011 HHS Data standards	Yes	Yes
Ethnicity	2023	2023	2011 HHS Data standards	Yes	Yes
Subsidy Indicator	2023	2023	To be set forth in guidance	Not Needed	Yes
ICHRA Indicator	2023	2023	To be set forth in guidance	Yes	Yes
Subscriber Indicator	2014[150]	2022	To be set forth in guidance	Not Needed	Yes
Plan ID	2014	2021	16 digits	Not Needed	No
Rating Area	2014	2021	2 digits	Not Needed	No

We summarize and respond to public comments received on the proposed collection and extraction of five new data elements and the extraction of three current data elements, along with the other risk adjustment issuer data requirements proposals, in the risk adjustment issuer data requirement proposals comments and responses section of this rule.

b. Limited Data Set

In conjunction with the collection and extraction of the new and current data element proposals, we proposed to exclude plan ID, ZIP Code, and rating area from the limited data set containing enrollee-level EDGE data that HHS makes available to qualified researchers.[151] However, we proposed to include race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator in the limited data set once they are available.[152]

We sought comments on this proposal.

After reviewing the public comments, we are finalizing the proposal to exclude plan ID, ZIP Code, and rating area from the limited data set containing enrollee-level EDGE data that HHS makes available to qualified researchers, and to include race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator in the limited data set once they become available. As explained earlier in this rule, race, ethnicity, ICHRA indicator, and subsidy indicator will become available beginning with the 2023 benefit year, and subscriber indicator will become available beginning with the 2022 benefit year.

We summarize and respond to public comments received on the enrollee-level EDGE limited data set proposals, along with the other risk adjustment issuer data requirements proposals, below.

c. Expansion of Permissible Uses of EDGE Data

We also proposed to expand the permitted uses of the data and reports (including data reports and ad hoc query reports) extracted from issuers' EDGE servers to include other HHS Federal health-related programs outside of the commercial individual and small group (including merged) markets.[153] This proposed expansion would apply to data that HHS already collects and extracts, as well as the collection and extraction of ZIP Code, race, ethnicity, subsidy indicator, ICHRA indicator, plan ID, rating area, and subscriber indicator as outlined in this rule. The proposed expansion to the permitted uses of the EDGE data and reports would apply as of the effective date of this final rule. Specifically, HHS proposed to expand the uses of the data and reports HHS extracts from issuers' EDGE servers to include not only the specific uses for purposes we identified in the 2020 Payment Notice (84 FR 17488)—that is, to calibrate and operationalize our individual and small group (including merged) market programs (including assessing risk in the market for risk adjustment purposes and informing updates to the AV Calculator), and to conduct policy analysis for the individual and small group (including merged) markets—but also for the purposes of informing policy analyses and improving the integrity of other HHS Federal health-related programs, to the extent such use of the data is otherwise authorized by, required under, or not inconsistent with applicable Federal law. We also noted that the enrollee-level EDGE data, including the data elements proposed for collection and extraction, may be subject to disclosure as otherwise required by law.[154]

We sought comment on the proposed expansion of the permissible uses of the data and reports HHS extracts from issuers' EDGE servers.

After reviewing the public comments, we are finalizing, as proposed, the expansion of the permitted uses of the data and reports HHS extracts from issuers' EDGE servers.

We summarize and respond to public comments received on the proposed expansion of the permissible uses of EDGE data, along with the other risk adjustment issuer data requirement proposals, below.

d. Burden for Collecting and Extracting Additional Data Elements

As stated above, we included information in the proposed rule (87 FR 631 through 632) on the burdens related

[150] Since the 2014 benefit year, issuers have been required to submit plan ID, rating area, and subscriber indicator to their EDGE servers to support HHS' calculation of risk adjustment transfers (81 FR 94101).

[151] See 87 FR 630. See also 84 FR 17487.

[152] See 87 FR 630.

[153] See 87 FR 630 through 631.

[154] See, for example, 2 U.S.C. 601(d).

to the proposals to collect and extract additional data elements.

We summarize and respond to public comments received on the burden for collecting and extracting additional data elements, along with the other risk adjustment issuer data requirement proposal below.

e. Encouraging the Use of Z Codes

In the proposed rule (87 FR 631), we sought comment on the collection and extraction of z codes (particularly Z55–Z65), a subset of ICD–10–CM encounter reason codes used to identify, analyze, and document SDOH.[155] We solicited comment on whether there are policies that HHS should pursue that could encourage consistent use of z codes by providers to support collection and use of the data for the HHS-operated risk adjustment program. In light of E.O. 13985 and E.O. 14009, HHS is interested in analyzing z code data to learn about the relationship between risk and the SDOH.

We summarize and respond to the public comments related to encouraging the use of z codes or additional data elements to support the operation of the HHS-operated risk adjustment program below.

f. Risk Adjustment Issuer Data Requirement Proposals Comments and Responses

After reviewing the public comments submitted, we are finalizing, with slight modification, the collection and extraction of the five new data elements (ZIP Code, race, ethnicity, ICHRA indicator, and subsidy indicator) beginning with the 2023 benefit year. Additionally, we are finalizing the extraction of plan ID and rating area beginning with the 2021 benefit year, and the extraction of the subscriber indicator beginning with the 2022 benefit year. We are also finalizing, as proposed, the expansion of the permitted uses of the data and reports (including data reports and ad hoc query reports) extracted from issuers' EDGE servers to include other HHS Federal health-related programs outside of the commercial individual and small group (including merged) markets, as well as coverage offered by non-Federal governmental plans.[156] Lastly, we are finalizing the proposal to exclude plan ID, ZIP Code, and rating area from the limited data set HHS makes available to requestors for research purposes, but to include race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator in that limited data set once available.

We summarize and respond to public comments received on all of the risk adjustment issuer data requirement proposals (§§ 153.610, 153.700, and 153.710) below.

Comment: Many commenters supported the proposal to collect and extract the five new data elements—ZIP Code, race, ethnicity, an ICHRA indicator, and a subsidy indicator. Many of these commenters stated that they believe collecting ZIP Code, race, ethnicity, an ICHRA indicator, and a subsidy indicator would assist in identifying health equity issues by allowing for improved tracking of the SDOH and discrimination in health care.

However, several commenters opposed the proposal to collect and extract the five new data elements due to general concerns related to release of information that issuers consider proprietary and enrollees' personally identifiable information (PII). Some of these commenters stated that collecting and extracting these additional data elements would increase the potential risk of a data security breach. Most of these commenters expressed concerns that the extraction of plan ID and rating area, and the collection and extraction of ZIP Code, may enable outside entities to identify issuers and individual members based on identifiers such as State and rating area, particularly when there is a small number of issuers in a State. Some of these commenters expressed concern about the security of enrollees' PII, explaining that the EDGE servers were initially designed so that HHS would receive only aggregate, summary-level data to address privacy concerns regarding transmitting and storing enrollees' personal information, and that in subsequent rulemaking HHS established the policy to receive enrollee-level data, which raised privacy concerns; therefore, collecting and extracting the proposed additional data elements also raises privacy concerns. One commenter recommended that HHS maintain the existing risk adjustment data collection approach and not collect and extract additional EDGE data elements, stating that the existing distributed data approach is implemented in a manner that alleviates privacy concerns by allowing health plans to control their data assets, which allows private health information to be retained by issuers without additional risk of transmitting and storing large amounts of sensitive data in a central database. This commenter also noted that the existing distributed data approach minimizes the risk of data security breaches.

Response: We are finalizing, with slight modification, the collection and extraction of ZIP Code, race, ethnicity, an ICHRA indicator, and a subsidy indicator beginning with the 2023 benefit year. We believe that the collection and extraction of these five new data elements will allow HHS to better analyze and assess risk patterns in the individual, small group, and merged markets in relation to geographic details (including ZIP Code) and demographic data (including ZIP Code, race, ethnicity, subsidy indicator, and ICHRA indicator). Specifically, collection and extraction of these data elements will allow HHS to analyze data at a more granular level than our current data allow and assess risk patterns and the impact of risk adjustment policies based on geographic, income, and other demographic differences. HHS will also be able to consider whether there are cost differentials for certain conditions based on demographic factors like race, ethnicity, or subsidy indicator.

We also agree with commenters that these new data elements will allow HHS to better identify and analyze health equity issues within the individual, small group, and merged market programs. As explained in the proposed rule, HHS' ongoing efforts to continuously improve HHS programs include considering ways to improve our analytical capacity to assess equity impacts of these programs. This includes improving our ability to identify potential refinements to the HHS risk adjustment methodology and consider demographic and geographic data when considering policy and operational changes to improve other HHS individual, small group, and merged market programs.[157] For example, we believe that collecting and extracting these data elements may help HHS assess the costs and use of benefits by various subpopulations related to our individual, small group, and merged

[155] See *Using Z Codes: The Social Determinants of Health; Data Journey to Better Outcomes.* (2021). CMS. *https://www.cms.gov/files/document/zcodes-infographic.pdf.* See also *Utilization of Z Codes for Social Determinants of Health Among Medicare Fee-for-Service Beneficiaries.* (2019). CMS. *https://www.cms.gov/files/document/z-codes-data-highlight.pdf.*

[156] Non-federal governmental plans are subject to many PHS Act federal market reform requirements. See, for example, 42 U.S.C. 300gg–21(a)(1)(A). See also 42 U.S.C. 300bb–1, *et seq.* HHS is generally responsible for enforcement of provisions of the PHS Act that apply to non-federal governmental plans. See, for example, 42 U.S.C. 300gg–22(b)(1)(B) and 45 CFR 150.301, *et seq.*

[157] As detailed later, we are finalizing the proposed expansion of permitted uses of the enrollee-level EDGE data to include other HHS Federal health-related programs outside of the commercial individual and small group (including merged) markets, as well as coverage offered by non-Federal governmental plans.

market programs, and may allow HHS to better determine whether new policies, regulations, or guidance may be necessary or appropriate to advance equity within these programs. We note that any changes to the risk adjustment methodology or other policies based on HHS' analysis of these data elements would generally be set forth through notice-and-comment rulemaking.

In response to commenters' concerns that collecting and extracting additional data elements would mean transmitting and storing enrollees' PII and that there would be increased risk of data security breaches, we note that we did not propose and are not finalizing any changes to the existing distributed data collection model applicable to the HHS-operated risk adjustment program. As noted by some commenters, HHS set up the distributed data environment to address privacy and security concerns regarding transmitting and storing enrollees' PII. In the proposed 2014 Payment Notice (77 FR 73118), we explained that using a distributed data collection model means that HHS does not directly collect data from issuers,[158] which limits transmission of data containing PII.[159] Instead, HHS accesses enrollment, claims, and encounter data on issuers' secure distributed data environments,[160] called EDGE servers.[161] Under this model, each issuer submits to its EDGE server the required data in HHS-specified electronic formats and must make these data accessible to HHS for use in the HHS-operated risk adjustment program.[162] This general framework remains unchanged. As is current procedure, issuers of risk adjustment covered plans will continue to provide HHS access to the applicable required risk adjustment data elements through the distributed data environment (that is, the issuer's EDGE server) in the HHS-specified electronic formats by the applicable deadline.[163] This includes providing HHS access to install, update, and operate common software and specific reference tables,[164] and executing commands provided by HHS to generate the EDGE reports within the designated timeframes. In addition, issuers will continue to retain control over their data assets subject to the requirements of the risk adjustment program operated under sections 1343 and 1321(c) of the ACA.[165]

Furthermore, HHS remains committed to protecting the privacy and security of enrollee health information and will continue to require issuers to use masked enrollee identification numbers.[166] Specifically, consistent with the requirement first established in the 2014 Payment Notice, issuers must establish a unique masked enrollee identification number for each enrollee that cannot include PII. As we explained in the 2018 Payment Notice (78 FR 15500), use of masked enrollee-level data safeguards enrollee privacy and security because masked enrollee-level data does not include PII.[167] The policies finalized in this rule also do not alter this approach or the existing privacy protections for enrollee PII or individual claim-level information, such as masked enrollee IDs and masked claims IDs.[168] We also note that the final policy adopted in this rule to exclude plan ID, rating area, and ZIP Code from the limited data set is part of our commitment to protect enrollee PII and strategy to mitigate the risk that entities that receive the limited data set could identify individual members, particularly in areas with a small number of issuers. Therefore, we generally disagree that the collection and extraction of these new data elements will increase risk of disclosure of enrollee PII.

We also appreciate the sensitivities related to protecting issuers' proprietary information and note that HHS has also taken several steps to protect information that issuers may consider to be proprietary. First, as noted above, the adoption and continued use of the distributed data collection model ensures each issuer retains control of their respective data. Second, only a limited data set of certain masked enrollee-level EDGE data elements is made available and this limited data set 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.[169] [170] Among other requirements, the data use agreement requires qualified researchers to explain the specific research purpose for which the data will be used and generally prohibits disclosure of the data.[171] We also strictly adhere to all requirements and CMS guidelines related to providing the limited data set to qualified researchers.[172] Third, the policy adopted in this final rule that excludes plan ID, rating area, and ZIP Code from the limited data set further mitigates the risk of disclosure of information that issuers may consider to be proprietary. These are the data elements that could present an increased risk that entities that receive the limited data set file could identify issuers based on identifiers such as State and rating area, particularly in areas with a small number of issuers.

For these reasons, we believe the policies finalized in this rule appropriately balance the different competing interests. More specifically, there are sufficient mitigation strategies in place such that the collection and extraction of these additional data elements presents no significant additional risk of disclosure of information that issuers may consider to be proprietary and it will improve HHS' ability to assess health equity impacts of HHS commercial individual and small group (including merged) market programs, including the HHS-operated risk adjustment program, as well as other HHS Federal health-related programs outside these commercial markets and coverage offered by non-Federal Governmental plans.

Comment: Several commenters noted the limitation of ZIP Code as a geographic identifier, asserting that ZIP Codes are not able to specifically identify a county or a State in certain situations. They also noted that ZIP Codes can change from year-to-year because ZIP Codes are established by the United States Postal Service to address mail delivery needs, not geographic boundaries. One commenter explained that census tract data would be a more accurate data element for geographic analysis than use of ZIP Codes because it can be used with the

[158] 77 FR 73162, 73182 through 73183. This policy was finalized in the 2014 Payment Notice final rule. See 78 FR 15497 through 15500.

[159] See 78 FR 15500. We explained that data are particularly vulnerable during transmission, and that the distributed data collection model eliminates this risk.

[160] 77 FR 73162.

[161] 81 FR 94101.

[162] 78 FR 15497.

[163] See 45 CFR 153.610(a). See also 45 CFR 153.700, et. seq.

[164] See, for example, 78 FR 15497 through 15498.

[165] See 42 U.S.C. 18063 and 18041(c).

[166] See 45 CFR 153.720. See also 78 FR 15509 and 81 FR 94101.

[167] See 45 CFR 153.720(b).

[168] In addition to use of masked enrollee IDs and masked claims IDs, another existing protection for enrollee PII is the exclusion of enrollee date of birth from the data issuers must make accessible to HHS on their EDGE servers.

[169] See Data Use Agreement. CMS. *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS-R-0235L.pdf.* See also 84 FR 17486 through 17490.

[170] Data Use Agreement. CMS. *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS-R-0235L.pdf.*

[171] Ibid. at paragraphs 3, 7.

[172] Further details on limited data set files available at *Limited Data Set (LDS) Files.* (2021, December 1). CMS. *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.*

Social Vulnerability Index (SVI) to obtain measures for SDOH, race, and ethnicity at the population level. This commenter also noted, however, that census tract data is not currently used by issuers and thus may not be readily available. In contrast, some commenters agreed it would be relatively easy for issuers to submit ZIP Code, as issuers readily have access to this data element.

Response: We are finalizing, as proposed, the collection and extraction of ZIP Code for several reasons. First, ZIP Code is a widely understood unit of geography. Second, while we recognize there are some advantages for using census tract data to conduct certain assessments and analysis of risk patterns based on geographic differences, we are concerned that issuers do not currently collect census tract data and we believe it would be more burdensome for issuers to collect and extract this data element than ZIP Code. In contrast, we believe that issuers already have access to enrollees' ZIP Code information. Third, while ZIP Codes can change over time, the majority of changes to ZIP Code occur at the level of the nine-digit ZIP+4 Code, while five-digit area codes generally remain stable from year to year. Therefore, to balance the desire to collect more granular geographic data with easing the burdens on issuers associated with collection of new data elements, we are finalizing the collection and extraction of the five-digit ZIP Code beginning with the 2023 benefit year.

Comment: Some commenters requested that HHS clarify which ZIP Code issuers would be required to report to their EDGE servers, for example, whether issuers should collect the ZIP Code associated with an enrollee's mailing address or rating area.

Response: Issuers will be required to report the enrollee's mailing address ZIP Code as reported by the enrollee. This means that small group market issuers will be required to report the employee ZIP Code and not employer ZIP Code. Consistent with prior practice, additional technical instructions related to how issuers must submit these new data elements, including ZIP Code, will be made available to issuers through the applicable benefit year's EDGE Server Business Rules and the EDGE Server Interface Control Document.

Comment: Some commenters expressed concern that there is no industry standard for collecting the race and ethnicity data elements and recommended that these data elements not be collected until such a standard is established. These commenters also explained that this lack of an industry standard means that the race and ethnicity data elements collected may not be accurate, and that there is no way to ensure that these data elements are accurate. Some of these commenters also noted that some state laws limit the manner by which issuers or SBE–FPs and State Exchanges can collect the race and ethnicity data elements, which may prevent issuers from collecting and submitting these data to HHS, but they did not offer citations or otherwise identify specific State laws.

Response: We are finalizing the proposal to collect and extract race and ethnicity data beginning with the 2023 benefit year and are also finalizing the accompanying proposal to require issuers to report race and ethnicity data in accordance with the 2011 HHS Data Standards beginning with the 2023 benefit year. While not an industry standard, the 2011 HHS Data Standards were developed under section 4302 of the ACA, which requires the Secretary of HHS to establish data collection standards for race, ethnicity, sex, primary language, and disability status. The 2011 HHS Data Standards [173] were promulgated to create a set of uniform data collection standards for inclusion in surveys conducted or sponsored by HHS. They are also the standards used by HHS, as the FFE administrator, to collect these data through the Exchange application. Therefore, we believe that the 2011 HHS Data Standards are an appropriate standard to guide the collection of race and ethnicity data by issuers of risk adjustment covered plans.

We also believe that by using the 2011 HHS Data Standards, we will be supporting the creation of a uniform industry standard that can help improve the accuracy and consistency of the data over time. As explained earlier, we are finalizing the proposal to structure the race and ethnicity data elements similar to current collections, where possible. Since the 2011 HHS Data Standards are consistent with how these data elements are captured in the current FFE online eligibility application, we believe that it is most appropriate to require data submission that conforms with the 2011 HHS Data Standards. However, we recognize that issuers may currently collect or have race and ethnicity data that does not conform to the 2011 HHS Data Standards. To address these situations, we intend to provide further instruction to issuers in guidance on how to appropriately map information they may currently collect or have to the race and ethnicity data fields for EDGE data submission.

We are also finalizing, as proposed, that we will provide a value for the race or ethnicity data elements that allows issuers to indicate that race or ethnicity are not known for a specific enrollee. This option will be available to issuers during the transitional approach. After the transitional approach ends (beginning in the 2025 benefit year), this option will similarly be available to issuers who comply with the good faith standard but are unable to populate the race or ethnicity EDGE data field for one or more enrollees.

We also note that although there may be State laws that limit the reporting and collecting of race and ethnicity data elements, the risk adjustment issuer data requirements, including but not limited to the proposals finalized in this rule related to collection and extraction of race and ethnicity data, are rooted in section 1343 of the ACA. Consistent with section 1321(c)(1) of the ACA, the Secretary is responsible for operating the risk adjustment program in any State that fails to do so. Since the 2017 benefit year, HHS has operated risk adjustment in all 50 States and the District of Columbia. 45 CFR 153.610(a) requires issuers of risk adjustment covered plans to submit and make accessible all required risk adjustment data in accordance with the data collection approach established by HHS in States where the Department operates the program. Specifically, HHS requires issuers of risk adjustment covered plans to submit specified data elements to their EDGE servers to support the calculation of risk adjustment transfers.[174] We also previously finalized policies related to the extraction and use of enrollee-level EDGE data (81 FR 94101 and 84 FR 17488). This rulemaking expands on those requirements and policies, including by expanding the list of data fields issuers must submit to their EDGE servers as part of the required risk adjustment data beginning in the 2023 benefit year.

[173] *HHS Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status.* (2011, October 30). HHS. *https://aspe.hhs.gov/reports/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-disability-0.*

[174] The full list of required data elements can be found in Appendix A of OMB control number 0938–1155 (Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment (CMS–10401)), which is currently being updated. The current Appendix A is available at *Supporting Statement For Paperwork Reduction Act Submissions.* OMB. *https://omb.report/icr/201712-0938-015/doc/79644301.pdf.* The previous version is available at *Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment (CMS–10401).* HHS. *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201712-0938-01.*

As detailed in the proposed rule (87 FR 628 through 629), we believe that collecting and extracting these new data elements serves a compelling government interest of promoting equity in health coverage and care, as well as the ACA's goal of making high-quality health care accessible and accordable for all individuals. Collecting and extracting race and ethnicity data will allow HHS to further assess and analyze actuarial risk, and risk patterns in the individual, small group and merged markets more than current data allows. HHS will also be able to analyze more subpopulations than our current data allows, thereby allowing consideration of more areas of health equity, as well as to better address discrimination in health care and health disparities, through pursuit of new risk adjustment policies. This policy is also narrowly tailored and represents the minimum data anticipated at this time to allow HHS to engage in this additional, more granular analysis. We also reiterate that HHS will conduct quality checks of the newly collected data elements and ensure that the response rate is adequate to support any analytical conclusions that could inform policy decisions.

Further, to the extent that race and ethnicity data could be considered protected health information (PHI),[175] the HIPAA Privacy Rule [176] generally permits health plans and covered health care providers to disclose PHI without obtaining authorization from the individual where such disclosures are required by law, such as when Federal or State statutes or regulations require the disclosure.[177] Additionally, as industry standards and State laws applicable to the collection and use of race and ethnicity data elements evolve, HHS will consider whether any changes to the risk adjustment program's approach for collection of these data elements would be appropriate.

Comment: Some commenters questioned the need for HHS to collect and extract race and ethnicity data as part of the risk adjustment data submissions when the FFE already collects these data.

Response: We acknowledged in the proposed rule (87 FR 631) that these data elements may also be collected by HHS from FFE or SBE–FP enrollees through the eligibility application process and by some State Exchanges from State Exchange enrollees. We further explained how this new risk adjustment data collection requirement would provide HHS with more uniform and comprehensive information. More specifically, the race and ethnicity data collected would represent all enrollees in risk adjustment covered plans in States where HHS operates the risk adjustment program, including coverage offered inside and outside of Exchanges—rather than just reflecting enrollees in coverage offered through Exchanges. Additionally, this new data collection provides HHS the ability to extract and aggregate race and ethnicity data elements with other claims and enrollment data accessible through issuer EDGE servers, which would not be possible with the data collected from consumers through other processes.[178]

Comment: Some commenters inquired whether issuers would be penalized if enrollees decline to provide race and ethnicity information, pointing to the fact that Exchange enrollees can decline to share these details on their application. One commenter requested that HHS consider approaching collection of race and ethnicity the same way HHS proposed collection of the ICHRA indicator, with an optional data field for the 2023 and 2024 benefit years, so that issuers can develop processes for collection, validation, and submission of these data elements.

Response: We are finalizing the proposal to collect and extract race and ethnicity data beginning with the 2023 benefit year. More specifically, issuers will be required to use the information they already have or ensure collection of race and ethnicity information to submit to their EDGE servers consistent with the 2011 HHS Data Standards.

Similar to how we have approached other new data collection requirements in the past, we agree with the commenter and are adopting a transitional approach for the 2023 and 2024 benefit years for the race and ethnicity data fields.[179] During this time, issuers are required to populate race and ethnicity data using data the issuers already have or collect. As such, an issuer will be required to report the race and ethnicity data in situations where a particular enrollee has provided these data to the issuer or if the issuer otherwise has these data for that particular enrollee. For example, QHP issuers may already receive race and ethnicity data elements from the applicable FFE, SBE–FP, or State Exchange at the time of enrollment, and reporting these data as collected through that process would be compliant with standards applicable during the 2023 and 2024 benefit years. We intend to provide further instruction to issuers in guidance on how to appropriately map information issuers have or collect to the race and ethnicity data fields for EDGE data submission.

Beginning with the 2025 benefit year, issuers will be required to populate the field using available sources and, in the absence of an existing source to populate these data elements for particular enrollees, they will be required to make a good faith effort to ensure collection of race and ethnicity data. HHS will provide additional details on what constitutes a good faith effort to ensure collection of the race and ethnicity data elements in the future. We intend to seek input from issuers and other stakeholders as we develop this good faith standard and determine the most feasible methods for issuers to ensure collection and submission of these data elements.[180]

Finally, we recognize that enrollees are not required to submit race and ethnicity information to the FFE through the eligibility application process, and that SBE–FPs and State Exchanges, and off-Exchange issuers, may similarly permit enrollees to decline to provide this information. As such, we will include an option for issuers to indicate that race or ethnicity are not known for a specific enrollee when submitting data to their EDGE servers. For example, an issuer that meets the good faith standard and reports this option in its 2025 benefit year EDGE data for a particular enrollee in these situations will be compliant with the applicable standard, and we would not penalize an issuer in such situations, as enrollees may decline to provide this information.

[175] 45 CFR 164.103 (definition of ''Protected health information'').

[176] 45 CFR 164.512(a).

[177] 45 CFR 164.512(a), 164.103 (definition of ''Required by law''). See 65 FR 82462, 82485 (December 28, 2000) for a discussion of 45 CFR 164.512(a) in the context of other mandatory Federal or state laws.

[178] For information on the challenges associated with linking the extracted enrollee-level EDGE data to other sources, see 87 FR 631 through 632.

[179] After consideration of comments, for simplicity and to minimize burden, we are adopting the same transitional approach for the ICHRA indicator for the 2023 and 2024 benefit years. For the 2023 and 2024 benefit year, issuers are required to populate the field for the ICHRA indicator using only data they already collect or have accessible regarding their enrollees. Then, beginning with the 2025 benefit year, the transitional approach will end, and issuers will be required to populate the field using available sources and, in the absence of an existing source for particular enrollees, to make a good faith effort to ensure collection and submission of the ICHRA indicator for these enrollees. The transition provides issuers with additional time to develop processes for collection, validation, and submission of these data elements.

[180] If the burden estimate for collection of the race, ethnicity, and/or ICHRA indicator data elements changes beginning with the 2025 benefit year, the information collection under OMB control number 0938–1155 would be revised accordingly and stakeholders would be provided the opportunity to comment through that process.

Comment: Several commenters expressed concern that collecting and extracting the race, ethnicity, or ICHRA data elements would impose additional administrative burden, require costly IT system builds, and mandate other operational updates to develop and test the submission of these data elements to issuer EDGE servers.

Response: We acknowledge concerns that the new data collection, particularly the data on race, ethnicity, and ICHRA indicator, could impose additional administrative burden and may require operational changes to develop, test, and validate submission of these data elements. As further detailed in the Information Collection section of this rule, we are updating our estimates of the burden and costs associated with this new data collection. Currently, all issuers that submit data to their EDGE servers [181] have automated the creation of data files that are submitted to their EDGE servers for the existing required data elements, and each issuer will need to update their file creation process to include the five new data elements, which will require a one-time administrative cost. In addition to adding this one-time cost, we also update the estimate to reflect that collection and submission of all five of the new data elements will require 5 hours of work by a management analyst (one hour of work per new data element collected) on an annual basis. We also will revise the information collection under OMB control number 0938–1155 to reflect these additional costs.

This estimate recognizes that information to populate the ICHRA indicator data field is not routinely collected by all issuers at this time, though most issuers currently collect race, ethnicity, ZIP Code, and a subsidy indicator information in some manner.[182] Because we are adopting a transitional approach under which issuers will be required to populate the race, ethnicity, and ICHRA indicator data fields using data they already have or collect for the 2023 and 2024 benefit years, issuers are not required to make any changes to the manner in which they currently collect the race, ethnicity, and ICHRA data elements for the 2023 and 2024 benefit year submissions. This transition period allows additional time for issuers to develop processes for collection and validation of the data required for the new data fields. After consideration of comments, including those related to the burden estimates, we are finalizing the collection and extraction of the five new data elements, with the modifications discussed in this section. We continue to believe that the benefits of collecting and extracting these data elements, including race, ethnicity, and the ICHRA indicator, outweigh the burdens and costs associated with the new requirement.

Comment: Several commenters expressed support for the collection and extraction of the ICHRA indicator. One of these commenters explained that collecting and extracting ICHRA indicator would allow HHS to better understand the types of employers offering ICHRAs and the characteristics of the employees enrolling in coverage using ICHRAs.

Conversely, several commenters stated that the ICHRA indicator was not readily available to issuers, and thus issuers would be unable to collect and submit information to populate the ICHRA indicator data field. Specifically, these commenters stated that requiring collection of information to populate the ICHRA indicator data field would require issuers to collect this data element directly from employers, as the FFE, SBE–FPs, and State Exchanges do not currently collect this data outside of SEP enrollments. These commenters also noted that collecting this data element from employers would be administratively burdensome. One commenter requested further guidance on how issuers would be expected to collect and report this data element.

Response: We agree that collecting and extracting ICHRA indicator data will allow HHS to better understand the characteristics of the employees enrolling in coverage using ICHRAs and will 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 (or merged) market risk pools. After considering public comments, we are finalizing this policy with slight modification to the transitional approach.

In the proposed rule (87 FR 631), we acknowledged that the ICHRA indicator may be collected by HHS from FFE or SBE–FP enrollees through the eligibility application process and that our intention would be to structure these data elements for EDGE data submissions similar to current collections, where possible. As noted above, the ICHRA indicator data element is intended to indicate whether a particular enrollee's health care coverage involves (or does not involve) an ICHRA. Issuers will be permitted to populate the ICHRA indicator with information from FFE or SBE–FP enrollees or enrollees through State Exchanges, or from other sources for collecting this information from these enrollees.

Currently, the FFE collects information about ICHRA availability from all applicants to determine whether they are eligible for a SEP, as individuals and their dependents who become newly eligible for an ICHRA may be eligible for a SEP. The FFE will also collect information about ICHRA affordability from applicants seeking financial assistance who attest to having ICHRA offers, as the details of the offer impact APTC eligibility. However, recognizing that issuers may not currently routinely collect or otherwise have access to the information for all of their enrollees needed to populate the ICHRA indicator, we are finalizing the adoption of a transitional approach for the 2023 and 2024 benefit years.[183] Under this transitional approach, similar to the race and ethnicity data fields, issuers will be required to populate the ICHRA indicator using information the issuer currently has access to or otherwise collects that could be used to populate the ICHRA indicator. For example, where an FFE enrollee is using a SEP, information about ICHRA availability is collected by the FFE, and the FFE may make these data available to issuers. In addition, an issuer may currently have or collect information that could be used to populate the ICHRA indicator in situations where the issuer is being paid directly by the employer through the ICHRA for the individual market

[181] Issuers that elect a risk adjustment default charge are not required to submit EDGE data. See 45 CFR 153.740(b) and 81 FR at 12237 –12238. See also, for example, Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year at 36 (2021, June 30). CMS. *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf.*

[182] The estimated burden associated with collection of the race, ethnicity, ZIP Code, and the subsidy indicator data is the additional effort and expense for issuers to compile and submit these additional data elements to their EDGE servers and to retain them as part of their risk adjustment records. If the burden estimate for collection of the race, ethnicity, or ICHRA indicator data elements 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 stakeholders would be provided the opportunity to comment through that process.

[183] In the proposed rule, we proposed a transitional approach whereby the ICHRA indicator would be optional for the 2023 and 2024 benefit years. See 87 FR at 631. After consideration of comments, for simplicity and to mitigate burdens, we are adopting the same approach for assessing compliance during the transition for populating the race, ethnicity and ICHRA indicator data fields.

coverage.[184] Then, beginning with the 2025 benefit year, the transition period will end, and issuers will be required to populate the ICHRA indicator data field using available sources (for example, with information from Exchanges, small employers, or by requesting information directly from enrollees) and, in the absence of such an existing source for particular enrollees, to make a good faith effort to ensure collection and submission of the ICHRA indicator for these enrollees. HHS will provide additional details on what constitutes a good faith effort to ensure collection of this data element in the future.[185]

As we typically do with other EDGE data elements, we will provide technical guidance to instruct issuers on the format and manner for submission of this data element via the applicable benefit year's EDGE Server Business Rules and the EDGE Server Interface Control Document.[186] We believe that providing a transitional period for the 2023 and 2024 benefit years balances the need to provide additional time for issuers to develop and test available options for collection, validation, and population and submission of the ICHRA indicator, with HHS' efforts to better analyze the ICHRA population, the employers that offer ICHRAs, as well as to investigate the impact of ICHRAs on the individual (and merged) market single risk pools and the HHS-operated risk adjustment program. HHS intends to seek input from issuers and other stakeholders to inform development of the good faith standard and determine the most feasible method for issuers to collect the information used to populate this data field.[187]

Comment: Many commenters supported the proposal to extract the three data elements issuers already submit to their EDGE servers—plan ID, rating area, and subscriber indicator—noting that extraction of these data elements would further HHS' ability to analyze and consider policy changes to the risk adjustment methodology. Two commenters supported the proposal because they believe extracting these data elements would allow HHS to assess and consider a plan-based approach to risk adjustment. One commenter suggested that HHS consider extracting plan ID and rating area earlier, beginning with the 2020 or 2021 benefit year enrollee-level EDGE data extractions and reports. This commenter noted that issuers already collect these data elements, and that waiting until the 2022 benefit year to extract these data and then using these data to further analyze risk patterns would delay any future modifications to improve the risk adjustment methodology until the 2026 benefit year at the earliest.

However, several commenters expressed concern that the extraction of plan ID, rating area, and subscriber indicator data would pose a risk to information that issuers consider proprietary and enrollee privacy, and that plan ID and rating area data are unnecessary for risk adjustment purposes since the risk adjustment program analyzes risk at the enrollee-level.

Response: We are finalizing the extraction of plan ID, rating area, and subscriber indicator with slight modification to the applicability date for extraction of two of these data elements. We will extract plan ID and rating area beginning with the 2021 benefit year, and will extract subscriber indicator beginning with the 2022 benefit year. HHS is committed to continuously considering ways to improve HHS programs, including ways to better assess risk patterns in the individual or small group (including merged) market programs, and believes that extracting plan ID and rating area as soon as feasible will improve HHS' ability to assess risk patterns and the impact of risk adjustment policies at a plan level. We are finalizing an earlier applicability date for extraction of plan ID and rating area because we share the commenter's concern that waiting until the 2022 benefit year could result in a significant delay in the pursuit of future modifications to improve the risk adjustment methodology and program requirements. Additionally, taking into consideration that issuers already submit plan ID and rating area data elements to their EDGE servers, extracting these data sooner would result in little to no additional issuer burden. Extracting plan ID and rating area will also improve HHS' ability to estimate the transfers impact of potential future policies using the enrollee-level EDGE data while minimizing additional burden to issuers with respect to analysis of such potential future policies.

While we acknowledge commenters' concerns that the extraction of plan ID, rating area, and subscriber indicator could pose a risk to information that issuers may consider to be proprietary and enrollee privacy, we believe that there are sufficient mitigation strategies in place such that the collection and extraction of these additional data elements presents no significant additional risk of disclosure of information that issuers consider to be proprietary or to enrollee privacy. For example, as discussed above in response to comments regarding privacy and security concerns related to the collection of new data elements, the adoption and continued use of the distributed data collection model ensures that each issuer retains control of their respective data. Additionally, HHS releases only a limited data set of select masked enrollee-level EDGE data elements only to qualified researchers and only if they meet the requirements for access to such file, 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. Finally, the policy adopted in this final rule that excludes plan ID, rating area, and ZIP Code from the limited data set further mitigates the risk of disclosure of information that issuers may consider to be proprietary and enrollee PII.

In response to commenters' assertion that plan ID and rating area are unnecessary for risk adjustment purposes since the risk adjustment program analyzes risk at the enrollee-level, we note that, since the 2014 benefit year, issuers have been required to submit plan ID, rating area, and subscriber indicator to their EDGE servers to support HHS' calculation of risk adjustment transfers (81 FR 94101). Furthermore, while the risk adjustment models are recalibrated on enrollee-level EDGE data, HHS uses available plan-level data, summary reports, and enrollee-level EDGE data to evaluate and analyze the performance of the risk adjustment program and inform future policy changes for the program. As explained in the proposed rule (87 FR 628), we will use rating area and plan ID to further assess risk patterns and the impact of risk adjustment policies. For example, the extraction of rating area will provide HHS more granular data to assess risk patterns and impact based on geographic differences. We therefore disagree that plan ID and rating area are

[184] Employers have flexibility to reimburse employees enrolled in ICHRAs for covered medical expenses they incur (including premiums for individual health insurance coverage) or to make the payment on behalf of the enrollee (including premiums for individual health insurance coverage).

[185] If the burden estimate for collection of ICHRA indicator changes beginning with the 2025 benefit year (after the transitional approach sends), the information collection under OMB control number 0938–1155 would be revised accordingly and stakeholders would be provided the opportunity to comment through that process.

[186] 45 CFR 153.610(a), 153.700(a), and 153.710.

[187] If the burden estimate for collection of ICHRA 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 stakeholders would be provided the opportunity to comment through the information collection process.

unnecessary for risk adjustment purposes.

Comment: Several commenters supported the proposed exclusion of plan ID, ZIP Code, and rating area from the limited data set. These commenters explained that excluding these data elements from the limited data set would mitigate concerns related to increased exposure of enrollees' PII, data security, and release of information issuers consider proprietary. One commenter also recommended that HHS consider excluding subscriber indicator from the limited data set, also noting concerns surrounding exposure of enrollees' PII.

Other commenters opposed the proposed exclusion of plan ID, ZIP Code, and rating area from the limited data set because exclusion of these data elements would limit qualified researchers' abilities to gain insight that could better inform policy and would also significantly restrict the actuarial use of the limited data set. One commenter recommended including a geographic variable in the limited data set in lieu of ZIP Code, plan ID, and rating area that would indicate placement on the urban-rural continuum. Another commenter recommended that HHS adopt a data use standard that would, for example, only include geographical data (such as plan ID, ZIP Code, and rating area) when there is more than one issuer with at least 5 percent of the enrollment in the rating area to mitigate the concerns with release of information issuers consider proprietary. Another commenter suggested that HHS evaluate whether there is a way to include ZIP Code in the limited data set, as this data element is particularly useful in community-based health equity research.

Response: We recognize and agree with commenters' that including plan ID, ZIP Code, and rating area would enhance the usefulness of the limited data set. However, we are finalizing the exclusion of these data elements from the limited data set to address stakeholder concerns related to providing geographic information, which they believe could result in the identification of certain issuers and the release of data these issuers perceive as competitive and proprietary. Specifically, we also recognize and agree with the concerns that including plan-level data, like plan ID (which represents the HIOS ID, State, product ID, standard component ID, and variant ID) and rating area in the limited data set could increase the risk of disclosure of information that issuers may consider to be proprietary and the risk that outside entities that receive the data for research may be able to identify issuers using State and rating area, particularly when there is a small number of issuers in a State.

We considered whether we could implement a formal data use standard that would only include geographical data based on the number of issuers in a rating area and on a threshold percentage of enrollment in that rating area. However, in considering this option, we recognize that the appropriate threshold percentage may vary based on market conditions, which could make it difficult to establish and maintain a non-arbitrary threshold. In addition, we would want to solicit comments on the establishment of any such threshold. Therefore, since we did not propose any such threshold, we are not finalizing one at this time. However, we will continue to consider if we can develop a standard for including geographical data in the limited data set based on certain characteristics in a rating area (for example, number of issuers) and would outline such a proposed threshold in future notice-and-comment rulemaking.

We similarly considered whether we could include a geographic variable to indicate placement on the rural-urban continuum. However, in collecting and extracting plan ID, rating area, and ZIP Code, we recognize that we may not have the appropriate data elements to accurately determine where on the rural-urban continuum an enrollee should be placed because areas are often defined as rural or urban based on county data, which we believe we may not be able to accurately identify using only plan ID, ZIP Code, and rating area.[188] In addition, ''rural'' and ''urban'' are not defined consistently. For example, the Federal government uses two main definitions for ''rural,'' and generally determines which geographic regions are considered urban based on the regions that meet the rural classification.[189] For these reasons, if we were to consider including any such geographic variable in the limited data set based on collection and extraction of plan ID, ZIP Code, and rating area, we would want to solicit comments before implementing such an approach. Since we did not propose including any such variable, we are not finalizing one at this time. However, we will continue to consider if we would be able to develop a geographic variable to indicate enrollee placement on the rural-urban continuum and would propose any such policy in future notice-and-comment rulemaking.

Although one commenter noted that inclusion of ZIP Code in the limited data set would be particularly useful for community-based health equity research, we believe that including ZIP Code, similar to plan ID and rating area, presents the risk that outside entities that receive the data for research may be able to identify issuers when there is a small number of issuers in a State. At this time, we believe that the risk of potential release of information that issuers may consider to be proprietary and the risk of identification of individual issuers by outside entities outweighs the additional benefits qualified researchers would gain from access to the ZIP Code data, as well as plan ID and rating area data. As such, we believe excluding ZIP Code, plan ID, and rating area from the limited data set but including race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator as they become available[190] represents the appropriate balance between these concerns and providing a limited data set that is useful to qualified researchers.

As detailed above, we also note that HHS has taken several steps to protect information that issuers may consider to be proprietary. With respect to the limited data set, we strictly adhere to all the requirements and CMS guidelines related to providing the limited data set to qualified researchers. This includes a requirement that, prior to receiving the limited data set file, qualified researchers must enter into a data use agreement that establishes the permitted uses or disclosures of the information and prohibits the recipient from identifying the information.[191] The data use agreement also requires qualified

[188] See, for example, 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas, 75 FR 37246 at 37246 (2010 June 28).

[189] See, for example, *Defining Rural Population.* (2020, June 25). HHS. *https://www.hhs.gov/guidance/document/defining-rural-population.* The two main definitions for ''rural'' used across the Federal government are developed by the U.S. Census Bureau and OMB. In addition, the Federal Office of Rural Health and Policy takes components from both of these main definitions when determining how to classify a geographic region.

[190] The subscriber indicator data field will be included in the limited data set beginning with the 2022 benefit year because it will be extracted beginning with the 2022 benefit year. The race, ethnicity, ICHRA indicator, and subsidy indicator data fields will be included in the limited data set beginning with the 2023 benefit year because they will be extracted beginning with the 2023 benefit year.

[191] See Data Use Agreement. CMS. *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS-R-0235L.pdf.* Further details on LDS files available at *Limited Data Set (LDS) Files.* (2021, December 1). CMS. *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.*

researchers to explain the specific research purpose for which the data will be used and generally prohibits disclosure of the data.

We also note that the limited data set includes masked enrollee-level data, and that inclusion of subscriber indicator in the limited data set would not create risk to enrollee privacy or security because it is intended to identify only whether a masked enrollee is the subscriber or dependent on a plan. Further, the limited data set file is subject to Federal laws and regulations in addition to CMS guidelines, and does not contain specific direct identifiers as set forth in the HIPAA Privacy Rule.[192] Specifically, a limited data set must exclude certain direct identifiers of the individual or relatives, employers, or household members of the individual, including, but not limited to, names, telephone numbers, social security numbers, medical record numbers, account numbers, health plan beneficiary numbers, biometric identifiers like finger and voice prints, and postal address information (not including town or city, State, and ZIP Code).[193] We note that race, ethnicity, ICHRA indicator, subsidy indicator, and subscriber indicator are not direct identifiers that must be excluded from a limited data set and would not add to the risk of enrollees being identified. In addition, consistent with how we created the limited data set in prior years, HHS will continue to exclude data from the limited data set that could lead to identification of certain enrollees.[194]

Comment: Several commenters supported expanding the permissible uses of the enrollee-level EDGE data as it would help inform HHS policy analysis and assessment of equity in health coverage and care, identify and address health disparities, and allow HHS to better understand the full impact of its policies, including changes to risk adjustment methodologies.

However, several commenters opposed the proposed expansion of the permissible uses of enrollee-level EDGE data beyond the uses established in the 2020 Payment Notice. Some of these commenters expressed concern that issuers submit data to their EDGE servers with the belief that the data's primary purpose would be for risk adjustment purposes or for development of the AV Calculator. These commenters noted that because of this belief, data collected through the EDGE servers may not be appropriate, reliable, or sufficiently quality checked for the proposed expanded uses.

Some of these commenters stated specific concerns with data quality and reliability of the race, ethnicity, and ICHRA indicator data. These commenters also explained that they believed race, ethnicity, and ICHRA indicator data were out of scope and not necessary for the purposes of operating the risk adjustment program. Several commenters noted that the proposal to expand the permissible uses of EDGE data would be inconsistent with the intended use of the distributed data environment to administer the HHS-operated risk adjustment program. One commenter requested that HHS adopt a requirement prohibiting use of EDGE data for purposes other than for recalibration of the risk adjustment model and development of the AV Calculator.

Response: In the 2014 Payment Notice (78 FR 15497 through 15500), we established the distributed data collection approach and other requirements related to data collection and reporting for purposes of the HHS-operated risk adjustment program. We also explained that we intended for issuers to provide HHS only those data that we believed were reasonably necessary for the risk adjustment program.[195] We disagree that expanding the permissible uses of data collected through the EDGE servers is inconsistent with the intent to establish the distributed data collection approach for collecting risk adjustment data. We also do not agree that the collection of the race, ethnicity, and ICHRA indicator data elements are out of scope; instead, we believe they are reasonably necessary for risk adjustment purposes. As explained in the proposed rule, the collection and extraction of these data elements, in combination with the other extracted data elements, will further HHS' ability to consider more areas of health equity when assessing risk patterns, better address discrimination in health care and health disparities, and identify ways to address health equity issues with regard to the HHS-operated risk adjustment program. More specifically, the additional data elements will allow HHS to conduct analysis at a more granular level than our current data allow, further assess risk patterns and the impact of the risk adjustment policies based on geographic, income, or other demographic differences, and investigate, by sub-population, whether there are cost differentials for certain conditions based on demographic differences (such as race, ethnicity, or subsidy indicator). For example, HHS believes that analysis of the race and ethnicity data elements will help HHS better monitor trends in the health insurance markets and identify potential refinements to the HHS risk adjustment methodology, including ways to address health equity issues and ensure that risk adjustment is not designed in a manner that furthers health inequities. Collection of the ICHRA indicator will allow HHS to investigate whether there are any unique characteristics of the ICHRA population and if ICHRA enrollment is impacting State individual (or merged) market risk pools. This analysis will help inform potential refinements to the risk adjustment methodology and policies for future benefit years. Therefore, the primary purpose and use for the data remains the risk adjustment program. We further note that HHS continuously evaluates the risk adjustment program and the data elements that we believe are reasonably necessary for risk adjustment purposes. For example, we have previously updated EDGE server data collection requirements to include two new data elements: (1) Regarding pharmacy claims, the number of days' supply for prescription drugs, and (2) an in/out-of-network claims indicator.[196] The proposal to collect and extract the race, ethnicity, and ICHRA indicator data elements followed a similar process.

After consideration of public comments, we are finalizing, as proposed, the expansion of the permitted uses of enrollee-level data to allow for more comprehensive study and analysis of potential changes of other HHS Federal health-related programs alongside HHS commercial market programs. In the 2018 Payment Notice (81 FR 94101), we noted that data collected through the EDGE servers will be most useful for risk adjustment purposes. However, we explained that we believed these data would also provide valuable information to validate the AV Calculator and to calibrate other HHS programs in the individual and small group (including merged) markets and finalized our policy to use the data provided to HHS through the EDGE servers for these additional purposes.[197] Similarly, we believe these data will be valuable in assessing policy and

[192] See 45 CFR 164.514(e)(1) and (2).

[193] For the complete list of direct identifiers that are excluded from the limited data set, see 45 CFR 164.514(e)(2)(i)–(xvi).

[194] See, for example, Creation of the 2019 Benefit Year Enrollee-Level EDGE Limited Data Sets: Methods, Decisions and Notes on Data Use. (2021, August 25). CMS. *https://www.cms.gov/files/document/2019-data-use-guide.pdf.*

[195] 78 FR 15500.

[196] 81 FR 94101.

[197] Ibid.

operational issues that are not in connection with programs centered around the individual or small group (including merged) commercial health insurance markets. For example, these data will allow HHS to assess the impact of potential policy changes to PHS Act requirements enforced by HHS that are applicable market-wide [198] and those that are applicable to non-Federal governmental plans.[199] In addition, many PHS Act provisions added by the *No Surprises Act* [200] apply to group health plans and health insurance issuers offering group or individual health insurance coverage, as well as to providers and facilities, rather than being centered around only non-grandfathered individual and small group health insurance coverage. As we consider policy changes related to implementing the new PHS Act requirements added by the *No Surprises Act,* we will be able to consult the enrollee-level EDGE data.

We also acknowledge stakeholders' concerns about the reliability and quality of these newly collected data elements. As detailed elsewhere in this rule, we will ensure that data quality and reliability checks are consistent with other data standard checks that HHS performs. Additionally, we will ensure that the response rate with respect to the submission of race, ethnicity, and ICHRA indicator data is adequate to support any analytical conclusions that could inform policy decisions.

Comment: Most commenters generally supported HHS pursuing efforts to improve more consistent collection and use of z codes by providers, with several of these commenters stating that using z codes in the HHS-operated risk adjustment program may incentivize more consistent use of z codes by providers. Some commenters also provided specific policies for HHS to consider to encourage increased and consistent use of z codes, including focusing on increased outreach to providers to improve provider awareness of coding guidelines for z codes, working to develop a uniform data collection approach and standardized definitions to support consistent z code use, developing electronic health records certification standards for capturing z codes, and incorporating reporting metrics for z codes into value-based programs.

Some commenters explained that because z codes are immature as a clinical tool and can be subjective in nature, HHS should first focus on steps to ensure z codes accurately reflect SDOH before pursuing other policies. One commenter stated that using z codes in the HHS-operated risk adjustment program without substantial preparation could widen existing gaps in recognized coding standards, and HHS should instead focus on promoting consistent and comprehensive diagnostic reporting using these recognized coding standards. Similarly, one commenter recommended that HHS increase awareness to encourage more consistent use of z codes by providers and revise z codes to ensure proper documentation of significant socioeconomic barriers to health before considering incorporating z codes into the risk adjustment program. Other commenters explained that requiring providers to use z codes would create additional administrative burden and thus providers should not be penalized for not using z codes.

Response: Given that we only solicited comments on how to encourage the use of z codes and did not propose specific policies in this area, we are not finalizing any specific policies related to the collection and extraction of z codes at this time. We appreciate the feedback and will continue to review and consider the public comments related to the collection and extraction of z codes to support the operation of the HHS-operated risk adjustment program.

Comment: Several commenters suggested that HHS consider collecting and extracting sexual orientation, gender identity, and additional diagnosis codes related to obesity to support the operation of the HHS-operated risk adjustment program. One of these commenters also suggested HHS collect and extract data related to nutritional deficiencies and excess alcohol use. Another commenter suggested HHS collect and extract disability and veteran status, as self-reported by enrollees.

Response: We appreciate these comments but did not propose and are not finalizing the collection or extraction of the additional data elements suggested by these commenters at this time. We may consider the additional data elements presented by these commenters for future benefit years and generally note that we would want to research whether there are existing data sources for the information as part of the consideration of whether to propose changes the risk adjustment data collection requirements as suggested. We also note that the more severe manifestations of nutritional deficiencies (for example, HCC 023 Protein-Calorie Malnutrition) and excess alcohol use (HCC 083 Alcohol Use with Psychotic Complications and HCC 084 Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications) are among the current payment HCCs in the risk adjustment models.[201]

6. Risk Adjustment User Fee for 2023 Benefit Year (§ 153.610(f))

HHS proposed a risk adjustment user fee for the 2023 benefit year of $0.22 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.[202] As described in the 2014 Payment Notice, HHS' operation of risk adjustment on behalf of States is funded through a risk adjustment user fee.[203] Section 153.610(f)(2) provides that, where HHS operates a risk adjustment program on behalf of a State, an issuer of a risk adjustment covered plan must remit a user fee to HHS equal to the product of its monthly billable member enrollment in the plan and the PMPM risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

OMB Circular No. A–25 established Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. The HHS-operated risk adjustment program provides special benefits as defined in section 6(a)(1)(B) of Circular No. A–25 to issuers of risk adjustment covered plans because it mitigates the financial instability associated with potential adverse risk selection.

For the 2023 benefit year, HHS proposed to use the same methodology to estimate our administrative expenses to operate the risk adjustment program as used for the 2022 benefit year. To calculate the user fee, we divided HHS' projected total costs for administering

[198] See, for example, 42 U.S.C. 300gg—300gg–28.

[199] Non-Federal governmental plans are subject to many PHS Act Federal market reform requirements. See, for example, 42 U.S.C. 300gg–21(a)(1)(A). See also 42 U.S.C. 300bb–1, et. seq. HHS is generally responsible for enforcement of PHS Act provisions applicable to non-Federal governmental plans. See, for example, 42 U.S.C. 300gg–22(b)(1)(B) and 45 CFR 150.301, et. seq.

[200] The Consolidated Appropriations Act, 2021 (CAA) was enacted on December 27, 2020 and includes Title I (No Surprises Act) in Division BB.

[201] There are also less severe manifestations of alcohol use disorder and nutritional deficiencies, but it was determined they did not meet the criteria for inclusion in the HHS risk adjustment models.

[202] For the 2023 benefit year, HHS will be operating the risk adjustment program in every state and the District of Columbia.

[203] 78 FR 15409 at 15416 through 15417.

the risk adjustment program on behalf of States by the expected number of billable member months in risk adjustment covered plans in States where the HHS-operated risk adjustment program will apply in the 2023 benefit year.

We estimated that the total cost for HHS to operate the risk adjustment program on behalf of States for the 2023 benefit year will be approximately $60 million. We projected a small increase in billable member months in the individual and small group (including merged) markets overall in the 2023 benefit year based on the enrollment increases observed between the 2019 and 2020 benefit years (prior to implementation of the ARP in 2021). As such, we proposed the 2023 benefit year risk adjustment user fee rate as $0.22 PMPM. We sought comment on the proposed risk adjustment user fee for the 2023 benefit year.

After consideration of comments, we are finalizing the 2023 benefit year risk adjustment user fee as proposed.

We summarize and respond to public comments received on the 2023 risk adjustment user fee below.

Comment: We received several comments in support of the 2023 risk adjustment user fee rate.

Response: We appreciate the support and are finalizing, as proposed, a risk adjustment user fee rate for the 2023 benefit year of $0.22 PMPM.

7. Compliance With Risk Adjustment Standards; High-Cost Risk Pool Funds—Audits of Issuers of Risk Adjustment Covered Plans (§ 153.620(c))

In the proposed rule (87 FR 633), HHS proposed that whenever HHS recoups high-cost risk pool funds as a result of audits of risk adjustment covered plans under § 153.620(c)(5)(ii), the high-cost risk pool funds recouped from an issuer in an applicable national high-cost risk pool [204] would be used to reduce high-cost risk pool charges for that national high-cost risk pool beginning for the current benefit year, if high-cost risk pool payments have not already been calculated for that benefit year. If high-cost risk pool payments have already been calculated for the current benefit year, we proposed to use the recouped high-cost risk pool funds to reduce the next applicable benefit year's high-cost risk pool charges for all issuers owing high-cost risk pool charges for that national high-cost risk pool.

Notwithstanding any reduction to a national high-cost risk pool's charges for a given benefit year, this policy would not impact the amount of high-cost risk pool payments made to eligible issuers, because the reduction in charges is due to the recoupment of funds as the result of an audit of a prior benefit year rather than a change in payments for the given benefit year. In addition, the high-cost risk pool charges and payments would continue to be calculated in accordance with the established policies, terms and factors.[205] [206]

We also clarified that when HHS recoups high-cost risk pool funds as a result of an audit, the issuer subject to the audit would then be responsible for reporting that adjustment to its high-cost risk pool payments or charges in the next MLR reporting cycle consistent with the applicable instructions in § 153.710(h). Additionally, for any benefit year in which high-cost risk pool charges are reduced as a result of recouped audit funds, issuers whose charge amounts are reduced would report the high-cost risk pool charges paid for that benefit year net of recouped audit funds in the next MLR reporting cycle consistent with § 153.710(h).

We also proposed that any high-cost risk pool funds recouped as a result of an actionable discrepancy or successful administrative appeal filed pursuant to §§ 153.710(d) and 156.1220, respectively, would be treated the same way, that is, any high-cost risk pool funds recouped based on an actionable discrepancy or successful appeal would be used to reduce high-cost risk pool charges for that national high-cost risk pool for the next benefit year for which high-cost risk pool payments have not already been calculated. Additionally, issuers would similarly be responsible for reporting any high-cost risk pool related adjustments that result from the recoupment of funds due to an actionable discrepancy or successful administrative appeal in the next MLR reporting cycle consistent with § 153.710(h).

We sought comment on these proposals.

After review of the comments received, we are finalizing these policies as proposed.

We summarize and respond to public comments received on these proposals below.

Comment: Commenters expressed general support for these proposals.

Response: After consideration of the relevant comments, we are finalizing, as proposed, the policies related to disbursement of high-cost risk pool funds recouped as a result of audits of risk adjustment covered plans under § 153.620(c), actionable high-cost risk pool-related discrepancies filed pursuant to § 153.710(d), and successful high-cost risk pool administrative appeals filed pursuant to § 156.1220.

8. Risk Adjustment Data Validation Requirements When HHS Operates Risk Adjustment (HHS–RADV) (§§ 153.350 and 153.630)

To ensure the integrity of the HHS-operated risk adjustment program, HHS conducts risk adjustment data validation (HHS–RADV) under §§ 153.350 and 153.630 in any State where HHS is operating risk adjustment on a State's behalf.[207]

In the proposed rule, we proposed refinements to the HHS–RADV error rate calculation methodology beginning with the 2021 benefit year and beyond to: (1) Extend the application of Super HCCs to also apply to coefficient estimation groups throughout the HHS–RADV error rate calculation processes; (2) specify that the Super HCC will be defined separately according to the age group model to which an enrollee is subject; and (3) constrain to zero any outlier negative failure rate in a failure rate group, regardless of whether the outlier issuer has a negative or positive error rate (87 FR 634 through 639).

We continue to believe these proposals will better align the calculation and application of error rates with the intent of the HHS–RADV program, thereby enhancing the integrity of HHS–RADV and the HHS-operated risk adjustment program.

We received some comments on HHS–RADV generally that were unrelated to any proposal in the proposed rule. As these comments are outside of the scope of this rulemaking, we will not address them at this time. We further describe the proposed refinements, as well as summarize and respond to comments on the proposals, in the sections that follow.

[204] The high-cost risk pool calculations under the HHS risk adjustment methodology involve two national risk pools—one for the individual market (including catastrophic and non-catastrophic plans, and merged market plans), and another for the small group market. See, for example, 81 FR 94080 through 94082.

[205] See 81 FR 94058, 94081. See also 84 FR 17454, 17467 (We are finalizing the $1 million threshold and 60 percent coinsurance rate for 2020 benefit year and beyond without requiring notice and comment on the high-cost risk pool thresholds each year.). We did not propose changes to the high-cost risk pool parameters for the 2023 benefit year and therefore will maintain the $1 million threshold and 60 percent coinsurance rate.

[206] For a visual illustration of the high-cost risk pool terms and factors, see 86 FR 24184 through 24185.

[207] HHS has operated the risk adjustment program in all 50 states and the District of Columbia since the 2017 benefit year.

a. Coefficient Estimation Groups in Error Estimation

First, we proposed to modify our process for grouping coefficient estimation groups in error estimation. In the 2020 HHS–RADV Amendments Rule (85 FR 76984 through 76989), we finalized a policy to ensure that HCCs that share a coefficient estimation group used in the risk adjustment models are sorted into the same failure rate groups by first aggregating any HCCs that share a coefficient estimation group into Super HCCs before applying the HHS–RADV failure rate group sorting algorithm. Since implementing the Super HCC policy, we found there are rare occasions where there is a minor misalignment between the calculation of risk adjustment PLRS values and HHS–RADV error estimation. To address these rare situations,[208] we proposed to extend the Super HCC policy finalized in the 2020 HHS–RADV Amendments Rule, such that HHS will apply the coefficient estimation group logic as expressed in the applicable benefit year's DIY software throughout HHS–RADV error estimation, rather than just at the sorting step that assigns HCCs to failure rate groups, beginning with the 2021 benefit year of HHS–RADV. This change would mean that an issuer would only need to validate one HCC in a coefficient estimation group to avoid further impacting an adjustment to an enrollee's risk score in HHS–RADV, aligning with how an enrollee's risk score would be calculated under the State payment transfer formula.

We also explained in the proposed rule that this update to the Super HCC policy would necessitate a change to the policy finalized in the 2021 Payment Notice (85 FR 29196 through 29198), which amended the outlier identification process to not consider an issuer as an outlier in any failure rate group in which that issuer has fewer than 30 HCCs.[209]

The 2021 Payment Notice policy was developed when individual HCCs were the unit of analysis for calculating failure rates. However, the proposed policy in this rule to de-duplicate coefficient estimation groups in HHS–RADV would alter the unit of analysis of failure rates to be de-duplicated Super HCCs, rather than individual HCCs. Although the unit of analysis would have changed, the underlying issue with sample size in the outlier identification process would remain the same. As such, we proposed to generally maintain the outlier identification approach adopted in the 2021 Payment Notice and proposed to not consider an issuer as an outlier in any failure rate group in which that issuer has fewer than 30 de-duplicated EDGE Super HCCs (which would include, as proposed below, maturity-severity factors for infant enrollees) beginning with 2021 benefit year HHS–RADV. Consistent with the policies adopted in the 2021 Payment Notice (85 FR 29196 through 29198), we also proposed to continue to include data from an issuer who has fewer than 30 de-duplicated EDGE Super HCCs in a failure rate group in the calculation of national metrics for that failure rate group, including the national mean failure rate, standard deviation, and upper and lower confidence interval bounds. However, the issuer would not have its risk score adjusted for that group, even if the magnitude of its failure rate appeared to otherwise be very large relative to other issuers. In addition, we clarified that under this proposal this issuer may be considered an outlier in other failure rate groups in which it has 30 or more de-duplicated EDGE Super HCCs.

We sought comment on these proposals and whether HCCs in coefficient estimation groups should be de-duplicated before they are sorted into failure rate groups and in all subsequent stages of HHS–RADV error estimation.

After reviewing the public comments, we are finalizing the proposal to extend the application of Super HCCs to apply coefficient estimation groups throughout the HHS–RADV error rate calculation methodology as proposed. Additionally, as proposed, we are finalizing the policy to not consider an issuer as an outlier in any failure rate group in which that issuer has fewer than 30 de-duplicated EDGE Super HCCs. However, we will continue to include data from an issuer who has fewer than 30 de-duplicated EDGE Super HCCs in a failure rate group in the calculation of national metrics for that failure rate group. Issuers with fewer than 30 de-duplicated EDGE Super HCCs in a failure rate group may still be considered an outlier in other failure rate groups in which they have 30 or more de-duplicated EDGE Super HCCs.

We summarize and respond to public comments received on the coefficient estimation groups in error estimation proposal below.

Comment: Several commenters supported the proposal to extend the application of Super HCCs to apply coefficient estimation groups throughout the error rate calculation process. A few of these commenters asserted that this change better aligns the error rate calculation with the intent of the HHS–RADV program and will enhance the integrity of HHS–RADV. Another commenter asserted this change will contribute to market stability and improve predictability.

Response: We are finalizing this methodological change and the accompanying policies as proposed. HHS agrees that these changes will contribute to market stability and improve issuers' ability to predict HHS–RADV adjustments. More specifically, extending the application of Super HCCs to apply coefficient estimation groups through the error rate calculation process better ensures that an issuer only needs to validate one HCC in a coefficient estimation group to avoid further impacting an adjustment to an enrollee's risk score in HHS–RADV and aligns the HHS–RADV methodology with the enrollee risk score calculation under the State payment transfer formula.

Comment: One commenter requested more information about the prevalence of enrollees that have multiple diagnoses in a Super HCC Group.

Response: As described in the proposed rule, the majority of HCCs in a Super HCC are in the same hierarchy, but in rare instances an individual enrollee may be recorded as having multiple conditions in a coefficient estimation group for HHS–RADV. Specifically, only 0.07 percent of enrollees sampled for HHS–RADV in 2018 had multiple HCCs recorded on EDGE that shared a coefficient estimation group but did not share an HCC hierarchy.

b. Defining Super HCCs Separately for Adults, Children, and Infants

In conjunction with the proposal to modify the application of coefficient estimation groups in section III.C.8.a. of this final rule, we also proposed to modify the Super HCC policy to apply coefficient estimation groups to enrollees according to the risk adjustment model to which they are subject. Under the current Super HCC policy finalized in the 2020 HHS–RADV

[208] It is rare for an enrollee to have two HCCs in the same coefficient estimation group that are not also in a hierarchical relationship. This situation occurred in no more than 0.1 percent of enrollees sampled for 2017 and 2018 HHS–RADV.

[209] Under the outlier identification policy finalized in the 2021 Payment Notice, data from an issuer who has fewer than 30 HCCs in a failure rate group is included in the calculation of national metrics for that failure rate group, including the national mean failure rate, standard deviation, and upper and lower confidence interval bounds. However, the issuer does not have its risk score adjusted for that group, even if the magnitude of its failure rate appeared to otherwise be very large relative to other issuers. In addition, we clarified that this issuer may be considered an outlier in other failure rate groups in which it has 30 or more HCCs.

Amendments Rule (85 FR 76987), coefficient estimation group logic from the adult models is applied to all enrollees, including those subject to the child and infant models. For a full description of the current and proposed Super HCC policies see the proposed rule (87 FR 635 through 639). In the proposed rule, we proposed to define Super HCCs based on each age group's model factor definitions separately, except for where child and adult coefficient estimation groups have identical definitions. These definitions are described in the relevant rows in the applicable benefit year's DIY software adult variable logic, child variable logic and infant variable logic. For example, for 2021 HHS–RADV, in the 2021 Benefit Year DIY Software,[210] the adult coefficient group definitions are in the ''HCC group'' rows in Table 6: Additional Adult Variables, the child coefficient group definitions are in the ''HCC group'' rows in Table 7: Additional Child Variables, and the infant coefficient group definitions are in the ''Severity level'', ''Maturity level'', ''Assign as IHCC AGE1 if needed'', ''Impose hierarchy'', and ''Maturity x severity level interactions'' rows in Table 8: Additional Infant Variables.

These relevant rows of the applicable benefit year's DIY software tables would be applied such that each instance of a Super HCC is only counted once per enrollee, even if that enrollee has multiple HCCs in that Super HCC. Furthermore, any payment HCCs that are not modified by the DIY software table logic rows referenced above would be treated as individual Super HCCs, such that all Super HCCs are aligned with how their component HCCs are treated in the risk adjustment models for the applicable benefit year. We proposed to apply this change beginning with the 2021 benefit year of HHS–RADV.

We sought comment on these proposals and whether Super HCCs should continue to be defined for all enrollees based on only the adult models, should be defined for adult enrollees based on the adult models and for child and infant enrollees based on the child models, or should be defined for each age group according to the age group risk adjustment model to which they are subject, as proposed.

After reviewing the public comments, we are finalizing the proposal to define Super HCCs based on each age group's model factor definitions separately, except for where child and adult coefficient estimation groups have identical definitions, as proposed.

We summarize and respond to public comments received on defining Super HCCs separately for adults, children, and infants below.

Comment: Several commenters supported the proposal to define Super HCCs for each age group according to the age group risk adjustment model to which they are subject as this change better aligns the error rate calculation with the intent of the HHS–RADV program and will enhance the integrity of HHS–RADV. A few commenters opposed defining Super HCCs separately for adults, children and infants and expressed concerns with the volatility of the HHS–RADV methodology. One of these commenters stated that this change would add more complexity to predicting failure rate groups without providing significant benefit. Another commenter opposed to this proposal stated that an increase in the number of factors used in sorting, compounded by relatively small sample sizes, would lead to greater volatility and higher premiums and that separating child conditions from adult conditions when defining Super HCCs would create more volatility for conditions that are potentially more similar to each other than conditions that are grouped together in other Super HCCs.

Response: We appreciate the support for these proposals and are finalizing the changes to define Super HCCs for each age group according to the age group risk adjustment model to which they are subject beginning with the 2021 benefit year of HHS–RADV, as proposed. When we established the current Super HCC grouping policy, we acknowledged the possibility of defining Super HCCs based on each model separately; however, we proposed and finalized Super HCCs based on only the adult models for a number of different reasons. These included concerns that using the child and infant models separately could lead to less stable failure rate group assignments year-over-year due to some infant model Super HCCs with very small sample sizes and recognition of the fact that the adult models' HCC coefficient estimation groups would be applicable to the vast majority of enrollees (including most children, considering the strong overlap between the structure of the adult and child models). We also believed that the use of the HCC coefficient estimation groups present in the adult models sufficiently balanced the representativeness and accuracy of HCC failure rate estimates across the entire population in aggregate.

However, in recognition of the differences in each age group model's definitions and due to the updates to HCC hierarchies used in the risk adjustment models beginning with the 2021 benefit year, we continued to consider these issues as we gained more experience with operating HHS–RADV and had access to additional years of HHS–RADV data to analyze. Based on the results of the further analysis, we do not believe that defining Super HCCs separately for adults, children and infants, except for where child and adult coefficient estimation groups have identical definitions, will increase volatility. Rather, as described in the proposed rule, our simulated analysis found evidence that this methodological change would increase model stability. The analysis found that 93.2 percent of factors would remain in the same failure rate group across subsequent benefit years, which contrasts with the 91.4 percent of factors that we would expect to remain stable between subsequent years if Super HCCs were only based on the definitions in the adult models. This minor improvement to stability in failure rate groupings may reduce uncertainties issuers face when modeling pricing, and thus is unlikely to have a negative impact on premiums, contrary to the concerns voiced by the commenter that the proposed refinement to the definition of Super HCCs will lead to greater volatility and higher premiums increase. Moreover, under the policy we are finalizing in this rule, beginning with the 2021 benefit year of HHS–RADV, Super HCCs will only be defined separately in cases where the child and adult coefficient estimation groups do not have identical definitions. This limits the number of cases in which the child and adult models diverge, thereby further limiting the volatility in the HHS–RADV methodology. Therefore, we generally disagree that the adoption of this methodological update and accompanying policies would add more complexity without providing significant benefit. Instead, we believe this is an appropriate refinement to the HHS–RADV methodology and error estimation process based on our experience operating the program and analysis of additional years of available data.

c. Negative Failure Rate Constraint

In the 2020 HHS–RADV Amendments Rule (85 FR 76994 through 76998), we finalized a policy to constrain outlier issuers' error rate calculations to zero in

[210] The January 7, 2022 version of the DIY software is available at *2021 Benefit Year Risk Adjustment Updated HHS-Developed Risk Adjustment Model Algorithm ''Do It Yourself (DIY)'' Software.* (2022). CMS.

cases when an issuer is a negative error rate outlier and its failure rate is negative, beginning with 2019 benefit year HHS–RADV. We finalized this policy to distinguish between low failure rates due to accurate data submission and failure rates that have been depressed through the presence of HCCs in the audit data that were not present in the EDGE data. If a negative failure rate is due to a large number of found HCCs, it does not reflect accurate reporting through the EDGE server for risk adjustment.

In the proposed rule, we proposed modifying the application of that policy beginning with the 2021 benefit year of HHS–RADV to constrain to zero the failure rate of any issuer who is a negative failure rate outlier in a failure rate group, regardless of whether the outlier issuer has a negative or positive error rate. To address cases where a positive error rate outlier issuer has a negative failure rate in one failure rate group and a positive failure rate in another failure rate group, we proposed to amend the application of the negative failure rate constraint policy such that, for the purposes of calculating the group adjustment factor (GAF), we would constrain to zero the failure rate of any failure rate group in which an issuer is a negative failure rate outlier, regardless of whether the outlier issuer has an overall negative or positive error rate. We proposed to adopt this policy beginning with the 2021 benefit year HHS–RADV.

We sought comment on this proposal.

After reviewing the public comments, we are finalizing the negative failure rate constraint policy, as proposed.

We summarize and respond to public comments received on the negative failure rate constraint policy below.

Comment: All commenters supported this proposal to constrain to zero the failure rate of any issuer who is a negative failure rate outlier in a failure rate group, regardless of whether the outlier issuer has a negative or positive error rate. Some of these commenters asserted that this modification of the negative failure rate constraint better aligns the error rate calculation with the intent of the HHS–RADV program and will enhance the integrity of HHS–RADV.

Response: We appreciate these comments and are finalizing the negative failure rate constraint policy as proposed and will apply it beginning with the 2021 benefit year of HHS–RADV. Although our experience to date leads us to believe that this scenario is unlikely to occur often, we agree this refinement is consistent with the intent of the HHS–RADV program and will enhance the integrity of HHS–RADV by further reducing potential incentives for issuers to use HHS–RADV to identify more HCCs than were reported to their EDGE servers for an applicable benefit year.

Comment: One commenter who supported the proposed policy stated that this change will address instability caused by negative error rates. This commenter also suggested it would help issuers understand the implications of the policy if HHS provided data to demonstrate the impact of extending the negative failure rate constraint from negative error rate outlier issuers to all outlier issuers, regardless of whether the outlier issuer has a negative or positive error rate.

Response: As explained in the proposed rule (87 FR 638), we believe this is an appropriate modification of the policy adopted in the 2020 HHS–RADV Amendments Rule to distinguish between low failure rates due to accurate data submission and failure rates that have been depressed through the presence of HCCs in the audit data that were not present in the EDGE data. If a negative failure rate is due to a large number of found HCCs, it does not reflect accurate reporting through the EDGE server for risk adjustment. It is rare, but possible, for a positive error rate outlier to have a negative failure rate in one failure rate group and a positive failure rate in another failure rate group. Specifically, across 2017, 2018 and 2019 HHS–RADV, there was only one instance in which an issuer had a negative failure rate in a failure rate group for which that issuer was an outlier, but had a total error rate that was positive. Despite the relative rarity of these cases, we continue to believe that this is an appropriate modification of the policy adopted in the 2020 HHS–RADV Amendments Rule. Therefore, to address these types of cases in future years of HHS–RADV, we are finalizing, as proposed, the amendment to the application of the negative failure rate constraint policy. Beginning with the 2021 benefit year of HHS–RADV, for the purposes of calculating the GAF, we will constrain to zero the failure rate of any failure rate group in which an issuer is a negative failure rate outlier, regardless of whether the outlier issuer has an overall negative or positive error rate.

9. Disbursement of Recouped High-Cost Risk Pool Funds—Discrepancies of Issuers of Risk Adjustment Covered Plans (§ 153.710(d))

HHS proposed that any funds recouped as a result of an actionable high-cost risk pool-related discrepancy under § 153.710(d) would be used to reduce high cost-risk pool charges for that national high-cost risk pool for the current benefit year if high-cost risk pool payments have not already been calculated for that benefit year. If high-cost risk pool payments have already been calculated for that benefit year, we proposed to use the high-cost risk pool funds recouped based on an actionable discrepancy to reduce the next applicable benefit year's high-cost risk pool charges for all issuers owing high-cost risk pool charges for that national high-cost risk pool. As elsewhere discussed in this preamble, we also proposed similar disbursement policies for high-cost risk pool funds HHS recoups as a result of audits of risk adjustment covered plans under § 153.620(c)(5)(ii) and successful administrative appeals under § 156.1220(a)(1)(ii). We also clarified that when HHS recoups high-cost risk pool funds as a result of an actionable discrepancy, the issuer that filed the discrepancy would then be responsible for reporting that adjustment to its high-cost risk pool payments or charges in the next MLR reporting cycle consistent with the applicable instructions in § 153.710(h). Additionally, for any benefit year in which high-cost risk pool charges are reduced as a result of high-cost risk pool funds recouped as a result of an actionable discrepancy, issuers whose charge amounts are reduced would be required to report the high-cost risk pool charges paid for that benefit year net of recouped funds as a result of an actionable discrepancy in the next MLR reporting cycle consistent with § 153.710(h). We sought comment on these proposals.

After consideration of the relevant comments, we are finalizing these policies as proposed.

We summarize and respond to public comments received on these proposals below.

Comment: We received several comments expressing general support for these proposals.

Response: We are finalizing, as proposed, the policies related to disbursement of high-cost risk pool funds recouped as a result of audits of risk adjustment covered plans under § 153.620(c), actionable high-cost risk pool-related discrepancies filed pursuant to § 153.710(d), and successful high-cost risk pool administrative appeals filed pursuant to § 156.1220.

10. Medical Loss Ratio Reporting Requirements (§ 153.710(h))

In the proposed rule (87 FR 639), we explained that HHS established a framework in prior rulemakings to guide

issuer treatment of certain payments and charges that could be subject to reconsideration for purposes of risk corridors and MLR reporting.[211] For example, because risk adjustment transfer amounts are factors in an issuer's MLR calculations, a delay in final risk adjustment payments and charges, including HHS–RADV adjustments to transfers, could make it difficult for issuers to comply with reporting requirements under the MLR program. A delay in final risk adjustment transfer amounts could occur due to audits, actionable discrepancies, or successful appeals. Therefore, we clarified in § 153.710(h)[212] how issuers should report certain ACA program amounts that could be subject to reconsideration for risk corridors and MLR reporting purposes.

In the proposed rule, we proposed to amend the introductory sentence in § 153.710(h)(1) and to add a proposed new paragraph (h)(1)(v) to separately address and explicitly capture a reference to HHS–RADV adjustments to make clear that HHS expects issuers to report HHS–RADV adjustments as part of their MLR reports in the same manner as they report risk adjustment payment and charge amounts (including high-cost risk pool payments and charges). That is, notwithstanding any HHS–RADV discrepancy filed under § 153.630(d)(2), or any HHS–RADV request for reconsideration under § 156.1220(a)(1)(vii) and (viii), unless the dispute has been resolved, issuers must report, as applicable, the HHS–RADV adjustment to a risk adjustment payment or charge as calculated by HHS in the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers.[213] We also proposed to add a reference to HHS–RADV discrepancies under § 153.630(d)(2) to the introductory sentence in § 153.710(h)(1).

We also proposed conforming amendments to paragraph (h)(2) to add a reference to HHS–RADV adjustments to address situations where there could be subsequent changes to HHS–RADV adjustments calculated by HHS in the applicable benefit year's HHS–RADV Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers, such as modifications resulting from an actionable discrepancy or successful appeal. In these situations, an issuer would be required to report during the current MLR reporting year any adjustment to an HHS–RADV adjustment made or approved by HHS before August 15, or the next applicable business day, of the current reporting year unless otherwise instructed by HHS. Issuers would be required to report any adjustment to an HHS–RADV adjustment made or approved by HHS where such adjustment has not been accounted for in a prior MLR Reporting Form, in the following reporting year.

Recognizing that flexibility is often needed in reporting these amounts on MLR forms, consistent with existing framework in § 153.710(h)(3), HHS would have the ability to modify these instructions in guidance in cases where HHS reasonably determines that these reporting instructions would lead to unfair or misleading financial reporting. Our intent in issuing any such guidance would be to avoid having the application of the instructions in exceptional circumstances lead to unfair or misleading financial reporting.[214]

Finally, we proposed a technical amendment to § 153.710(h)(3) to replace the current cross-reference to paragraph (g)(1) and (2) of this section with a reference to paragraph (h)(1) and (2) of this section to point to the correct sections that contain the relevant reporting instructions. We inadvertently omitted this update as part of the amendments in the 2022 Payment Notice (85 FR 786 through 78605 and 86 FR 24194 through 24195) to incorporate an EDGE materiality threshold as part of § 153.710 that redesignated the risk corridors and MLR reporting instructions provisions from paragraph (g) to paragraph (h).

We sought comments on these proposals.

After reviewing the public comments, we are finalizing the proposed amendments to § 153.710(h) to make clear that HHS expects issuers to report HHS–RADV adjustments as part of their MLR reports in the same manner as they report risk adjustment payment and charge amounts (including high-cost risk pool payments and charges). For greater clarity, the regulation text we adopt in this final rule at § 153.710(h)(2) contains a non-substantive change to also include a reference to HHS–RADV adjustments in the second sentence to align with the addition of the same reference in the first sentence.[215] We are also finalizing the technical correction to § 153.710(h)(3) to point to the correct sections that contain the relevant reporting instructions.

We summarize and respond to public comments received on proposed medical loss ratio (MLR) reporting requirements (§ 153.710(h)) and policies below.

Comment: One commenter supported the proposal to amend § 153.710(h) to make clear that HHS expects issuers to report HHS–RADV adjustments as part of their MLR reports in the same manner as they report risk adjustment payment and charge amounts (including high-cost risk pool payments and charges). We received two comments on the MLR reporting cycle and its interaction with the risk adjustment payment and charge timing, including a suggestion that HHS consider changing the deadline for reporting during the current MLR reporting year any adjustment (including HHS–RADV adjustments) made or approved by HHS before August 15, or the next applicable business day, to June 30 to avoid creating the need for issuers to refile MLR reports after the July 31 deadline to account for these adjustments.

Response: We appreciate these comments and are finalizing the amendments, as proposed, to address and explicitly capture a reference to HHS–RADV adjustments. The changes to the regulation make clear and codify HHS' expectation that issuers report HHS–RADV adjustments as part of their MLR reports in the same manner as they report and with the same deadlines associated with the risk adjustment payment and charge amounts (including high-cost risk pool payments and charges) that were established in the 2017 Payment Notice (81 FR 12236).

As for the MLR reporting cycle, we continue to believe that the August 15 date provides the necessary flexibility to account for adjustments to issuers' MLR reports as a result of risk adjustment payment and charge amounts, including HHS–RADV adjustments. Therefore, we did not propose, and are not finalizing, changes to the existing reporting deadlines in § 153.710(h) as applied to HHS–RADV adjustments or other payments and charges that could be

[211] See 45 CFR 153.710(h).

[212] These instructions were previously codified in 45 CFR 153.710(g) and recently redesignated to 45 CFR 153.710(h). See 79 FR 13789 through 13790 and 86 FR 24194 through 24195.

[213] For example, the 2022 benefit year HHS–RADV Summary Report for non-exiting issuers will be published in summer of 2024 and those issuers would be expected to report those amounts in their 2023 MLR Reports (filed by July 31, 2024).

[214] See, for example, Treatment of Risk Corridors Recovery Payments in the Medical Loss Ratio and Rebate Calculations. (2020, December 30). CMS. *https://www.cms.gov/files/document/mlr-guidance-rc-recoveries-and-mlr-final.pdf.*

[215] This editorial revision in no way changes or otherwise affects the requirements under the proposed text and more clearly and consistently captures that HHS expects issuers to report HHS–RADV adjustments as part of their MLR reports in the same manner as they report risk adjustment payment and charge amounts.

subject to reconsideration for purposes of risk corridors and MLR reporting.

11. Deadline for Submission of Data (§ 153.730)

A risk adjustment covered plan must submit data that is necessary for HHS to calculate risk adjustment payments and charges to HHS in States where HHS is operating the risk adjustment program.[216] [217] In the 2014 Payment Notice (78 FR 15434), HHS established that the deadline for issuers to submit the required risk adjustment data is April 30 of the year following the applicable benefit year.

In the proposed rule (87 FR 639 through 640), we did not propose to change this deadline but proposed to amend § 153.730 to address situations when April 30 does not fall on a business day. Currently, when April 30 falls on a non-business day, HHS exercises enforcement discretion to extend the deadline to the next applicable business day.[218] Recognizing there will be future benefit years when April 30 does not fall on a business day, HHS proposed to amend § 153.730 to provide that when April 30 of the year following the applicable benefit year falls on a non-business day, the deadline for issuers to submit the required risk adjustment data would be the next applicable business day. We sought comments on this proposal.

After consideration of the comment received, we are finalizing the amendment to § 153.730 as proposed.

Comment: One commenter supported this proposal because this amendment would clarify expectations for when reporting must be completed.

Response: We are finalizing the amendment to § 153.730 to clarify that when the April 30 following the applicable benefit year deadline for issuers to submit the required risk adjustment data falls on a non-business day, the deadline for issuers to submit the required risk adjustment.

D. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

1. Non-Interference With Federal Law And Non-Discrimination Standards (§ 155.120(c))

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 640), we proposed to amend 45 CFR 155.120(c) such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. As explained in the Supplementary Information section earlier in the preamble, HHS will address this policy, as well as the public comments submitted in response to this proposal, in future rulemaking.

2. Civil Money Penalties for Violations of Applicable Exchange Standards by Consumer Assistance Entities in Federally-Facilitated Exchanges (§ 155.206)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 640 through 641), we proposed to make a technical correction to 45 CFR 155.206(i) to add language that would cross-reference the authority to implement annual inflation-related increases to civil money penalties (CMPs) pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act).[219] Because of an oversight, this language was not added to § 155.206(i) as part of prior efforts and rulemaking to implement the 2015 Act.[220] Additionally, a reference to § 155.206 and any accompanying adjusted CMP amounts have not been included in HHS' annual inflation update rulemakings.[221] Therefore, we proposed to amend § 155.206(i) to add the phrase ''as adjusted annually under 45 CFR part 102'' after the phrase ''$100 for each day'' to correct this oversight. The associated CMP table in 45 CFR 102.3 is updated annually, and § 155.206(i) was added in the recent annual update.[222] To date, no CMPs have been imposed under this authority, but any that are imposed will reflect the current inflationary adjusted amount as required by the 2015 Act and will be calculated in accordance with applicable OMB guidance to all Executive Departments on the implementation of the 2015 Act.

We did not receive any comments in response to the proposed amendments to § 155.206(i) or the accompanying policies detailed in the related preamble discussion. For the reasons stated in the proposed rule, we are finalizing the proposed amendments to § 155.206(i).

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)

a. Required QHP Comparative Information on Web-Broker Websites and Related Disclaimer

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 641 through 643), we proposed to amend § 155.220(c)(3)(i)(A) to include, at proposed new §§ 155.220(c)(3)(i)(A)(*1*) through (c)(3)(i)(A)(*6*),[223] a list of the QHP comparative information web-broker non-Exchange websites are required to display consistent with § 155.205(b)(1). We also proposed to revise the disclaimer requirement in § 155.220(c)(3)(i)(A) so that web-broker non-Exchange websites would be required to prominently display a standardized disclaimer provided by HHS stating that enrollment support is available on the Exchange website and provide a web link to the Exchange website where enrollment support for a QHP is not available using the web-broker's non-Exchange website.

We proposed to codify new §§ 155.220(c)(3)(i)(A)(*1*) through (*6*) to require web-broker websites to display premium and cost-sharing information, the summary of benefits and coverage established under section 2715 of the PHS Act; identification of the metal level of the QHP as defined by section 1302(d) of the ACA or whether it is a catastrophic plan as defined by section 1302(e) of the ACA; the results of the

[216] See 45 CFR 153.610 and 153.710. Since the 2017 benefit year, HHS has operated the risk adjustment program in all 50 states and the District of Columbia.

[217] Issuers of reinsurance-eligible plans in states where HHS-operated the reinsurance program were similarly required to submit the data necessary for HHS to calculate reinsurance payments. See, for example, 45 CFR 153.420 and 153.710. The reinsurance program under section 1341 of the ACA was a temporary program that applied to the 2014—2016 benefit years. The risk adjustment program under section 1343 of the ACA is a permanent program and therefore is the primary focus of this discussion.

[218] See 81 FR 12204 at 12234 n.20; see also Evaluation of EDGE Data Submissions for 2016 Benefit Year. (2016, December 23). CMS. *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-2016-Q_Q-Guidance_20161222v1.pdf.*

[219] Sec. 701 of the Bipartisan Budget Act of 2015, Public Law 114–74, which amended the Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law 101–410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C.A. § 2461 note 2(a)).

[220] See Department of Health and Human Services; Adjustment of Civil Monetary Penalties for Inflation; Interim Final Rule, 81 FR 61538 (2016, September 6).

[221] See, for example, the Department of Health and Human Services; Annual Civil Monetary Penalties Inflation Adjustment; Final Rule, 85 FR 2869 (2020, January 17). See also Department of Health and Human Services; Adjustment of Civil Monetary Penalties for Inflation and the Annual Civil Monetary Penalties Inflation Adjustment for 2021, 86 FR 62928 (2021, November 15).

[222] See the Department of Health and Human Services; Annual Civil Monetary Penalties Inflation Adjustment, 87 FR 15100 (2022, March 17).

[223] While the citation in the preamble in the proposed rule referred to amendments to add new § 155.220(c)(3)(i)(A)(*1*) through (c)(3)(i)(A)(*5*), the discussion of the proposal and the proposed regulations made clear that the proposal would add new § 155.220(c)(3)(i)(A)(*1*) through (c)(3)(i)(A)(*6*). See, for example, 87 FR 641– 642 and 721–722.

enrollee satisfaction survey as described in section 1311(c)(4) of the ACA; quality ratings assigned in accordance with section 1311(c)(3) of the ACA; and the provider directory made available to the Exchange in accordance with § 156.230 as the minimum QHP comparative information web-broker non-Exchange websites must display for all available QHPs.

In addition, we proposed to modify the language in § 155.220(c)(3)(i)(A) that served as the basis for the current plan detail disclaimer requirement [224] to instead require web-broker non-Exchange websites that do not support enrollment in all available QHPs to provide notice to consumers of that fact, and direct consumers to the Exchange website where they may obtain enrollment support. We proposed to revise § 155.220(c)(3)(i)(A) to state that web-broker websites must disclose and display the QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(c); and to the extent that enrollment support for a QHP is not available using the web-broker's website, prominently display a standardized disclaimer provided by HHS. This disclaimer would state that enrollment support for the QHP is available on the Exchange website, and provide a web link to the Exchange website. This proposal to modify the disclaimer requirement in § 155.220(c)(3)(i)(A) would ensure that consumers still receive information on those QHPs for which a web-broker website does not provide enrollment support and directions to where they can obtain enrollment support.

We sought comments on these proposals. After reviewing the public comments, and for the reasons discussed in this final rule and the proposed rule, we are finalizing these requirements as proposed.

We summarize and respond to public comments received on the proposals related to required QHP comparative information on web-broker websites and the associated disclaimer.

Comment: Most commenters supported the proposals to require web-broker websites to display QHP comparative information and the associated disclaimer. Numerous commenters stated the proposals would ensure that consumers who use web-broker websites have access to standardized comparative information on QHPs so they can review, understand, and compare all available options and select the one that best fits their needs. Some commenters indicated these proposals would increase transparency on web-broker websites and reduce the risk that consumers are influenced based on the financial interests of web-brokers or by providing a favorable display of QHP information for QHPs for which the web-broker receives compensation for enrollments.

Response: We appreciate the support for the proposals related to required QHP comparative information on web-broker websites and the associated disclaimer. We agree that these proposals will increase transparency and better enable consumers using web-broker websites to compare and understand the QHP options available to them.

Comment: Some commenters stated that the proposals were a positive step, but that HHS should do more to support consumers' ability to compare plans, such as requiring web-broker websites to display all plans neutrally and refrain from segregating some QHPs at the bottom of their website pages.

Response: HHS is committed to continuing to consider ways to expand support for consumers using non-Exchange websites. However, we did not propose a requirement for the neutral display of plans in the proposed rule and note that a neutral display requirement generally is inconsistent with HHS' proposal under § 155.205(b)(1) to require web-broker websites to differentially display HHS-designed standardized plan options beginning with the PY 2023 open enrollment period in a manner consistent with how standardized plan options are displayed on *HealthCare.gov*, unless HHS approves a deviation.

We also recognize that some web-broker websites historically have displayed limited comparative information for some QHPs at the end of a list or the bottom of a website page. HHS disagrees, however, that requirements stricter than those we finalize in this rule are necessary to address these practices. Current HHS rules prohibit web-broker websites from displaying QHP recommendations based on compensation [225] an agent, broker, or web-broker receives from QHP issuers.[226] [227] Additionally, in the August 17, 2021 Web-broker website Display Bulletin,[228] we reminded web-brokers that, consistent with the prohibition in § 155.220(c)(3)(i)(L), their websites must refrain from filtering the display of QHPs in a manner that favors QHPs for which the web-broker receives compensation from issuers for enrollments. Based on our observations and experience, web-brokers that in past years displayed limited comparative information on certain QHPs at the bottom of their website pages did so because the web-broker did not have an appointment or other financial relationship with the QHPs' issuers. With the adoption of the amendments and policies in this rule, which we believe will further limit the behavior and practices identified by the commenter, we are of the view that adopting more stringent or different guidelines is not necessary at this time. Rather, the combination of the existing requirements and the changes finalized in this rule, place sufficient limitations to prevent web-broker websites from inappropriately segregating some QHPs at the bottom of their non-Exchange website pages.

Comment: Two commenters requested that we provide flexibility in terms of how the new standardized disclaimer under § 155.220(c)(3)(i)(A) must be displayed. Specifically, they expressed a preference for web-brokers to be permitted to display the disclaimer in a manner that would not require the disclaimer to be repeated next to each QHP for which it applied, so long as the website design otherwise clearly indicated to consumers for which QHPs the disclaimer applied (for example, by displaying a visual cue beside each QHP for which the disclaimer applied that references the text of the disclaimer in a single location elsewhere on the website page).

Response: We are finalizing as proposed the amendments to § 155.220(c)(3)(i)(A), to require a web-broker's non-Exchange website, to the extent that enrollment support for a QHP is not available using its non-

[224] The current plan detail disclaimer states: ''[Name of Company] isn't able to display all required plan information about this Qualified Health Plan at this time. To get more information about this Qualified Health Plan, visit the Health Insurance Marketplace® website at *HealthCare.gov*.'' See Section 5.3.2. Federally-Facilitated Exchanges (FFEs) and Federally-Facilitated Small Business Health Options Program (FF–SHOP) Enrollment Manual *(pp.53)*. (2021, August 18). *https://www.cms.gov/files/document/ffeffshop-enrollment-manual-2021.pdf*.

[225] The term ''compensation'' includes commissions, fees or other incentives as established in the relevant contract between an issuer and the web-broker.

[226] See 45 CFR 155.220(c)(3)(i)(L). See also 84 FR 17515 through 17521 and 17552 through 17553.

[227] As detailed in this rule, we are also finalizing the proposals to further expand upon and clarify the prohibition on web-broker non-Exchange websites from displaying QHP recommendations based on compensation received from QHP issuers in 45 CFR 155.220(c)(3)(i)(L).

[228] Web-broker website Display Bulletin. *(2021,* August 17*). CMS. https://www.cms.gov/files/document/web-broker-website-display-bulletinfinal08172021.pdf*.

Exchange website, prominently display a standardized disclaimer provided by HHS stating that enrollment support for the QHP is available on the Exchange website, and provide a link to the Exchange website. Historically, one of the criteria to satisfy the prominent display requirement for the plan detail disclaimer required that it be provided separately for each QHP where plan information is not displayed, and the text we provided informed consumers that the web-broker's website is not able to display all required plan information about the specific QHP(s) where the disclaimer appeared.[229] However, we recognize that our historical approach governing the prominent display of the plan detail disclaimer and the accompanying text does not translate well to the new disclaimer requirement in § 155.220(c)(3)(i)(A) finalized in this rule that shifts the focus to informing consumers about any limitations on enrollment support. Therefore, we generally agree with these commenters and intend to provide some flexibility in terms of how we will interpret and apply the requirement to prominently display the new standardized enrollment support disclaimer under § 155.220(c)(3)(i)(A). Our goal in implementing and enforcing this new requirement will be to ensure consumers are clearly informed about any enrollment limitations on a web-broker's non-Exchange website and similarly have clear instructions for accessing *HealthCare.gov* if they wish to enroll in those QHPs. We note our intent to generally apply the standards for prominent display of this new standardized disclaimer as have been described and applied previously in relation to the prominent display of other required disclaimers on web-broker websites.[230] For example, we will consider this new disclaimer to be prominently displayed if it is displayed in close proximity to where QHP plan information appears, so that it is noticeable to the consumer. As such, the new enrollment support disclaimer must be written in a font size no smaller than the majority of text on the website page, be noticeable in the context of the website by (for example) using a font color that contrasts with the background of the website page, using the exact language provided by HHS, and including a functioning link to *HealthCare.gov*. We also clarify that we will consider the display of the new enrollment support standardized disclaimer where the enrollment button (or other similar mechanisms) would otherwise appear for a particular QHP on the web-broker's non-Exchange website to comply with the criterion that the disclaimer is noticeable to consumers. We further clarify that we would similarly consider a web-broker website in compliance with this criterion if a visual cue is displayed where the enrollment button (or another similar mechanism) would otherwise appear for a particular QHP that clearly directs the consumer to the required standardized disclaimer on the same website page or otherwise displays the required standardized disclaimer (for example, in a pop-up bubble that appears while hovering over the visual cue on the website). In both circumstances, to be considered fully compliant with the prominent display framework, the enrollment support disclaimer must also be noticeable using a font color with appropriate contrasts in the context of the website page or pop-up bubble, be written in a font size that is no smaller than the majority of the surrounding text, use the exact language provided by HHS, and include a functioning link to *HealthCare.gov*. We will provide additional operational and technical guidance on the display of the enrollment support disclaimer in advance of the start of the plan year 2023 open enrollment period to allow time for implementation. We will also take appropriate steps to similarly finalize the exact language for the new disclaimer so it can be implemented in advance of the start of the next open enrollment period.

Comment: One commenter suggested we establish a safe harbor such that web-brokers are not held responsible for the accuracy of QHP comparative information obtained from Exchange public use files or the Marketplace API and displayed on their websites.

Response: Although we recognize that the Exchange public use files and Marketplace API data may contain errors, we did not propose and decline to adopt the suggested safe harbor at this time. First, we note that typically when we have discovered incorrect QHP comparative information on web-broker websites, it has not been due to incorrect Exchange data. Instead, in these circumstances, the errors have been attributable to faulty processes adopted by web-brokers to ingest and display QHP comparative information, whether the data is sourced from the Exchange or directly from QHP issuers. Second, HHS has processes in place for addressing Exchange data corrections, which includes making necessary updates to the Exchange public use files to reflect the corrections.[231] Web-brokers are expected to update the QHP comparative information on their websites when such Exchange data errors are corrected, which in cases when web-brokers are using the Marketplace API will occur automatically. We also notify web-brokers when updates are made to the Exchange public use files so web-brokers that do not use the API may make updates to their systems as needed. However, we also clarify that we would not otherwise hold web-brokers responsible in circumstances where the incorrect QHP comparative information is the result of data errors in the Marketplace public use files or Marketplace API. Consistent with the standard in § 155.220(j)(3), HHS would consider the circumstances for why a web-broker website fails to provide correct information if the web-broker otherwise acted in good faith.

Comment: One commenter requested clarification that requiring web-broker websites to display all available QHPs does not constitute a web-broker endorsing QHP issuers with which it is not appointed.

Response: The amendments to § 155.220(c)(3)(i)(A) that we are finalizing in this rule do not modify or otherwise change the long-standing requirement in § 155.220(c)(3)(i)(B) for web-broker non-Exchange websites to provide consumers the ability to view all QHPs offered through the Exchange.[232] Instead, the revisions to § 155.220(c)(3)(i)(A) that we finalize in this rule identify the required minimum QHP comparative information that must be displayed on web-broker non-Exchange websites for all available QHPs in the applicable consumer's area. In response to the comment, we further acknowledge that requiring web-broker websites to display all available QHPs regardless of appointment status with QHP issuers should not be perceived as

[229] Federally-Facilitated Exchange (FFE) and Federally-Facilitated Small Business Health Options Program (FF–SHOP) Enrollment Manual (pp. 53–54). (2021, August 18). *https://www.regtap.info/uploads/library/ENR_FFEFFSHOPEnrollmentManual2021_5CR_090921.pdf.*

[230] Ibid. Also see *Guidance for Web-brokers on Displaying Mandatory Standardized Disclaimers.* (2015, April 24). CMS. *https://www.cms.gov/cciio/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Guidance-web-brokers-displaying-disclaimers.pdf.*

[231] Health Insurance Exchange Public Use Files (Exchange PUFs) General Information. (2022). CMS. *https://www.cms.gov/files/document/exchange-pufs-geninfofacts-py22.pdf.*

[232] This requirement was previously codified at § 155.220(c)(3)(ii) and first established in regulations that were effective in 2012. See 77 FR 18309 at 18334 through 18336 and 18449. It is designed to ensure that web-broker websites provide consumers with access to the same information they would have if they used the Exchange website. See 77 FR 18335–18336.

an endorsement of QHP issuers with which the web-broker is not appointed.

Comment: One commenter requested that we clarify whether § 155.220(c)(3)(i)(A)(*6)* requires web-broker websites to host static files or whether they are permitted to provide links to issuers' websites in instances where information is subject to change and may be best presented dynamically (for example, in the case of provider directories).

Response: We clarify that, as finalized, § 155.220(c)(3)(i)(A)(*6*) requires web-broker non-Exchange websites that assist consumers with Exchange enrollments to include the provider directory made available to the Exchange under § 156.230 as part of the required minimum QHP comparative information. We further clarify that web-broker websites that provide a link to the appropriate provider directory web pages on the applicable QHP issuer's website would satisfy this requirement. The provider directory field in the Exchange public use files consists of links to the applicable QHP issuers' provider directory website pages. Finally, we remind web-brokers and other stakeholders, that web-broker websites may obtain the required QHP comparative information from the Exchange (that is, from the Exchange public use files or Marketplace API) or directly from QHP issuers, as reflected in the introductory clause at § 155.220(c)(3)(i)(A).

Comment: Two commenters opposed these proposals. One commenter stated that these proposals will add little value for consumers; harm the consumer experience when using web-broker websites; and make it more difficult for web-brokers to serve their consumers. This commenter suggested that the goal of these changes may be to drive consumers to use *HealthCare.gov*. Another commenter expressed concern that these proposals encroach on State authority to regulate the business of insurance and mentioned a possible, unspecified conflict with existing State regulations.

Response: We respectfully disagree that these changes will harm consumers. We believe that these changes will instead make it easier for consumers to compare QHPs when using web-broker websites and identify the best option for their unique circumstances. For example, if web-broker websites are not required to provide basic QHP comparative information for all available QHPs, such as premium and cost-sharing information, there is no reasonable way for consumers using those websites to compare all available options other than navigating to multiple websites. Therefore, we also believe these changes will make it easier, rather than more difficult, for web-brokers to assist their customers. This also is not an attempt to drive consumers away from non-Exchange websites. The existing web-broker plan detail disclaimer requirement mandates that consumers are provided a functional link to *HealthCare.gov*. The maintenance of such a requirement for the new disclaimer that must appear when the web-broker website does not support enrollment in a QHP is an appropriate and necessary exercise of HHS' authority to establish requirements governing web-broker participation in FFEs and SBE–FPs. We remain committed to the FFE direct enrollment program and believe consumers should have access to multiple options to enroll in coverage. In addition, we emphasize that these changes largely codify existing policies for the interim approach in place beginning with the PY 2022 open enrollment period pending future rulemaking on these issues. They also represent an appropriate evolution of our enforcement approach regarding the required display of QHP comparative information on web-broker websites under § 155.220(c)(3)(i)(A). While we released more limited QHP details in the early years of Exchanges, that is no longer the case. QHP plan information has been more readily accessible for some time, both through public use files and the Marketplace API. In addition, enrollment through direct enrollment channels (including web-broker websites) has continued to grow year after year.[233] Therefore, we continued to consider these issues over the years and continue to believe the approach finalized in this rule is in the best interests of Exchange consumers using web-broker websites because it will aid them in comparing QHP options without having to navigate to multiple websites.

With respect to the commenter that expressed concern about encroachment on State regulatory authority or alleged conflict with State regulations, we note that the requirement to display QHP comparative plan information and use an appropriate disclaimer has been part of the framework governing the use of web-broker websites since the inception of the Exchanges.[234] We are not aware of any potential conflicts with existing State regulations and generally welcome information from State regulators or other stakeholders about any specific suspected conflicts. We also remain committed to working collaboratively with States with respect to issues related to agent and broker participation in the FFEs and SBE–FPs, including with respect to any issues that may cause confusion for web-brokers as to what is expected of them with respect to website display requirements applicable in FFE and SBE–FP States.

b. Prohibition of QHP Advertising on Web-Broker websites

Section 155.220(c)(3)(i)(L) currently prohibits web-broker non-Exchange websites from displaying QHP recommendations based on compensation[235] an agent, broker, or web-broker receives from QHP issuers. In the proposed rule (87 FR 643), we proposed to amend § 155.220(c)(3)(i)(L) to provide that web-broker non-Exchange websites are also prohibited from displaying QHP advertisements, or otherwise providing favored or preferred placement in the display of QHPs, based on compensation agents, brokers, or web-brokers receive from QHP issuers.

We are finalizing the proposal to amend § 155.220(c)(3)(i)(L) to ensure that QHP advertisements are not mistakenly understood as QHP recommendations that the web broker deems to be in the best interest of the consumer. As we discuss in greater detail in the responses to the comments in this section, the intent of this amendment is to ensure that consumers are able to make informed decisions about the best option for their specific circumstances, and are not influenced by favorable placement based on advertising or compensation from issuers to agents, brokers, or web-brokers. However, this amendment is not intended to stifle innovative developments, such as filtering, that can help inform customers of the options that best fit their needs.

We sought comment on the proposed amendments to § 155.220(c)(3)(i)(L) and the prohibition on QHP advertising on web-broker websites, which we summarize and respond to below.

Comment: Most commenters supported the proposals related to

[233] See, for example, *CMS Releases Final Snapshot for the 2021 Federal Exchange Open Enrollment Period.* (2021, January 12). CMS.*https://www.cms.gov/newsroom/press-releases/cms-releases-final-snapshot-2021-federal-exchange-open-enrollment-period.*

[234] We note at the time this regulatory provision was codified at § 155.220(c)(3)(i). See 78 FR 54134 and 54135.

[235] The term ''compensation'' includes commissions, fees or other incentives as established in the relevant contract between an issuer and the web-broker. See 84 FR 17515.

§ 155.220(c)(3)(i)(L) and the prohibition on QHP advertising on web-broker websites, or otherwise providing favored or preferred placement in the display of QHPs based on compensation agents, brokers, or web-brokers receive from QHP issuers. One commenter asserted that the display of QHPs on web-broker websites should be based on factors that will help consumers choose the best option for their needs and allowing preferred placement of QHPs based on compensation from issuers does not place consumer interests first. Another commenter noted that agents, brokers, and web-brokers have not been required to provide unbiased information to consumers, and this proposal would help improve transparency for consumers. One commenter stated that this proposal will improve the shopping experience on web-broker websites by increasing the likelihood that consumers select plans that are the best fit for them based on costs, benefits, provider networks, and drug formularies instead of advertising paid for by issuers. Another commenter stated web-broker websites should not direct a consumer toward a plan unless the direction is based on that consumer's needs. One commenter indicated they were supportive of the proposals to ensure consumers using web-broker websites are not provided biased information in a way that benefits the advertiser rather than the consumer. Many other commenters shared similar sentiments as those described above.

Response: We appreciate comments in support of the proposed amendments to § 155.220(c)(3)(i)(L) and the prohibition on QHP advertising on web-broker websites. We agree that the display of QHPs on web-broker websites should be based on factors that assist consumers in making informed decisions about the best option for their specific circumstances, and should not be influenced by favorable placement based on advertising or compensation from issuers to agents, brokers, or web-brokers. After consideration of comments, we are finalizing as proposed the amendments to § 155.220(c)(3)(i)(L) and the prohibition on QHP advertising on web-broker websites.

At the same time, we remain committed to the development and use of innovative consumer-assistance tools by web-brokers to help consumers select QHPs that best fit their needs. As such, we also clarify that web-brokers will continue to be able to offer filtering capabilities or decision support tools that the consumer can use to navigate or refine the display of QHPs consistent with existing CMS guidelines.[236] For example, a web-broker can offer consumers additional sort functionality to alter the order of the QHPs listed, as long as the web-broker website still provides consumers the ability to view all QHPs offered through the Exchange regardless of how the consumer chooses to sort the QHPs (for example, from lowest to highest premium or deductible). A web-broker may also allow the consumer to apply filters (for example, metal level, provider network type, issuer) to the full list of available QHPs to refine the consumer's search. If a consumer selects a certain filter (for example, bronze metal level), the web-broker website must display all QHPs offered through the relevant Exchange that satisfy that filter's description. The use of any filters or tools must comply with other applicable requirements; for example, the use of filters or other tools to refine the display of QHPs cannot result in the favorable placement of those QHPs for which a web-broker receives compensation for enrollments in relation to all other available QHPs consistent with § 155.220(c)(3)(i)(L) and applicable guidance on permissible filtering of QHPs on web-broker websites. We believe that the framework for the display of QHP information captured in § 155.220(c)(3)(i), as amended by this rule, coupled with the flexibility to develop innovative consumer assistance tools to filter or refine the list of available QHPs strikes the right balance to protect and support consumers enrolling in Exchange coverage through web-broker websites.

In response to commenters stating web-broker websites have not been required to provide unbiased information, we note a variety of requirements have been in place for some time that require web-broker websites to provide consumers information about QHPs in an unbiased fashion. For example, § 155.220(c)(3)(i)(B) requires web-broker websites to provide consumers the ability to view all QHPs offered through the Exchange without respect to compensation arrangements web-brokers have with QHP issuers. Similarly, § 155.220(c)(3)(i)(A) has required web-broker websites to provide certain QHP comparative information for all available QHPs or a standardized disclaimer with a link directing consumers to the Exchange in cases when the comparative information is not provided; we note that we are also taking additional steps in this rule to ensure consumers using web-broker websites have access to the same information for all available QHPs as they would if they used the Exchange website. In addition, § 155.220(c)(3)(i)(L) already prohibited web-broker websites from displaying QHP recommendations based on compensation agents, brokers, or web-brokers receive from QHP issuers and will be further enhanced by the changes to § 155.220(c)(3)(i)(L) finalized in this rule that will further protect consumers by prohibiting QHP advertising and preferred placement of QHPs on web-broker websites based on compensation from QHP issuers.

Comment: One commenter did not oppose the proposal if it is limited to advertising or preferred placement based on compensation from issuers on web-broker website pages for enrollment through the Exchange (that is, if the prohibition does not apply to web-broker website pages marketing non-QHPs and QHPs for enrollment outside the Exchange). Another commenter requested clarification that the proposal was not intended to prohibit advertising on website pages marketing other non-QHP product types, and that the proposal was instead intended only to apply the prohibition to web-broker website pages supporting enrollment in QHPs through the Exchange.

Response: We clarify the amendment to § 155.220(c)(3)(i)(L) and the prohibition on QHP advertising only applies to web-broker website pages displaying or marketing QHPs for enrollment through the Exchange. In other words, this framework would extend to web-broker websites and pages for which enrollment would occur through a direct enrollment pathway (including both the Classic and Enhanced direct enrollment pathways). It would not, however, extend to other web-broker website pages, such as those marketing products—whether QHPs or non-QHPs—for enrollment outside the Exchange. We did not propose to extend it in this manner because the framework in § 155.220 is part of the procedures the Secretary established under section 1312(e) of the ACA under which agents and brokers (including web-brokers) can enroll consumers in QHPs offered through Exchanges.

Comment: One commenter recommended that the proposed prohibition on QHP advertising and preferred placement on web-broker websites not be interpreted to prohibit the display of additional QHP information beyond the required QHP comparative information for a subset of QHPs. The commenter explained that

[236] Web-broker website Display Bulletin. (2021, August 17). CMS. *https://www.cms.gov/files/document/webbroker-website-display-bulletinfinal08172021.pdf.*

some web-brokers have arrangements with issuers to display information about plan designs or features that include the display of information not available in Exchange public use files or the Marketplace API, and that the display of this additional information can highlight distinctions between plans and help consumers select plans that best meet their needs.

Response: We did not propose and are not finalizing a general prohibition on web-broker websites displaying QHP information beyond what is provided by the Exchange (for example, made available in the Exchange public use files or through the Marketplace API) or directly from QHP issuers. Similarly, we confirm that the requirement to display minimum required QHP comparative information captured in § 155.220(c)(3)(i)(A)(*1*) through (*6*) as finalized in this rule does not prohibit the display of additional QHP information the web-broker obtains directly from QHP issuers. We further note and confirm that the regulatory text at § 155.220(c)(3)(i)(A) envisions that QHP information would be provided to web-brokers by Exchanges and QHP issuers. At the same time, however, web-brokers that elect to display such additional information must ensure compliance with other applicable requirements. For example, the display of additional information received from an issuer for its QHPs cannot result in the favorable placement of those QHPs in relation to all other available QHPs consistent with § 155.220(c)(3)(i)(L) and applicable guidance on permissible filtering of QHPs on web-broker websites.[237] Similarly, any payments received from QHP issuers to display additional information on web-broker websites cannot result in favored or preferred placement in the display of QHPs on the web-broker's website.

Comment: One commenter supported the proposal only in the context of consumer-facing web-broker websites, and requested different treatment of agent/broker-facing web-broker websites.[238] The commenter expressed concern that if the proposal applied to agent/broker-facing web-broker websites, it could inadvertently jeopardize innovation by web-brokers related to educating agents and brokers about a large number of QHP offerings, in particular those offered by new market entrants, and differences in the design of those QHPs' benefits, networks, and other plan features. Similarly, the commenter further explained that web-brokers often host issuer direct enrollment websites [239] based on compensation from issuers and in doing so often provide additional features or integrations associated with those issuer partnerships that are available to agents and brokers using their web-broker websites (for example, better premium payment integration, the ability to enroll in the issuers' plans outside the Exchange), and was concerned the proposed amendments to § 155.220(c)(3)(i)(L) would disincentivize the development of these additional features.[240] Lastly, the commenter requested clarification that visual cues associated with the display of particular issuers' QHPs on a web-broker's website (for example, to indicate the availability of additional functionality such as payment integration) are not prohibited by this proposal.

Response: We appreciate that some web-brokers may wish to have additional flexibility and provide additional resources to their agent and broker partners. The amendments to § 155.220(c)(3)(i)(L) and the prohibition of QHP advertising on web-broker websites, which we are finalizing as proposed, apply to web-broker websites used to enroll consumers in Exchange coverage whether or not the web-broker websites are consumer-facing (that is, intended to be used by consumers independently) or agent/broker-facing (that is, intended to be used by agents or brokers assisting consumers). They are intended to prohibit these activities to the extent they constitute advertising, preferred placement, favorable display, or other types of promotion of particular QHPs based on payment from the issuers offering those QHPs. These changes build on the existing prohibition on the display of QHP recommendations based on the compensation received by the agent, broker, or web-broker from QHP issuers.

As finalized, § 155.220(c)(3)(i)(L) does not prohibit web-brokers from educating agents and brokers generally about the availability and nature of new plan designs or plan features, or the existence of QHPs offered by issuers that have newly entered a market. Web-brokers may educate agents and brokers by offering filtering capabilities that enable agents and brokers to quickly identify particular QHPs with certain characteristics and corresponding training on the existence and purpose of those filtering capabilities. Similarly, § 155.220(c)(3)(i)(L) does not apply to additional features web-brokers may make available to QHP issuers that engage them to develop or maintain an issuer-specific direct enrollment website through which individual consumers—or persons assisting consumers such as agents and brokers—may view information on and complete enrollment in the issuers' QHPs,[241] so long as the means through which web-brokers inform agents and brokers of such features do not constitute advertising, preferred placement, favorable display, or other types of promotion of particular QHPs based on compensation from the issuers offering those QHPs. For example, § 155.220(c)(3)(i)(L) is not intended to prohibit a web-broker from informing its agent or broker clients of the availability of particular features on its web-broker website that may only be available for particular issuers' QHPs,[242] such as enhanced payment integration or the ability to enroll in an issuer's plans outside the Exchange, because it is possible to provide that information without it being presented as advertising, preferred placement, favorable display, or other types or means of promotion of particular QHPs. Lastly, in response to comments, we clarify that visual cues (such as an icon)

[237] *Ibid.*

[238] Consumer-facing web-broker websites are those used independently by consumers without the assistance of an agent or broker. Agent/broker-facing web-broker websites are used by agents or brokers assisting consumers; in this case, the consumers agents or brokers are assisting may never view the web-broker websites that are being used by the agents or brokers assisting them. Generally, Exchange rules governing web-broker websites do not distinguish between consumer-facing and agent/broker-facing web-broker websites. However, this commenter requested that we create such a distinction.

[239] Web-brokers may function as QHP issuer direct enrollment technology providers. See § 155.20.

[240] In this case, we believe the commenter is intending to convey that a QHP issuer relying on a web-broker as a QHP issuer direct enrollment technology provider would be less likely to engage the web-broker to provide these additional features (whether only on its issuer-specific direct enrollment website or through the web-broker's own website) if it could not also pay the web-broker to advertise the availability of its QHPs and these additional features to agents and brokers using its web-broker website.

[241] Here, and elsewhere, when we refer to a web-broker's website without indicating it is an issuer-specific website hosted by a web-broker acting as a QHP issuer direct enrollment technology provider, we are referring to the web-broker's own non-Exchange website subject to the requirements of § 155.220(c) and other applicable rules governing such web-brokers and their non-Exchange websites subject to the requirements of § 155.220(c).

[242] As described earlier in this rule, web-broker websites may not support enrollment in all available QHPs. Web-broker websites may provide additional comparative information about some QHPs that they have obtained directly from QHP issuers (for example, comparative information not available in the Exchange public use files or Marketplace API). Similarly, web-broker websites may provide additional features that may only be available for particular issuers' QHPs, such as enhanced payment integration or the ability to enroll in an issuer's plans outside the Exchange.

associated with the display of particular issuers' QHPs (for example, to indicate the availability of additional functionality such as payment integration) are also not prohibited. However, we reiterate that any related compensation or payment received by such web-brokers from QHP issuers to display additional information must not result in the favorable placement of those QHPs in relation to all other available QHPs consistent with § 155.220(c)(3)(i)(L) and our guidance on permissible filtering of QHPs on web-broker websites.

Comment: One commenter expressed concern that the proposal could limit the ability of web-broker websites to offer tools, such as filtering capabilities, that enhance the user experience. The commenter requested we clarify that functionality that allows plan filtering based on user preferences (presumably consumer or agent/broker users) is not prohibited, even if the result of a particular user's filtering choices is to favor the display of plans for which the web-broker receives compensation for enrollments.

Response: We agree that it is important that web-brokers continue to have the flexibility to offer certain permissible filtering tools to assist Exchange consumers shopping for QHPs on web-broker non-Exchange websites. As noted earlier, we remain committed to supporting the development and use of innovative consumer-assistance tools by web-brokers to help consumers select QHPs that best fit their needs, but reiterate that such tools must comply with other applicable requirements. This includes, but is not limited to, the existing prohibition on the display of QHPs based on the compensation received by the agent, broker, or web-broker, as well as the amendment to § 155.220(c)(3)(i)(L) and the prohibition of QHP advertising on web-broker websites we are finalizing in this rule. When used in this context, ''advertisements'' include any form of marketing or promotion of QHPs based on payment from QHP issuers. Consistent with existing CMS guidance on permissible filters,[243] this would not prohibit a web-broker non-Exchange website from offering consumers filtering capabilities that, when applied neutrally, happen to result in the favorable display of QHPs offered by issuers from whom the web-broker receives compensation for enrollment in those QHPs. For example, HHS would not deem a web-broker website out of compliance with applicable requirements, as finalized in this rule, if a neutral filter selected by the consumer orders all available QHPs from lowest to highest premium and the lowest premium QHPs happen to be ones for which the web-broker received compensation or payment from QHP issuers. In such circumstances, the web-broker website would need to include the required minimum QHP comparative information (including premium) for all available QHPs and the default listing of QHPs on the web-broker website would need to provide that information for all QHPs offered on the Exchange by all QHP issuers, unless the consumer or agent/broker using the web-broker's non-Exchange website actively removes that default filter. Similarly, if an otherwise neutral filter is available for a consumer that, if selected, produces a list favoring a particular issuer's QHPs (for example, a filter that limits the display of QHPs to those offered by specific issuers actively selected by the consumer), making that filter available is not prohibited so long as the web-broker website complies with other applicable requirements. This would include the use of a default listing of QHPs that includes the required minimum QHP comparative information for all QHPs offered on the Exchange unless the consumer actively removes the default filter.

Comment: One commenter expressed concern that the proposal would prohibit web-brokers from listing QHPs offered by issuers with which it is appointed and from whom it receives compensation for enrollments favorably as compared to those offered by issuers with which it is not appointed (that is, listing all of the former before all of the latter).

Response: In the 2020 Payment Notice (84 FR 17454), we codified the existing prohibition on the display of QHP recommendations based on compensation the agent, broker, or web-broker receives from QHP issuers. In addition, as explained above, we have transitioned from the use of enforcement discretion that permitted web-brokers to only display issuer marketing name, plan marketing name, product network type, and metal level for some QHPs, beginning with the PY 2022 open enrollment period. As part of this transition, we also previously clarified that with web-broker websites displaying standardized QHP comparative information for all available QHPs beginning with the PY 2022 open enrollment period, to comply with the current standard in § 155.220(c)(3)(i)(L) that prohibits the display of QHP recommendations based on compensation an agent, broker, or web-broker receives from QHP issuers, web-broker websites must refrain from filtering the display of QHPs in a manner that favors QHPs for which the web-broker receives compensation from issuers for enrollments. In other words, consistent with currently applicable requirements, web-brokers must not display some QHPs at the bottom of their website pages simply because they are not appointed with the issuers that offer those QHPs. We did not propose to change the prohibition on the display of QHPs based on the compensation received by an agent, broker, or web-broker from QHP issuers for enrollment in QHPs. Instead, we proposed and are finalizing the extension of the prohibition under § 155.220(c)(3)(i)(L) to also prohibit advertising of QHPs on web-broker websites. As outlined above, to comply with the new framework and applicable requirements, web-broker websites cannot more favorably display QHPs for which the agent, broker, or web-broker receives compensation from issuers for enrollment in QHPs and also cannot more favorably display QHPs for which the agent, broker, or web-broker receives payment for advertising purposes. This includes a prohibition on the favorable display based on which QHPs are offered by issuers with whom the agent, broker, or web-broker has an appointment.[244]

Comment: Two commenters were opposed to this proposal. One commenter asserted that prohibiting QHP advertising on web-broker websites lessens the incentive for web-brokers to become direct enrollment entities and continue to innovate. Instead, the commenter suggested we allow QHP advertising, but require that advertisements be identified as such. Another commenter conveyed concern about this proposal encroaching on State authority to regulate the business of insurance and mentioned a nonspecific possible conflict with existing State regulations.

Response: We appreciate the concern that prohibiting QHP advertising on web-broker websites may reduce incentives to become a direct enrollment entity, but do not believe that risk outweighs the benefit to consumers of the prohibition. We

[243] Web-broker Website Display Bulletin. (2021, August 17). CMS. *https://www.cms.gov/files/document/webbroker-website-display-bulletinfinal08172021.pdf.*

[244] See the previous preamble regarding the new standardized disclaimer under § 155.220(c)(3)(i)(A), as amended, for details on how information about which QHPs the web-broker website does not support enrollment in should be shared with consumers. Not having an appointment with a particular issuer is the primary reason why web-broker websites would not support enrollment in particular QHPs.

considered the option of allowing some form of QHP advertising so long as the advertisements were clearly identified as advertisements. However, as described in the proposed rule (87 FR 643), even if QHP advertisements are clearly identified, we believe it is not in the interest of consumers to allow them on web-broker websites that facilitate enrollment in Exchange coverage.

With respect to commenters that expressed concern with encroachment on State regulatory authority or alleged conflict with State regulations, we note that the requirement at § 155.220(c)(3)(i)(L) prohibiting web-broker websites from displaying QHP recommendations based on compensation an agent, broker, or web-broker receives from QHP issuers is not new.[245] For additional information in response to this comment, please see the response to the same comment on the prior proposal in III.D.3.(a).

c. Explanation of Rationale for QHP Recommendations on Web-Broker Websites

In the proposed rule (87 FR 643), we proposed to amend § 155.220 to add a new paragraph (c)(3)(i)(M) that would require web-broker websites to prominently display a clear explanation of the rationale for explicit QHP recommendations and the methodology for the default display of QHPs on their websites (for example, alphabetically based on a plan name, from lowest to highest premium, etc.).

We are finalizing this requirement because we believe it will provide consumers with a better understanding of the information being presented to them on web-broker websites and enable them to make better informed decisions and select QHPs that best fit their needs. We believe that a clear explanation for the bases of the recommendations displayed to them on web-broker websites (whether explicit or implicit), will help consumers assess the value of the recommendations (for example, whether a recommendation is based on the factors most important to them).

We sought comment on this proposal, which we summarize and respond to below.

Comment: Most commenters supported this proposal and the addition of § 155.220(c)(3)(i)(M). Several commenters stated that requiring web-broker websites to disclose the basis for their plan recommendations and display of plans increases transparency. Numerous other commenters who supported these changes stated these changes would help consumers be better informed. One commenter indicated this would enhance decision support tools for consumers and increase the chance they find the plan that best meets their needs.

Response: We agree that this proposal and the addition of § 155.220(c)(3)(i)(M) will increase transparency and ensure consumers are better informed and more likely to choose the plan that is best for them.

Comment: Several commenters requested web-broker websites be afforded flexibility in terms of the content and placement of the required explanations. In particular, some commenters requested that the required explanations not be so detailed that they are difficult for consumers to understand and may dissuade some consumers from completing the enrollment process.

Response: We appreciate the desire for flexibility and do not intend to be prescriptive in terms of the content or placement of the required explanations of the rationale for QHP recommendations or the methodology for the default display of QHPs. We understand there are currently many variations in the design and content of web-broker websites and it would be difficult to develop a one-size-fits all standardized approach with respect to the content or placement of the explanations. In addition, there will necessarily be variations in the rationales for the plan recommendations and methodologies for the default display of plans used by different web-broker websites and they may also frequently change. For those reasons, we intend to allow web-broker websites significant flexibility in terms of the content and placement of the required explanations as long as the explanations are prominently displayed, clearly articulated, and provide consumers reasonable insight into the rationale for the QHP recommendations and the methodology for the default display of QHPs. We expect explanations to be short and easy for consumers to understand. Generally, we believe that a single phrase or a few sentences will suffice (for example, ''we recommend this plan because it has the lowest monthly premium and includes your preferred providers in-network''; ''plans are displayed alphabetically''; ''plans are displayed from lowest to highest premium''). To be considered prominently displayed, web-broker websites must adhere to the same general requirements that apply to disclaimers that must be prominently displayed on web-broker websites.[246] For example, the explanations must be written in a font size no smaller than the majority of text on the website page and be noticeable in the context of the website by (for example) using a font color that contrasts with the background of the website page.

Comment: Several commenters expressed concerns that the complex algorithms web-broker websites may have developed to produce their plan recommendations or default plan displays are likely too complicated to explain in a consumer-friendly manner. Some other commenters worried that requiring these explanations may require the disclosure of closely-held proprietary information.

Response: As explained previously, the intent of § 155.220(c)(3)(i)(M) is not to require lengthy or complicated explanations, but to provide consumers basic insight into the key factors underlying the information web-broker websites are presenting to consumers (or agents/brokers assisting consumers). We understand that in some cases web-broker websites may have adopted very complex algorithms for plan recommendations or default display of plans, and we do not intend that the intricate details underlying those proprietary models be described or disclosed. However, we expect in all cases there are core principles or criteria that form the foundation for QHP recommendations or default display methodologies and we do expect those to be disclosed to assist the consumer with making informed choices. We continuously review web-broker websites and will consider future updates and clarifications to this policy based on lessons learned and our experience implementing this new standard for web-broker websites.

d. Federally-Facilitated Exchange Standards of Conduct (§ 155.220(j))

In the proposed rule (87 FR 644), we proposed to amend § 155.220(j)(2)(i) such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. As we explain in the **SUPPLEMENTARY INFORMATION** section earlier in the

[245] See 84 FR 17563.

[246] See, for example, Federally-Facilitated Exchange (FFE) and Federally-Facilitated Small Business Health Options Program (FF–SHOP) Enrollment Manual (pp. 53–54). (2021, August 18). *https://www.regtap.info/uploads/library/ENR_FFEFFSHOPEnrollmentManual2021_5CR_090921.pdf.* Also see *Guidance for Web-brokers on Displaying Mandatory Standardized Disclaimers.* (2015, April 24). CMS. *https://www.cms.gov/cciio/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Guidance-web-brokers-displaying-disclaimers.pdf.*

preamble, HHS will address this policy, as well as the public comments submitted in response to this proposal, in future rulemaking.

i. Providing Correct Information to the FFEs

In the proposed rule (87 FR 644), we proposed to add new § 155.220(j)(2)(ii)(A) through (D) to codify additional details regarding the requirement that agents, brokers, and web-brokers provide correct information to FFEs and SBE–FPs. More specifically, we proposed to capture specific examples of what it means to provide correct information to the FFEs and SBE–FPs for the consumer's email address, mailing address, telephone number, and household income projection based on our experience operating the FFEs and the Federal platform on which certain State Exchanges rely. We also proposed to amend § 155.220(j)(2)(ii) to make clear that the proposed standards of conduct related to agents, brokers, and web-brokers providing the FFEs and SBE–FPs with correct information listed in new § 155.220(j)(2)(ii)(A) through (D) are not exhaustive, but are simply illustrative of areas where HHS has identified a need for more direct and clear guidance. We refer readers to the proposed rule (87 FR 644 through 647) for additional information and background on these proposals.

We are generally finalizing as proposed § 155.220(j)(2)(ii)(A) through (D), except that we are not finalizing the proposal to add § 155.220(j)(2)(ii)(A)(*1*) that would have prohibited agents, brokers, and web-brokers from entering consumer email addresses with 'disposable' domains that expire after a set period of time.[247] [248] We considered that agents, brokers, and web-brokers do not control the type of email domains consumers choose to use, own, or have access to. We also considered that there are available alternatives that HHS could use to systematically block the entry of disposable email addresses that expire after a set period of time.

We are finalizing the other provisions we proposed to under new § 155.220(j)(2)(ii)(A), which provide that an agent, broker, or web-broker may only enter an email address on an application for Exchange coverage or for APTC and CSRs for QHPs sold through an FFE or SBE–FP that belongs to the consumer or the consumer's authorized representative. The regulation text also clarifies that email addresses may only be entered on applications submitted to an Exchange with the consent of the consumer or the consumer's authorized representative, and that properly entered email addresses are required to adhere to certain guidelines. The guidelines we are finalizing in this rule, which were proposed to be added at new § 155.220(j)(2)(ii)(A)(*2*) and (*3*), will be captured in new § 155.220(j)(2)(ii)(A)(*1*) through (*2*), which are renumbered consistent with our decision to not finalize § 155.220(j)(2)(ii)(A)(*1*). We are otherwise finalizing these two guidelines for email addresses as proposed.

We are also finalizing the proposal to add new § 155.220(j)(2)(ii)(B), which provides that an agent, broker, or web-broker may only enter a telephone number on an application for Exchange coverage or an application for APTC and CSRs for QHPs that belongs to the consumer or their authorized representative designated in compliance with § 155.227. We reiterate that a telephone number belongs to the consumer if they, or their authorized representative, are accessible at the number and have access to the number. We are also finalizing the addition of text to § 155.220(j)(2)(ii)(B) to provide that telephone numbers entered on applications submitted to an Exchange may not be the personal number or business number of the agent, broker, or web-broker assisting with or facilitating enrollment through an FFE or assisting the consumer in applying for APTC and CSRs for QHPs, or their business or agency, unless the telephone number is actually that of the consumer or their authorized representative.

We are finalizing the proposal to add new § 155.220(j)(2)(ii)(C), which requires that an agent, broker, or web-broker may only enter a mailing address on an application for Exchange coverage or application for APTC and CSRs for QHPs that belongs to, or is primarily accessible by, the consumer or their authorized representative designated in compliance with § 155.227. We reiterate that consumer mailing addresses entered on applications submitted to an Exchange must not be for the exclusive or convenient use of the agent, broker, or web-broker, and must be an actual residence or a secure location where the consumer or their authorized representative may receive correspondence, such as a P.O. Box or homeless shelter. We are also finalizing that mailing addresses entered on applications submitted to an Exchange may not be that of the agent, broker, or web-broker, or their business or agency, unless it is the rare situation where that address is the actual residence of the consumer or their authorized representative.

Fourth, to minimize consumer harm stemming from the APTC reconciliation process on the tax return, as well as to protect Exchange operations from inaccurate APTC and CSR determinations, we are finalizing § 155.220(j)(2)(ii)(D), which requires that, when submitting household income projections used by the Exchange to determine a tax filer's eligibility for APTC in accordance with § 155.305(f) or CSRs in accordance with § 155.305(g), an agent, broker, or web-broker may only enter a household income projection for a consumer that the consumer (or the consumer's authorized representative designated in compliance with § 155.227) has authorized and confirmed is an accurate estimate of their household income. Failure to provide correct information on household income can harm consumers by creating liability during the APTC reconciliation process on the tax return or delaying the issuance of a tax refund, as well as preventing the efficient operation of the Exchange. CSRs are similarly tied to a consumer's household income reducing the amount that certain eligible individuals have to pay for deductibles, copayments, and coinsurance. Incorrect projections of a consumer's household income would also lead to incorrect CSR determinations, which would harm QHP issuers and prevent the efficient operation of the Exchange. We reiterate that good-faith income projections, versus an income projection designed to achieve the lowest monthly rate, would better protect the consumer from the unexpected cost and burden of repaying large amounts of APTC.

Finally, for greater clarity, the regulation text we adopt in this final rule at § 155.220(j)(2)(ii)(A) through (D) contains a non-substantive change to each proposed paragraph (A) through (D) to eliminate duplicate references to information ''on an Exchange application'' or ''entered on an Exchange application.'' These editorial revisions in no way change or otherwise

[247] Gibbs, M. (2006) Disposable email addresses foil marketing plan, Real but temporary email addresses to get you through the verification process. *NetworkWorld. https://www.networkworld.com/article/2301492/disposable-email-addresses-foil-marketing-plans.html.*

[248] We also removed the reference to this standard (that is, the phrase ''that is secure, not disposable'' was removed) in the introductory language in § 155.220(j)(2)(ii)(A). In addition, we are capturing the email address guidelines proposed to be added at new § 155.220(j)(2)(ii)(A)(*2*) and (*3*) in new § 155.220(j)(2)(ii)(A)(*1*) through (*2*) instead. We also make a non-substantive change to eliminate duplicate references to information ''on an Exchange application'' in § 155.220(j)(2)(ii)(A) through (D).

affect the requirements under the proposed versions of the text and more clearly and consistently indicate that the applications that are the subject of these provisions are applications submitted to Exchanges for coverage under a QHP, with or without APTC and CSR.

We sought comment on these proposals. After reviewing the public comments, and as stated above, we will not finalize § 155.220(j)(2)(ii)(A)(*1*) concerning disallowing agents, brokers, and web-brokers entry of temporary email addresses on consumers' behalf because agents, brokers, and web-brokers do not control the type of email domains consumers choose to use, own, or have access to. However, we are finalizing the other sections as proposed.[249] While we are not finalizing § 155.220(j)(2)(ii)(A)(*1*), we strongly encourage agents, brokers, and web-brokers to avoid using such temporary email addresses in applications as a best practice.

We summarize and respond to public comments received on the proposals related to the standard in § 155.220(j)(2)(ii) that agents, brokers, and web-brokers provide correct consumer information to the FFEs below.

Comment: A number of commenters supportive of the proposal generally requested that HHS dedicate funds to compliance, monitoring, and enforcement efforts in order to address agent, broker, and web-broker compliance with relevant Exchange standards of conduct. While the majority of comments pertaining to monitoring and enforcement were general in nature, several commenters indicated they supported continuing to clarify standards of agent, broker, and web-broker conduct. One commenter also recommended that Exchange user fees could be used to fund future oversight initiatives.

Response: We are finalizing, as proposed, the amendments to § 155.220(j)(2)(ii) and the accompanying policies related to the provision of correct consumer information by agents, brokers, and web-brokers to the FFEs. These finalized amendments and policies also apply to agents, brokers, and web-brokers assisting with enrollments in SBE–FPs.[250] The amendments to § 155.220(j)(2)(ii) provide clear, concise, and direct guidance to agents, brokers, and web-brokers assisting consumers with enrollment in QHPs sold on the FFEs and SBE–FPs about the standards of conduct and behavior expected of them. We also generally note that we intend to include these new, clarifying standards as part of existing monitoring and oversight of agents, brokers, and web-brokers assisting consumers with enrollments through FFEs and SBE–FPs. We appreciate the recommendations provided. They will be taken into consideration for future rulemaking and policy development. However, we are not finalizing the amendment to § 155.220(j)(2)(ii)(A)(*1*) because agents, brokers, and web-brokers do not control the type of email domains consumers choose to use, own, or access.

Comment: Many commenters supportive of the proposal requested that HHS add regulatory text to require agents, brokers, and web-brokers to check consumers' eligibility for Medicare and Medicaid in addition to their eligibility for private insurance through the FFEs.

Response: We agree with the commenters that consumers eligible for Medicare and Medicaid should be informed about those options. Indeed, in order to enroll a consumer in QHP coverage on the Exchange, agents, brokers, and web-brokers must use the Exchange's Single Streamlined Application, which first verifies Medicare and Medicaid eligibility, where applicable. If a web-broker's website is used to complete the application, the application and website must, among other requirements, request the minimum amount of information to verify eligibility for the programs and benefits included in the Single Streamlined Application as enumerated in § 155.405(a), which, again, would include a requirement to collect information necessary to verify Medicare and Medicaid eligibility, as applicable.[251] HHS also provides training to agents, brokers, and web-broker entities participating in the FFEs and SBE–FPs on how to help connect Medicare-eligible consumers to Medicare and potentially Medicaid-eligible consumers with Medicaid enrollment resources.[252] HHS is finalizing the amendment to § 155.220(j)(2)(ii)(D) to require agents, brokers, and web-brokers only to enter a household income projection for a consumer that the consumer, or the consumer's authorized representative, has authorized and confirmed as an accurate estimate. However, we did not propose and are not finalizing regulatory text to mandate agents, brokers, and web-brokers assisting with enrollments in FFEs and SBE–FPs to check a consumer's eligibility for Medicare and Medicaid.

Comment: Some commenters who were neutral on the proposal stated that HHS already has the established infrastructure which allows for agents, brokers, and web-brokers to be penalized for their misconduct, and additional standards of conduct, including submitting an attestation to the accuracy of the information, relying on consumers to provide accurate household income projections, and clarifying parameters around consumer contact information, create an extra burden on compliant agents, brokers, and web-brokers.

Response: With the exception of § 155.220(j)(2)(ii)(A)(*1*), we are generally finalizing, as proposed,[253] the amendments to § 155.220(j)(2)(ii) and the accompanying policies related to the FFE standard of conduct that agents, brokers, and web-brokers provide correct consumer information to the FFEs. HHS does not agree that these revisions will create an extra burden on compliant agents, brokers, and web-brokers because the revisions only further elucidate what was already required under HHS' rules. The proposals we finalize do not create new obligations or standards of conduct, and should not cause an appreciable increase in the burden on agents, brokers, and web-brokers that already comply with the FFE standards of conduct. Rather, they provide clarity and additional examples consistent with existing guidance on how to provide correct consumer information on applications submitted to the FFEs or SBE–FPs. As detailed in the proposed rule, these amendments and

[249] Consistent with the decision to not finalize § 155.220(j)(2)(ii)(A)(*1*), the phrase ''that is secure, not disposable'' was removed from the introductory language in § 155.220(j)(2)(ii)(A). In addition, the email address guidelines proposed to be added at new § 155.220(j)(2)(ii)(A)(*2*) and (*3*) will instead be captured in new § 155.220(j)(2)(ii)(A)(*1*) through (*2*). These guidelines are otherwise being finalized as proposed.

[250] See 45 CFR 155.220(l).

[251] See 45 CFR 155.220(c)(1) and (c)(3)(ii)(B).

[252] See *Returning Agents' and Brokers' Guide to Plan Year 2022 Marketplace Registration and Training*. (2021). CMS. *https://www.cms.gov/files/document/plan-year-2022returning-agents-and-brokers-guide-marketplace-registration-and-training.pdf* and New *Agents' Guide* to *Training*. (2021). CMS. *https://www.cms.gov/files/document/plan-year-2022new-agents-and-brokers-guide-marketplace-registration-and-training.pdf*.

[253] Consistent with the decision to not finalize § 155.220(j)(2)(ii)(A)(*1*), the phrase ''that is secure, not disposable'' was removed from the introductory language in § 155.220(j)(2)(ii)(A). In addition, the email address guidelines proposed to be added at new § 155.220(j)(2)(ii)(A)(*2*) and (*3*) will instead be captured in new § 155.220(j)(2)(ii)(A)(*1*) through (*2*). We also make a non-substantive change to eliminate duplicate references to information ''on an Exchange application'' in § 155.220(j)(2)(ii)(A) through (D). These guidelines are otherwise being finalized as proposed.

clarifications were developed in response to common errors HHS identified on applications submitted by agents, brokers, and web-brokers to the FFE, and will help supplement existing guidance to facilitate the submission of accurate information to the FFEs. The supplementary guidance clarifies how to come into compliance with the existing requirements in § 155.220(j)(2)(ii), which HHS believes will make the process of enrolling consumers more straightforward, due to clearer expectations concerning existing standards from the agency and a reduction in errors filling out the application. Moreover, it protects consumers and enhances the efficient operation of the Exchange.

ii. Prohibited Business Practices

In the proposed rule (87 FR 647), we proposed to amend § 155.220(j)(2) to add several standards of conduct for agents, brokers, and web-brokers that assist consumers with applying for and enrolling in coverage through an FFE or SBE–FP, with or without APTC and CSRs. Similar to the standards first established in the 2017 Payment Notice (81 FR 12203), these additional standards are also intended to protect against agent, broker, and web-broker conduct that is harmful to consumers or frustrates the efficient operation of the Exchange. Specifically, we proposed to codify standards related to the use of scripting and other automation interactions with our Systems or the DE Pathways (including both Classic DE and EDE), identity proofing consumer accounts on *HealthCare.gov,* and providing assistance with SEP enrollments. HHS proposed these new FFE standards of conduct for agents, brokers, and web-brokers assisting consumers in FFEs and SBE–FPs because it has observed practices in these areas that have caused or can cause harm to consumers, as well as impede the efficient operation of the Exchange. We described these proposals, as well as summarize and respond to the comments on each, in the sections that follow.

iii. Prohibited Automated Interactions With CMS Systems

To enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange and assist individuals in applying for APTC and CSRs for QHPs, agents, brokers, and web-brokers must comply with the regulatory requirements contained in § 155.220, including the requirement that such agents, brokers, and web-brokers comply with the terms of applicable agreements between the agent, broker, or web-broker and the Exchange.[254] One such agreement, the ''Agent Broker General Agreement for Individual Market Federally-Facilitated Exchanges and State-Based Exchanges on the Federal platform (IM General Agreement),'' [255] sets forth requirements related to automation. Specifically, section IV(c)(i)(4) of the IM General Agreement provides that scripting and other automation of interactions with CMS Systems or the DE Pathways are strictly prohibited, unless approved in advance by CMS. While these requirements are addressed in the IM General Agreement, they are not currently explicitly set forth in the regulation. Therefore, we proposed to amend § 155.220(j)(2) to add the proposed new § 155.220(j)(2)(vi) to codify requirements and limitations on the use of automation and align the regulation with the IM General Agreement (87 FR 647). The codification of the requirements and limitations in the proposed § 155.220(j)(2)(vi) would provide that an agent, broker, or web-broker that assists with or facilitates enrollment of qualified individuals, qualified employers, or qualified employees, in coverage in a manner that constitutes enrollment through an FFE or SBE–FP, or assists individuals in applying for APTC and CSRs for QHPs sold through an FFE, or SBE–FP must not engage in scripting and other automation of interactions with CMS Systems or DE Pathways, unless approved in advance in writing by CMS. CMS Systems to which CMS-registered agents, brokers, and web-broker may have access include *HealthCare.gov,* and the CMS Enterprise Portal.

HHS proposed this standard of conduct because it has observed instances where unauthorized automated browser-based interactions with Exchange systems have led to unauthorized enrollments or unauthorized application changes. The risk of harm to consumers and the efficient operation of the Exchange is heightened when automated interactions occur because more consumer information can be downloaded using automation than through a manual process. Allowing automation would also create significant traffic in the system, which could result in an increased risk of system speed slowdowns and stability issues, as these automated interactions would cause a lot more system activity per user than anticipated and planned. We sought comments on these concerns and this proposal.

We also sought comments on the appropriate uses of automation that may contribute to the efficient operation of the FFEs and SBE–FPs, and the DE Pathways.

We received one comment generally supportive of the proposal because it would codify HHS' enforcement authority and align the regulation with requirements applicable to agents, brokers, and web-brokers in agreements with the FFE and SBE–FPs.

After considering the responsive comments, we are finalizing the addition of the new § 155.220(j)(2)(vi) as proposed.

iv. Identity Proofing

HealthCare.gov utilizes identity proofing to verify the identity of a consumer when a new Exchange account is created. We proposed to amend § 155.220(j)(2) to add the proposed new § 155.220(j)(2)(vii), which would provide that when identity proofing accounts on *HealthCare.gov,* agents, brokers, or web-brokers must only use an identity that belongs to the consumer (87 FR 648 through 649).

We are finalizing this amendment to § 155.220(j)(2) because we have observed situations, despite the current identity proofing process,[256] in which agents have used the same identity information to complete the identity proofing process for multiple consumer Exchange accounts, which can harm consumers and prevent the efficient operation of the Exchange. Such behavior also undermines the purpose of identity proofing consumers and is often associated with unauthorized enrollments, identity theft, and fraud.

We sought comment on this proposal.

We received one comment responsive to and supportive of the proposed amendment to add new § 155.220(j)(2)(vii) clarifying that agents, brokers, and web-brokers must use a consumer's correct information for RIDP

[254] 45 CFR 155.220(d).

[255] *Agent Broker General Agreement for Individual Market Federally-Facilitated Exchanges and State-Based Exchanges on the Federal Platform.* (2019). HHS. *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/ab_py2020_im_general_agreement_final_1.pdf.*

[256] Identity proofing is required when a consumer creates an account on *HealthCare.gov* via an EDE site, and when a consumer works with an agent or broker in person. Under the existing process, when a consumer creates an account on *HealthCare.gov* or an EDE site, they go through a remote identity proofing (RIDP) process. The RIDP process is an Experian service that takes basic demographic information regarding the consumer and requires the consumer to answer multiple choice questions correctly to proceed. This is done to ensure the consumer is a real person, to protect the consumer's personal information, and to prevent someone else from creating an Exchange account and applying for Exchange coverage in another's name without their knowledge or consent.

process and only for the RIDP process for that consumer.

After considering the responsive comment, we are finalizing the addition of a new § 155.220(j)(2)(vii) as proposed.

v. Providing Information to Federally-Facilitated Exchanges in Connection With Special Enrollment Periods

Section 155.420(a)(1) provides that the Exchange must provide SEPs during which qualified individuals may enroll in QHPs and enrollees may change QHPs. We proposed to amend § 155.220(j)(2) to add the proposed new § 155.220(j)(2)(viii), which would state that when providing information to FFEs that may result in a determination of eligibility for an SEP under § 155.420, agents, brokers, and web-brokers must obtain authorization from the consumer to submit the request for a determination of eligibility for a SEP (although this authorization does not need to be in writing) and make the consumer aware of the specific triggering event and SEP for which the agent, broker, or web-broker will be submitting an eligibility determination request on the consumer's behalf (87 FR 648). Under this proposed standard of conduct, agents, brokers, and web-brokers providing assistance with SEP enrollments would be required to make reasonable, good faith efforts to ascertain the consumer's eligibility for the SEP, consistent with the existing standard under § 155.220(j)(3). We proposed this requirement to address circumstances HHS has observed during which consumers who apply for QHP enrollment through an SEP with the assistance of an agent, broker, or web broker are not made aware of the basis upon which their QHP application claims entitlement to an SEP, or who otherwise did not authorize an agent, broker, or web-broker to enroll them in a QHP or make a change to their current QHP enrollment.

The purpose of SEPs is to promote access to health insurance coverage and continuous coverage by allowing individuals to enroll outside of the open enrollment period only if they experience certain SEP triggering events; this helps to avoid and control against adverse selection that would destabilize the Exchanges. The purpose of proposing to codify this requirement in the proposed new § 155.220(j)(2)(viii) is to ensure the validity and integrity of the SEP process, avoid Exchange destabilization, and create clear, enforceable standards to help mitigate consumer harm by establishing that agents, brokers, and web-brokers are responsible for providing information to the FFE that is accurate to the best of their knowledge, and to which the consumer has attested.

We sought comment on these proposals.

We received one comment responsive to and generally supportive of the proposal that when providing information to the Exchange related to an SEP enrollment, agents, brokers, and web-brokers must obtain authorization from the consumer to submit the request for an eligibility determination, make the consumer aware of the specific triggering event, and of the specific SEP for which the agent, broker, or web-broker is submitting the eligibility determination request on the consumer's behalf.

After considering the responsive comment, we are finalizing the addition of a new § 155.220(j)(2)(viii) as proposed.

4. Premium Calculation (§ 155.240(e))

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 648), we proposed to add language at § 155.240(e)(2) to apply the premium calculation methodology currently applicable in the FFEs and SBE–FPs to all Exchanges, beginning with PY 2024. We further discuss these proposed changes in the Administration of Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions (§ 155.340) section of this final rule where we proposed to require all Exchanges to prorate premium and APTC amounts in cases where an enrollee is enrolled in a particular policy for less than the full coverage month. We sought comment on these proposals.

We received public comments on the proposed amendments to the premium calculation at § 155.240(e). After considering of the comments received, we are not finalizing any amendments to § 155.240.

Comments related to the proposed amendments at § 155.240(e) are addressed in section III.D.9 of the preamble, regarding the Administration of Advance Payments of the Premium Tax Credit and Cost Sharing (§ 155.340), where we present a unified summary of comments on the proposal to clarify that an Exchange is required to prorate the calculation of premiums for individual market policies and the calculation of APTC. We are codifying the proposed APTC proration methodology as the methodology Exchanges on the Federal platform (FFE and SBE–FP) will continue to use, but we are not finalizing the requirement for State Exchanges to use the FFE's methodology to prorate premium or APTC amounts. Additional information on the policy we are finalizing is also provided in section III.D.9. of the preamble of this final rule.

5. Eligibility Standards (§ 155.305)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 648), we proposed a technical amendment to § 155.305(f)(1)(i) to clarify that the income eligibility standards used by the Exchange for determining whether an individual is an applicable taxpayer for purposes of APTC eligibility are the same as the income thresholds at IRS regulation 26 CFR 1.36B–2(b). Whereas the current regulation states that expected household income must be ''greater than or equal to 100 percent but not more than 400 percent of the FPL for the benefit year for which coverage is requested,'' the proposed amendment specifies the individual must have an expected household income which will qualify the tax filer as an applicable taxpayer according to 26 CFR 1.36B–2(b). In turn, 26 CFR 1.36B–2(b) outlines the FPL percentage thresholds that are used for determining PTC eligibility. In practice, the Federal and State Exchanges have always relied on thresholds outlined in 26 CFR 1.36B–2(b) to determine APTC eligibility, but we noted that this proposed change allows for greater regulatory consistency and minimizes the need to update § 155.305(f)(1)(i) in response to legislative changes that may alter FPL percentage thresholds, as occurred for certain years under the ARP.

We are finalizing the proposal as proposed.

Comment: Two commenters provided general support for this technical amendment and no commenters opposed *it.*

Response: We thank the comments for their general support of this technical amendment and believe this change aligns with current practice and will ensure greater consistency going forward.

6. Eligibility for Advance Payments of the Premium Tax Credit (§ 155.305(f)(5))

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 648), we proposed to amend § 155.305(f)(5) to require that Exchanges must calculate APTC in accordance with 26 CFR 1.36B–3, which defines the calculation of the PTC amount, and subject to the prorating methodology at proposed § 155.340(i). We further discussed these proposals in the Administration of Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions (§ 155.340) section of the proposed rule. We sought comment on this proposal.

We received public comments on the proposed amendments to § 155.305(f)(5). In the following comments and responses, we discuss comments specific to the proposal for this section. We are codifying the proposed APTC proration methodology as the methodology Exchanges on the Federal platform (FFE and SBE–FP) will continue to use, but we are not finalizing the requirement for State Exchanges to use the FFE's methodology to prorate premium or APTC amounts. For a unified summary of all comments on the proposal (to clarify that an Exchange is required to prorate the calculation of premiums for individual market policies and the calculation of APTC and for more information on the policy we are finalizing), we refer readers to the section III.D.9 of the preamble on Administration of Advance Payments of the Premium Tax Credit and Cost Sharing (§ 155.340).

Comment: A few commenters noted that the proposed regulatory amendment to part § 155.305(f)(5) did not appear in the corresponding section of the Regulatory Text section of the proposed rule.

Response: HHS appreciates the comments identifying this technical error. The proposed regulatory amendment at § 155.305(f)(5) was inadvertently omitted from the published proposed regulation text. HHS is correcting this technical error by including amendments to § 155.305(f)(5) in the Regulatory Text section of this final rule as described in the preamble to the proposed rule, and consistent with the policy adopted in this final rule, as described in the section III.D.9 of the preamble on Administration of Advance Payments of the Premium Tax Credit and Cost Sharing (§ 155.340).

7. Verification Process Related to Eligibility for Insurance Affordability Programs—Employer Sponsored Plan Verification (§ 155.320)

Strengthening program integrity with respect to subsidy payments in the individual market continues to be a top HHS priority. Accordingly, in the proposed rule (87 FR 649 through 651), we proposed to revise § 155.320(d)(4) to provide each Exchange with the flexibility to tailor its employer sponsored plan verification process based on its assessment of the risk of inappropriate payments of APTC and CSRs as a result of associated risk and composition of their enrolled population.

Specifically, we proposed to allow Exchanges to implement a verification method that utilizes an approach based on a risk assessment identified through analysis of an Exchange's experience in relation to APTC/CSRs payments. We refer to the proposed rule (87 FR 649), where we provided additional background and rationale for the proposals.

First, we proposed to revise § 155.320(d)(4) by removing the requirement that the Exchange select a random sample of applicants for whom the Exchange does not have data as specified in § 155.320(d)(2)(i) through (iii) effective upon the finalization of the final rule and adding new language at § 155.320(d)(4) under which an Exchange would be permitted to design its verification process for enrollment in or eligibility for qualifying coverage in an eligible employer sponsored plan based on the Exchange's assessment of risk for inappropriate payment of APTC/CSRs or eligibility for CSRs, as appropriate. The proposed language at § 155.320(d)(4) would provide all Exchanges with the flexibility to determine the best means to design and implement a process to verify an applicant's enrollment in or eligibility for employer sponsored coverage, through analyses of relevant Exchange data, research, studies, and other means appropriate and necessary to identify risk factors for inappropriate payment of APTC or eligibility for CSRs. As previously discussed earlier in this rule, Exchanges must continue to use the procedures set forth in § 155.320(d)(4)(i) until a new alternate procedure becomes effective. We also proposed to retain the current requirement at § 155.320(d)(4)(i)(A) that the Exchange provide notice to the applicant, but amend it such that it is contingent on whether the Exchange will be contacting the employer of an applicant to verify whether an applicant is enrolled in an eligible employer sponsored plan or is eligible for qualifying coverage in an eligible employer sponsored plan for the benefit year for which coverage is requested.

Second, to provide more flexibility for Exchanges, we proposed no longer applying the requirement at § 155.320(d)(4)(i)(D), which requires the Exchange to make reasonable attempts to contact an employer listed on an applicant's Exchange application to verify whether an applicant is enrolled in an employer sponsored plan or is eligible for qualifying coverage in an eligible employer sponsored plan.

Third, we proposed to remove the requirement at § 155.320(d)(4)(i)(F), which states that after 90 days from the date on which the Exchange first provides notice to an applicant as described in § 155.320(d)(4)(i)(A), the Exchange must redetermine eligibility for APTC and CSRs if the Exchange is unable to obtain the necessary information from an applicant's employer regarding enrollment in or eligibility for qualifying coverage in an employer sponsored plan. We continue to believe that these proposed changes provide Exchanges with the flexibility to implement a verification process for enrollment in or eligibility for an employer sponsored plan that is tailored to risks observed in their respective populations. As previously discussed earlier in the preamble, Exchanges must continue to use the procedures set forth in § 155.320(d)(4)(i) until a new alternate procedure becomes effective.

Finally, we proposed to remove the option for Exchanges to follow the procedures outlined in § 155.320(d)(4)(ii) to develop an alternative verification process that is approved by HHS.[257] The revisions to § 155.320(d)(4)(i) provide enough flexibility for Exchanges to develop a risk-based verification process for eligibility for or enrollment in employer sponsored coverage. Therefore, extending § 155.320(d)(4)(ii) indefinitely would prove to be redundant in light of the proposed changes discussed earlier in the preamble.

We are finalizing these proposals as proposed. Specifically, we require that any risk-based verification process be reasonably designed to ensure the accuracy of the data and be based on the activities or methods used by an Exchange such as studies, research, and analysis of an Exchange's enrollment data. We expect that this risk assessment would be informed by and identified through research and analysis of an Exchange's experiences with current and past enrollments, and not solely based on previously published research or literature. For example, if an Exchange's experience is that applicants from large companies that have different classes of employees, who may or may not qualify for employer sponsored coverage due to the number of hours they work per week, represent a higher risk of improper APTC/CSR payments, then the Exchange may implement a risk-based verification process to confirm whether applicants employed by such companies appropriately are allowed APTC/CSRs.

Given that the risk-based approach to verify whether an applicant has received an offer of coverage through an employer or is enrolled in employer sponsored coverage depends largely on

[257] In the proposed rule, we neglected to delete a reference to § 155.320(d)(4)(ii) in the regulation text. We are deleting that reference in the regulation text in this final rule, consistent with the proposal.

an Exchange's assessment of risk and unique populations, we noted in the proposed rule that we believe that there are various ways in which a risk-based approach can be operationalized. Below we outline a few scenarios to provide illustrative examples of the procedures an Exchange may follow.

The first scenario concerns Exchanges that do not have access to an approved trusted data source that provides accurate and up-to-date information regarding enrollment or pre-enrollment in coverage offered through an employer and have determined that manual verification, such as conducting random sampling of enrollees to determine if any had an offer of affordable coverage through their employer but chose to enroll in an Exchange QHP with APTC/CSR instead, requires significant resources to conduct and have determined that the risk for improper APTC/CSR payment is low. In this scenario, Exchanges may make a reasonable determination and decide to accept a consumer(s)' attestation without any further manual verification, similar to current procedures to accept attestation only for residency and incarceration status.

Conversely, if an Exchange has determined a high risk for improper APTC/CSR payment exists within its enrolled population, but also does not have access to an approved trusted data source for electronic verification, an Exchange may make a reasonable determination that conducting manual verification as part of its risk-based approach, such as conducting random sampling, is the appropriate risk-based approach to conduct employer sponsored coverage verification.

Because we found that the risk for improper APTC payment is low in Exchanges using the Federal eligibility and enrollment platform, these Exchanges would leverage the current attestation questions on the single, streamlined application and accept attestation without further verification against other trusted data sources. The attestation questions include, ''Are any of these people currently enrolled in health coverage? '' and ''Will any of these people be offered health coverage through their job, or through the job of another person, like a spouse or parent? ''. We would also accept attestations related to employer sponsored coverage because we currently lack access to another approved data source to verify whether an applicant has an offer of employer sponsored coverage that is affordable and meets minimum value standards. In the 2019 study referenced earlier in the preamble, we examined whether the use of other data sources would be feasible to verify offers and affordability of employer sponsored coverage, such as the National Directory of New Hires (NDNH) database. We determined that all available data sources were insufficient and did not provide the necessary information to satisfy the requirement, or would require legislative changes to give Exchanges permission to access and use them for verification of employer sponsored coverage. We noted that additional data source access, such as the NDNH, would improve accuracy and reduce the administrative burden to consumers for the income verification step during the eligibility process.

Finally, under this proposal, we clarified that since SBE–FPs use the *HealthCare.gov* platform for eligibility and enrollment determinations, SBE–FPs would be required to follow the approach outlined above consistent with CMS regulations and the agreements SBE–FPs sign with us. Current Federal platform agreements require that SBE–FPs adhere to the same policy and operations as Exchanges that use the Federal eligibility and enrollment platform regarding eligibility for and enrollment in QHP coverage.

Furthermore, in accordance with § 155.120(c), an Exchange's verification program cannot be discriminatory in nature, and State Exchange's verification processes will be monitored by HHS in accordance with its authority under §§ 155.1200 and 155.1210. In designing their verification program, Exchanges should pay special attention to known risks, including risk pool manipulation or steering high risk employees from the group health market into the Exchanges. The goal of proposing this policy was to ensure that only applicants eligible for APTC/CSRs benefit from these subsidies, and we would exercise our oversight authorities to ensure an Exchange's verification policies are not used to prevent any particular class of applicants from enrolling in QHP coverage with APTC/CSRs. We continue to believe that this approach would allow Exchanges to proactively identify and target applicants who may, for example, have an incentive to enroll in Exchange coverage with APTC/CSRs rather than their employer sponsored plan that meets minimum value and affordability standards. Further, we believe that a risk-based approach for verification of eligibility for employer sponsored eligibility or coverage verification would allow Exchanges to identify a larger population of Exchange enrollees who would be ineligible for APTC/CSRs due to an offer of employer sponsored coverage, as compared to the random sampling method. We continue to believe that the new policy we proposed would more effectively protect the integrity of Exchange programs, as Exchanges would be able to mitigate the risk of improper Federal payments in the form of APTC during the year more effectively.

We sought comment on these proposals.

After reviewing the public comments, we are finalizing these proposals as proposed, with some non-substantive revisions for clarity. These include removing the reference to paragraph (d)(4)(ii) in paragraph (d)(4), as this paragraph has been removed and is no longer necessary, and streamlining language under paragraph (d)(4)(i)(A) to make it clearer that Exchanges must notice employers, if employer notification is part of an Exchange's risk-based approach.

We summarize and respond to public comments received on the verification process related to eligibility for insurance affordability programs—employer sponsored plan verification (§ 155.320) below.

Comment: The majority of commenters supported HHS' proposal to provide all Exchanges with the flexibility to tailor their employer sponsored coverage verification procedures based on the Exchange's own assessment of the risk for inappropriate payments of APTC/CSRs in their enrolled populations. The commenters agreed with HHS' prior study findings that the current sampling process outlined in paragraph (d)(4)(i) requires significant Exchange resources with little return on investment given the low volume and risk of consumers with offers of employer sponsored coverage who inappropriately enroll in Exchanges with APTC/CSRs and stated that HHS' study results were consistent with State Exchanges' own observations. Commenters also agreed with HHS that an employer sponsored coverage verification approach should provide State Exchanges with enough flexibility and more opportunities to use verification processes that are evidence-based, while imposing the least amount of burden on consumers, States, employers, and taxpayers. Commenters also noted that increased flexibility to use a risk-based approach allows all Exchanges to focus and expend resources on expanding coverage. Finally, commenters stated that they appreciated how the proposed risk-based approach provides State Exchanges with the freedom to review their own data and determine the most appropriate verification approach for

employer sponsored coverage that accurately reflects the risk for inappropriate APTC/CSR payments within their unique populations.

Response: HHS agrees that the current random sampling process required under § 155.320(d)(4)(i) is not only burdensome for States, employers, consumers, and taxpayers, but it also does not provide enough flexibility to all Exchanges to develop a process for employer sponsored coverage verification that more accurately reflects their respective enrolled Exchange populations. As discussed in the proposed rule (87 FR 649), HHS shares the same concerns regarding the feasibility and effectiveness of sampling and agrees that a verification process should be evidence-based and informed by certain risk-factors for inappropriate payment of APTC/CSRs. HHS also agrees that additional flexibilities are important to help States better serve their populations and to allow for Exchange staff time and resources to be better spent on activities that help promote and retain enrollment in Exchanges.

Comment: A few commenters supported the proposed changes, but also recommended that HHS revise paragraph (d)(4)(i) to state that all Exchanges can accept an applicant's attestation when an Exchange determines that the risk for improper APTC/CSR payment is low and does not have access to an available, approved data source to verify whether an applicant has an offer of or is enrolled in coverage offered through an employer. Some of these commenters further questioned what additional information or value a State's own study or risk assessment would bring if HHS already conducted studies on the risk for inappropriate APTC/CSR payments and as discussed in the preamble of the proposed rule that, as part of their risk-based approach, Exchanges using the Federal eligibility and enrollment platform would accept attestations in absence of an approved data source, and requested that HHS clarify who is responsible for conducting the risk assessment, how it should be conducted, and how State Exchanges can meet this assessment requirement.

Response: HHS reiterates and reminds State Exchanges that it is their responsibility to conduct their own risk-assessments for inappropriate APTC/CSRs payments; while HHS determined based on its study that the Exchanges that use the Federal platform will use an attestation-based approach to employer sponsored coverage verification, State Exchanges cannot rely on the findings of the studies that HHS conducted to serve as the basis for their risk-based approaches for employer sponsored coverage verification as this study pertained to Exchanges that use the Federal eligibility and enrollment platform. Similarly, the risk-based approach and subsequent verification processes for employer sponsored coverage verification must be based on an Exchange's own data analysis and research, and State Exchanges may not solely rely on previously published literature, research, and/or the studies conducted by HHS as justification for their risk-based approach. Furthermore, State Exchanges have the sole responsibility and flexibility to determine the manner of assessment that is suitable for their respective populations and markets, and should propose their assessment approach to HHS for review. However, the process that is appropriate for some State Exchanges may not be to solely accept attestation for all applicants. Therefore, HHS disagrees with commenters that changes to paragraph (d)(4)(i) to explicitly state that all Exchanges may accept attestation when an Exchange does not have access to an available data source are necessary.

Comment: A few commenters stressed the importance of and urged HHS to explore other relevant, reliable third-party data sources that could be used to verify offers of or enrollment in employer sponsored coverage, such as whether HHS could gain access to firm-level data about employer sponsored insurance through the annual ACA reports that are filed with the IRS or access to the NDNH to help Exchanges determine whether certain companies offer coverage to their employees.

Response: We agree with the importance of relevant and reliable third-party data sources to verify offers of or enrollment in employer sponsored coverage such as the NDNH. As part of the 2019 study discussed in the preamble to the proposed rule and this final rule, HHS explored the feasibility of using the NDNH, or other data sources such as reporting from IRS, the Department of Labor (DOL), or State quarterly wage data to verify eligibility for employer sponsored coverage. However, HHS determined that either available data sources were insufficient and did not provide the necessary information to satisfy the requirement, or, in the case of the NDNH, legislative changes would be required to give Exchanges permission to access and use the data source for verification of employer sponsored coverage.

For example, HHS found that these data sources, such as IRS Forms 1095–B and 1095–C, DOL, and State wage quarterly data, are subject to significant time lags and that HHS would not have access to reliable, up-to-date information regarding employment when needed the most, immediately before and after the annual individual market Exchange open enrollment period. Finally, HHS also considered using data available to Exchanges using the Federal eligibility and enrollment platform to automatically verify the loss of minimum essential coverage for verification of special enrollment period eligibility (see preamble discussion at § 155.420 in section III.D.10. of the final rule). However, not all employers participate in the database to verify loss of minimum essential coverage nor does it provide information on whether an applicant has an offer of employer sponsored coverage so it would not be a reliable verification source for verifying employer sponsored coverage.

Additionally, Exchanges are not among the entities Congress authorized to access NDNH data.[258] HHS explored the feasibility of creating a new database that Exchanges could leverage with employer contact information and information on the coverage offered, but because HHS currently lacks the statutory authority to require employers to share contact information or information about coverage offered for this purpose, employer participation in such a database would be purely voluntary, and therefore, may not be sufficiently effective. Granting HHS and Exchanges the authority to pursue either of these options would require an act of Congress.

Comment: Two commenters that were neutral in their support of the proposed changes, stressed that Exchanges should be prohibited from implementing risk-based approaches that are discriminatory in nature, specifically that Exchanges cannot target consumers solely based on income status, as a targeted, income-based verification process for employer sponsored coverage would have disproportionate, adverse impacts on applicants of color and other underserved groups. One commenter further recommended that HHS modify the language under paragraph (d)(4) to prevent States from needlessly imposing procedural burdens on consumers seeking to enroll in coverage offered through Exchanges.

Response: HHS agrees with commenters that an Exchange's risk-based approach to verify whether an applicant is enrolled in or has been

[258] See 42 U.S.C. 653(j) (identifying the entities that are authorized to access NDNH data and the permissible purposes for which those entities may use NDNH data).

offered coverage through an employer must not be discriminatory in nature, especially towards applicants who have household income levels within a certain percentage of the Federal Poverty Level (FPL), as applicants of color or other underserved groups are more likely to be targeted by such practices. As such, HHS reminds States and Exchanges that per § 155.120(c), an Exchange's verification program cannot be discriminatory in nature, and State Exchange's verification processes will be monitored by HHS in accordance with its authority under §§ 155.1200 and 155.1210, nor should an Exchange and/or a State's risk-based approach place any additional, unnecessary procedural burdens or barriers to enrollment for consumers seeking to enroll in Exchange coverage.

Comment: Two commenters opposed HHS' proposal that Exchanges use a risk-based approach to determine the best process to verify whether an applicant has an offer of or is enrolled in coverage through an employer. One commenter stated that HHS should continue to verify offers of or enrollment in employer sponsored coverage and that Exchanges using the Federal eligibility and enrollment platform should not rely solely on consumer attestations as the ACA states that these applicants are not eligible to receive APTC/CSRs; this is similar to how Exchanges verify other eligibility criteria like annual household income, or enrollment in other qualifying coverage such as Medicare, Medicaid, CHIP, or, if applicable, the Basic Health Program (BHP). Another commenter opposed the proposal and stated that, in addition to many individuals with offers of or enrollment in coverage offered through an employer benefitting from APTC/CSRs inappropriately, HHS should consider the tax consequences for individuals and liability concerns for applicable large employers (ALE) that receive IRS 226–J letters because one or more of their employees received APTC through an Exchange. The commenter further noted that the process of penalty enforcement is arduous and costly for the IRS and affected ALEs and that more effective employer sponsored coverage verification could significantly reduce the volume of enforcement actions that are ultimately resolved in the favor of the ALE and that HHS should work with the IRS to improve the verification process at the national level and not pursue the risk-based approach.

Response: As discussed in the preamble, HHS has confirmed via two separate research studies conducted multiple years apart that the risk of an applicant choosing to forego enrolling in employer sponsored coverage that is affordable and meets minimum value standards to enroll in an Exchange QHP with APTC/CSR remains low. Also, HHS has determined that reliable and accurate data sources exist for the other eligibility criteria that commenters flagged, such as IRS data for annual household income, Medicare enrollment data that is provided to CMS via the Social Security Administration, and State Medicaid Agency data to verify Medicaid/CHIP enrollment. As HHS has noted, the same quality and caliber of data on employer sponsored coverage do not exist due to the various limitations discussed earlier in the preamble.

Furthermore, HHS understands the concerns raised by the commenter regarding the process of assessing employer shared responsibility payments (ESRP), and that more robust real-time verification of consumers' access to employer sponsored coverage may result in some employers avoiding the ESRP process. However, as noted in an earlier response in this section of the preamble, options for obtaining the necessary data are limited. In the absence of Congressional action to provide access to the NDNH or to create a new database with mandatory employer reporting, HHS remains committed to working with IRS to use the information currently available to ensure our processes are fair to both consumers and employers.

8. Annual Eligibility Redetermination (§ 155.335)

We solicited comments on incorporating the net premium, MOOP, deductible, and annual out-of-pocket costs (OOPC) of a plan into the re-enrollment hierarchy as well as on additional criteria or mechanisms HHS could consider to ensure the Exchange hierarchy for re-enrollment aligns with plan generosity and consumer needs, with consideration for the potential impact of the proposed amendments to the actuarial value *de minimis* guidelines. For example, HHS could consider re-enrolling a current bronze QHP enrollee into an available silver QHP with a lower net premium and higher plan generosity offered by the same QHP issuer. Additionally, HHS could consider 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, that has lower OOPC. Please see the proposed rule preamble (87 FR 651 through 652) for a complete description of the comment solicitation.

We will consider proposing amendments to the re-enrollment hierarchy at § 155.335(j) in future rulemaking.

We summarize and respond to public comments received on annual eligibility redetermination (§ 155.335) below.

Comment: Some commenters opposed the proposal to revise the re-enrollment hierarchy and explicitly expressed that HHS should retain the current re-enrollment hierarchy. These commenters stated that consumers choose to enroll in plans for a number of reasons and that the Exchange cannot accurately predict the factors most valuable to consumers; thus, revising the re-enrollment hierarchy could lead to consumer confusion and dissatisfaction. A few commenters noted that the discretion to select the most appropriate plans for consumers should be left to the issuers. Two commenters expressed concern about enrollees being auto enrolled without their knowledge or explicit approval.

A few commenters encouraged HHS to focus on enhancing the consumer shopping experience and decision support tools to improve initial plan selection and alert consumers of plans that better meet their needs instead of altering the re-enrollment hierarchy in the Exchanges. A couple of commenters explained that improving consumer education can help ensure consumers understand all aspects of cost-sharing and how they impact coverage, which will help consumers make an initial plan selection that best meets their needs. One commenter suggested that HHS could rebrand the concept of metal levels to make actuarial values more accessible to consumers.

Response: HHS understands the importance of ensuring a revised re-enrollment hierarchy does not result in consumer confusion or harm and will take these comments into account in considering whether to revise the current re-enrollment hierarchy as part of future rulemaking.

Comment: Commenters submitted comments regarding the incorporation of consumer cost into the re-enrollment hierarchy. Several commenters encouraged HHS to take net premium and/or total OOPC into account for the re-enrollment hierarchy. Some commenters cited research in Covered California's market which showed that 30 percent of households whose coverage was automatically renewed were certain to be better off in a different plan. Furthermore, these commenters referenced that, 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. For this reason, a number of commenters expressed that re-enrollment should prioritize consumer affordability rather than continuity of issuer and product line, stating that the vast majority of consumers who do not make active selections during the OEP care more about cost than issuer or provider network. One commenter cautioned that net premium itself is not always a reliable factor to determine the best plan for a consumer. Another commenter recommended that the plan's net premium, MOOP, deductible, and annual OOPC be considered only when the enrollee's current QHP is not available and the enrollee's product no longer includes a plan that is at the same metal level as, or one metal level higher or lower than, the enrollee's current QHP. A few commenters stated that including OOPC and plan generosity into re-enrollment rules will be particularly beneficial for when enrollees are eligible for cost-sharing reductions and are not enrolled in a silver plan. One commenter explicitly requested that if an enrollee is shifted to a different metal level plan, then that enrollee should remain enrolled in a plan offered by the same issuer to prevent potential adverse consequences of an enrollee losing access to medications or experiencing increased drug costs. However, two commenters expressed that incorporating OOPC into the hierarchy would likely lead to increased enrollment in plans with lower OOPC for prescription drugs. Two other commenters explained the critical importance of auto re-enrollment policies for immigrants and racial and ethnic minorities who face barriers, such as lack of in language outreach and notices, and are disproportionately impacted by cost increases due to lower wealth and discretionary income.

Response: HHS will take comments regarding the incorporation of consumer costs into the re-enrollment hierarchy into account in future rulemaking.

Comment: We received multiple comments with specific recommendations regarding how the priority of the current hierarchy could be modified. Multiple commenters raised concerns with § 155.335(j)(1)(i) which ensures the enrollee's coverage will be renewed in the same plan as their current QHP, unless the current QHP is not available through the Exchange. Commenters explained that the current policy does not provide flexibility for enrollees to be re-enrolled into a different plan even if market conditions increase costs. For this reason, some commenters recommended that § 155.335(j)(1)(i) be amended to allow the enrollee's coverage to be renewed into a different plan if there is no change in the issuer, product, service area, provider network, and prescription drug formulary, and the new plan is more generous and has lower net premiums. These commenters urged the Exchange to provide accessible notices and reasonable opportunities for the consumer to return to their former plan or drop coverage. Furthermore, a few commenters recommended that enrollees should be eligible for a 60-day special enrollment period after the close of the annual individual market Exchange Open Enrollment Period or at the start of the plan year to allow enrollees whose was coverage was shifted to choose a different plan. This commenter stated that if the *de minimis* guidelines proposed in this rule at §§ 156.135 and 156.140 are finalized HHS should not alter the hierarchy for within-metal level changes.

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 consumers may be re-enrolled in a plan with far higher costs if the issuer and provider networks types are prioritized. These commenters expressed that the vast majority of enrollees who do not make active selections during the open enrollment period care more about cost than the issuer or provider network. All of these commenters recommended that HHS prioritize keeping the consumer's net premium and approximate actuarial value (AV) at levels as close as possible to the enrollee's current QHP. One commenter recommended HHS should perform targeted outreach to consumers who have been auto re-enrolled and whose premium has increased and should extend the open enrollment period, outlined in § 155.410, to January 31 and require coverage to begin February 1.

Response: HHS will take comments on factors to consider prioritizing in the re-enrollment hierarchy into account in future rulemaking. HHS understands the importance of comments that urged the Exchange to provide accessible notices and reasonable opportunities for enrollees to select a QHP that is different from their auto reenrollment option. Currently, 45 CFR 156.1255 and its implementing guidance outline the information a QHP issuer must provide in renewal and re-enrollment notices to qualified individuals. Additionally, a qualified individual is eligible under § 155.420(d)(1)(i) for a special enrollment period (SEP) to enroll in or change from one QHP to another if the qualified individual loses minimal essential coverage. If the enrollee's current plan is no longer available for renewal, HHS would consider this a loss of minimum essential coverage that would trigger a SEP.

Comment: Several commenters recommended provider network considerations be incorporated into any revised re-enrollment hierarchy. 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 plans. Furthermore, two commenters cautioned that not including provider network considerations in the re-enrollment hierarchy could have negative consequences for racial and ethnic minority groups and those living with disabilities who rely on providers with certain cultural backgrounds or longtime key providers. Two commenters recommended that HHS use provider network as the foremost criterion.

Response: HHS will take these comments regarding incorporating provider networks in the re-enrollment hierarchy into account in future rulemaking.

Comment: A few commenters recommended that SBEs, SBE–FPs, or States performing plan management functions should have the flexibility to determine the appropriate criteria for re-enrollment determinations with respect to their unique markets. One commenter explained that incorporating new criteria and mechanisms into re-enrollment determinations could impose significant operational and financial burdens on SBEs. Another commenter stated that a substantial number of enrollees actively select their auto re-enrollment option which could indicate enrollees trust their State or issuer. One commenter proposed HHS should work with States to design safe and appropriate flexibility for issuers to facilitate plan changes after open enrollment, but only when the change would lower premiums and/or OOPC for members with everything else (network, benefits, deductibles, MOOPs) being the same or better for consumers. This commenter raised the concern that the examples HHS provided in the comment solicitation could conflict with State law requirements.

Response: HHS will take these comments regarding State flexibility into account in future rulemaking.

Comment: A few commenters urged HHS to conduct stakeholder engagement and provide transparency on the re-

enrollment process to all stakeholders. Two commenters requested additional clarification on the proposed changes to the re-enrollment hierarchy for the Exchanges while one commenter requested that HHS provide further transparency into the alternate enrollment process. One commenter recommended that HHS conduct further stakeholder feedback and consumer testing prior to finalizing any revisions to the re-enrollment hierarchy.

Response: HHS will take these considerations into account in future rulemaking, including how to incorporate transparency and stakeholder feedback into a revised re-enrollment hierarchy.

9. Administration of Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions (§ 155.340)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 648 through 653), we proposed to amend §§ 155.240(e), 155.305(f)(5), and 155.340 to clarify that an Exchange is required to prorate the calculation of premiums for individual market policies and the calculation of the APTC in cases where an enrollee is enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month. The proposed APTC proration methodology was the product of (1) the APTC applied on the policy for one month of coverage divided by the number of days in the month, and (2) the number of days for which coverage is provided on that policy during the applicable month. HHS proposed to require all Exchanges, including the Exchanges on the Federal platform (FFE and SBE–FP) and State Exchanges that operate their own eligibility and enrollment platforms, to implement this proposed proration methodology beginning with PY 2024. Please see the proposed rule preamble (87 FR 648 through 649 and 652 through 653) for a complete description of the proposed policy.

After considering the comments received, under HHS' authority to administer APTC, we are codifying the proposed APTC proration methodology as the methodology Exchanges on the Federal platform will continue to use, but we are not finalizing the requirement for State Exchanges to use the proposed methodology to prorate premium or APTC amounts. Rather, we will formalize additional efforts under existing Exchange program integrity and oversight authorities to ensure that, beginning with PY 2024, State Exchanges will implement an APTC methodology consistent with the requirement we are finalizing at § 155.305(f)(5) at 155.340(i), described later in this section, that will not cause the amount of APTC applied to an enrollee's monthly premium to exceed their total monthly PTC amount as defined in 26 CFR 1.36B–3. We note that all the Exchanges on the Federal platform (FFE and SBE–FP) would implement HHS' codified methodology because all Exchanges on the Federal platform rely on the Federal platform to perform the proration calculations, and the Federal platform is not designed to implement different methodologies by State. We believe that this final policy will ensure Exchange compliance with IRS rules and equal treatment for enrollees across Exchanges, while minimizing the burden for State Exchanges and granting State Exchanges flexibility in how to comply with these APTC calculation requirements when an enrollee is enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month. We will require State Exchanges to prospectively report their PY 2024 methodology in the year prior to implementation (in 2023) and will allow State Exchanges the option to report their PY 2023 methodology in 2022. Any State that begins operating a State Exchange for PY 2024, or for subsequent plan years, will also be required to comply with this timeline by prospectively reporting the methodology for the following plan year during their first reporting cycle.

To support this policy, we are finalizing a series of conforming amendments to parts §§ 155.305(f)(5) and 155.340. We are not amending as proposed § 155.240(e), which establishes the methodology the Exchanges on the Federal platform (FFE and SBE–FP) use to prorate premiums, to add new paragraph § 155.240(e)(2), which would have established a methodology for State Exchanges using their own platform to prorate premiums. However, we are amending § 155.305(f)(5), which currently provides that Exchanges must calculate APTC in accordance with 26 CFR 1.36B–3, by adding that Exchanges must also calculate APTC in accordance with new paragraph § 155.340(i) where we describe the requirements for calculating APTC when policy coverage lasts less than the full coverage month. In new paragraph § 155.340(i)(1), we establish that Exchanges on the Federal platform will be required to use the APTC proration methodology described at § 155.340(i)(1)(i) and (ii), and at new paragraph § 155.340(i)(2) we establish that State Exchanges will be required to calculate APTC in accordance with a methodology that does not cause the amount of APTC applied to an enrollee's monthly premium to exceed their expected total monthly PTC amount when an enrollee is enrolled in a policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month, and to report the methodology to HHS in accordance with the requirements of 155.1200(b)(2).

Most of the comments on proposed amendments to the administration of APTC (§ 155.340) were presented in combination with comments on the other proposed amendments that made up the proposal to require premium and APTC proration (§§ 155.240(e), 155.305(f)(5)). We summarize and respond to public comments received on all three sections in a unified summary below.

Comment: Several commenters expressed their support for the proposal to require that all Exchanges prorate both premium amounts and APTC amounts and noted that the proposal would ensure accurate and consistent calculation of APTC which would support consumer protection. One commenter observed that the proposal would lower the operational burden for issuers participating across multiple types of Exchanges. One commenter stated that the proposed policy would encourage enrollees to enroll in a new QHP if enrollment was terminated mid-month.

However, the majority of commenters opposed the proposal and criticized the proposed APTC proration methodology, and its potential impact on enrollees. Several commenters asserted that the proposed methodology is not necessary to ensure that the calculation of APTC does not cause excess APTC because calculating APTC in the same way as PTC; that is, using the calculations defined at 26 CFR 1.36B–3(d) will not result in excess APTC. Several commenters included examples of how the proposed proration methodology would result in less generous amounts of APTC for enrollees, and asserted that the proposed methodology would reduce plan affordability, in contrast to the stated goals of HHS and the Administration. Others stated that the requirement to prorate premiums is not supported by the PTC regulation.

Response: We are not finalizing the policy as proposed. We will codify the method of APTC proration as proposed

for the Exchanges using the Federal platform, but we will grant flexibility to State Exchanges to use a methodology that does not cause the amount of APTC applied to an enrollee's monthly premium to exceed their expected total monthly PTC amount when an enrollee is enrolled in a policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month. We will require State Exchanges to report their methodology to HHS in accordance with the requirements of § 155.1200(b)(2).

PTC is calculated for each month of the tax year retrospectively, and therefore can account for the changes in an applicable enrollee's premium month to month before the final amount is calculated at the time of tax filing. However, Exchanges administer APTC prospectively to issuers by advancing premium assistance to issuers based on enrollees' eligibility determinations and elections, which may also change month-to-month (and before final reconciliation occurs), putting affected enrollees at risk of repaying the excess APTC.

The proposal sought to align the manner in which HHS administers APTC with the IRS' PTC calculation for all Exchanges, by establishing a consistent methodology for administering APTC in instances when there is a change in the applicable enrollee's coverage mid-month, which the PTC regulation accounts for at 26 CFR 1.36B 3(d)(1)(i) by retrospectively calculating the monthly enrollment premiums to ensure that PTC does not exceed that amount. We believe the ability to account for mid-month coverage changes is most important when an enrollee is enrolled in two policies in the same coverage month. The examples included by commenters take into consideration only mid-month terminations, but do not consider mid-month terminations followed by mid-month enrollments into a new plan. In such instances when there are multiple policies in a single policy month, HHS data on APTC payment reflects that some State Exchanges are not prorating or otherwise accounting for a potential over-payment of APTC.

Under 26 CFR 1.36B–3(d), PTC eligibility for a partial month of coverage is calculated as the lesser of the premiums for the month (reduced by any amount of such premiums refunded), or the adjusted monthly premium for the applicable second lowest cost silver plan (SLCSP) reduced by the taxpayer's monthly contribution amount.

HHS remains concerned that when an enrollee is enrolled in more than one policy during a single coverage month, and the Exchange applies APTC to each of those policies based on the eligibility requirements under 26 CFR 1.36B–2 without prorating both policies or conducting a reconciliation between them, the calculation will in some cases cause the total monthly APTC to exceed the amount that would be calculated under 26 CFR 1.36B–3(d). HHS data indicate that when Exchanges do not link the two policies to account for the excess APTC, the Exchanges tend to apply the maximum eligible APTC amounts, capped at the prorated premium amount, for both policies. When added together the total applied APTC often exceeds the maximum expected PTC amount for which the enrollee will be eligible for that month.

However, if the Exchange applied the proration methodology used by the Exchanges on the Federal platform (that is, FFE and SBE–FPs) which is the product of (1) the APTC applied on the policy for 1 month of coverage divided by the number of days in the month, and (2) the number of days for which coverage is provided for that policy during the applicable month, the calculation would not cause the total APTC for the month to exceed the PTC allowed for the month.

Further, we acknowledge the concern raised by commenters that under the proposed policy, prorating the APTC amounts applied to enrollee's monthly premium could result in a lower total amount of APTC than if the non-prorated amounts of APTC capped at the reduced premium were applied to an enrollee's monthly premium. We appreciate the perspective on affordability, and agree that the non-prorated amount of APTC would likely be more generous than the prorated amount if a mid-month termination was not followed by enrollment in another plan. However, since many mid-month terminations are followed by enrollment in a new plan, we remain concerned that applying both plans' non-prorated APTC amounts could exceed the maximum expected monthly PTC amount for which the enrollee taxpayer will be eligible. When an enrollee is enrolled in more than one plan during one coverage month and has APTC from both policies applied to their premium, the generosity of non-prorated APTC amounts described by commenters has the potential to result in APTC over-payments and to trigger a costly tax liability which could surprise the enrollee later. Income tax liability due to excess APTC could pose a significant financial burden to applicable enrollees, particularly low-income enrollees. Further, if this partial month of coverage triggered a higher applied APTC, it has the potential to confuse enrollees about their true monthly member responsibility for their new plan, creating confusion about the affordability of health care coverage offered by an Exchange. Therefore, we determined that the benefit of avoiding potential, unexpected tax liability and of reducing potential confusion outweighs the cost to enrollees of potentially lower APTC payments for those enrolled in two policies for partial months within one coverage month.

We acknowledge that proration based on the number of coverage days, like the methodology currently used by Exchanges on the Federal platform, is not the only approach to address the issue of excess APTC. For example, a monthly calculation linking two partial month policies for an applicable taxpayer to account for changes in APTC could also align with the current PTC regulation at 26 CFR 1.36B–3(d). However, in practice, HHS has noticed that State Exchanges often do not prorate or link the two mid-month policies, which leads to APTC payments that exceed an enrollee's expected monthly PTC amount.

However, in an effort to preserve State Exchange flexibility and to be responsive to the concerns regarding the proposed methodology, we are modifying the finalized policy to require only that State Exchanges use a methodology that ensures that their calculation of APTC does not cause the amount of APTC applied to an enrollee's monthly premium to exceed their expected monthly PTC amount when an enrollee is enrolled in a policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month, and to report the methodology to HHS in accordance with the requirements of § 155.1200(b)(2).

Comment: A few commenters who supported the proposal expressed hesitancy regarding the State Exchanges' ability to implement the proposed methodology and requested maximum flexibility for the State Exchanges in their implementation of the policy and the timing of implementation. Additionally, many opposing commenters, specifically several State Exchanges, noted that the proposal would impose significant implementation burden on States Exchanges. These commenters expressed concern that the estimated implementation cost would be extremely burdensome to State

Exchanges, and the complex, resource-intensive IT and administrative systems builds would require them to divert large portions of their budget away from other priority operations such as Medicaid unwinding related to the PHE among other projects. In addition, several commenters explained that State Exchanges are already implementing their own successful methods of ensuring that their calculation of APTC does not cause excess APTC, some of which already include prorating premiums, and that these State Exchanges should not be required to cease their effective methods, in favor of the proposed proration methodology. One commenter asserted that HHS does not have the authority to require Exchanges to implement the proposed proration methodology for premium and APTC amounts. Several of these commenters remarked that State Exchanges have the best insight into their Exchange populations and HHS should defer to their authority on how to approach the issue of APTC over-payment in their jurisdiction without limiting their flexibility.

Response: We maintain that regulating the administration of APTC is within HHS' statutory authority, as defined in section 1412 of the ACA, which grants authority to the Secretary of HHS to establish a program for APTC, and in HHS regulation under § 155.340, which establishes HHS' requirements regarding administration of the APTC. However, in light of comments regarding the need for more State Exchange flexibility, as noted earlier, we are not finalizing the policy as proposed.

We appreciate the competing priorities of State Exchanges and the potential costs of implementing the proposed policy. In the proposed rule, we acknowledged that implementing the proposed methodology would require implementation and operational costs and time on the part of most State Exchanges. We estimated a one-time implementation cost of approximately $1 million dollars for each State Exchange, and we address specific comments on the estimated cost of implementation further in the comment and response section of the Regulatory Impact Analysis in this final rule. In an effort to be responsive to State Exchange concerns, we are finalizing the method of APTC proration as proposed for the Exchanges using the Federal platform, but HHS will require only that, beginning with PY 2024, State Exchanges use a methodology that ensures that the calculation of APTC does not cause APTC applied to an enrollee's monthly premium to exceed the enrollee's expected monthly PTC amount when the enrollee is enrolled in a policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month, and to report the methodology to HHS in accordance with the requirements of § 155.1200(b)(2). We estimate that State Exchanges will be required to prospectively submit their planned PY 2024 methodology for the first time through the State-based Marketplace Annual Reporting Tool (SMART) tool in the summer of 2023 and will provide the option for State Exchanges to submit their methodology for PY 2023 through the SMART tool in the summer of 2022. HHS believes that finalizing this modification will provide the State Exchanges flexibility and sufficient time to implement a new methodology, if necessary, and to report the methodology to HHS.

HHS will be available to work with State Exchanges and address questions as they prepare to report on their methods to ensure that APTC calculations do not cause excess APTC for enrollees.

Comment: Several commenters opposing the proposal asserted that there is no need to issue regulations on the issue of APTC over-payment. Some of these commenters noted that the topic of APTC over-payment and the potential resulting income tax liability is not being reported as a problem by States Exchanges, consumers, or consumer advocacy groups. A few commenters noted that if this type of over-payment does occur, it is rare, and affects very few enrollees. Further, some of these commenters stated that if State Exchanges were over-paying APTC and exceeding premium amounts for partial-month coverage, enforcing compliance with the existing PTC rule would sufficiently address the issue.

Response: We remain concerned about the issue of APTC over-payments among State Exchanges, as described in the previous response. Recent APTC payment data indicates that APTC over-payments due to mid-month coverage changes cost the Federal government approximately $0.5 million to $1 million annually. While the issue of APTC over-payment may not impact very many enrollees annually, we believe that these over-payments are a legitimate source of consumer harm and may trigger a Federal income tax liability for the applicable enrollee. However, we agree that the reference at § 155.305(f)(5) to current PTC regulations at 26 CFR 1.36B–3(d) sets a clear enough standard to hold all Exchanges sufficiently accountable to making correct payments of APTC. In an effort to ensure compliance with the existing IRS PTC rules, we are finalizing the requirement that State Exchanges use a methodology that ensures that their calculation of APTC does not cause the amount of APTC applied to an enrollee's monthly premium to exceed their expected monthly PTC amount when an enrollee is enrolled in a policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month, and to report the methodology to HHS in accordance with the requirements of § 155.1200(b)(2).

10. Special Enrollment Periods—Special Enrollment Period Verification (§ 155.420)

In 2017, the 2017 Market Stabilization final rule preamble (82 FR 18346, 18355 through 18358) explained that HHS would implement pre-enrollment verification of eligibility for certain special enrollment periods in all Exchanges on the Federal platform. HHS also clarified its intention to not establish a regulatory requirement that all Exchanges conduct special enrollment period verifications to allow State Exchanges additional time and flexibility to adopt policies that fit the needs of their State (82 FR 18355 through 18358). However, all State Exchanges conduct verification of at least one special enrollment period type, and most State Exchanges have implemented a process to verify the vast majority of special enrollment periods requested by consumers.

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 653), we proposed to amend § 155.420 to add new paragraph (g) to state that Exchanges may conduct pre-enrollment verification of eligibility for special enrollment periods, at the option of the Exchange, and that Exchanges may provide an exception to pre-enrollment special enrollment period verification in special circumstances, which could include natural disasters or public health emergencies that impact consumers or the Exchange. We further proposed that Exchanges' pre-enrollment verification process must be implemented in a manner that is not based on a prohibited discriminatory basis. This is to encourage State Exchanges to conduct special enrollment period verification, but also allow the FFEs, SBE–FPs, and State Exchanges to maintain flexibility in implementing and operating special enrollment period verification.

Since 2017, Exchanges on the Federal platform implemented pre-enrollment

special enrollment period verification for certain special enrollment period types commonly used by consumers to enroll in coverage. New consumers, meaning consumers who are not currently enrolled in coverage through the Exchange, who apply for coverage through a special enrollment period type that requires pre-enrollment verification by the Exchanges on the Federal platform must have their eligibility electronically verified using available data sources or submit supporting documentation to verify their eligibility for the special enrollment period before their enrollment can become effective. As stated in the HHS Marketplace Stabilization Rule (82 FR 18355 through 18360), pre-enrollment special enrollment period verification is only conducted for consumers newly enrolling due to the potential for additional burden on issuers and confusion for consumers if required for existing enrollees.

While pre-enrollment special enrollment period verification can decrease the risk for adverse selection and improve program integrity, it can also deter eligible consumers from enrolling in coverage through a special enrollment period because of the barrier of document verification. Younger, often healthier consumers submit acceptable documentation to verify their special enrollment period eligibility at much lower rates than older consumers, which can negatively impact the risk pool. Additionally, our experience operating the FFEs and the Federal platform shows that pre-enrollment special enrollment period verification disproportionately negatively impacts Black and African American consumers who submit acceptable documentation to verify their special enrollment period eligibility at much lower rates than White consumers.

To support program integrity and streamline the consumer experience, we also proposed that the Exchanges on the Federal platform would conduct pre-enrollment verification of eligibility for only one type of special enrollment period—the special enrollment period for new consumers who attest to losing minimum essential coverage.[259] The loss of minimum essential coverage special enrollment period type comprises the majority, about 58 percent, of all special enrollment period enrollments on the Exchanges on the Federal platform and has electronic data sources that can be leveraged for auto-verification. By verifying eligibility for this special enrollment period type and not for other special enrollment periods, the Exchanges on the Federal platform could limit the negative impacts of special enrollment period verification and decrease overall consumer burden without substantially sacrificing program integrity.

We sought comment on these proposals.

After reviewing the public comments, we are finalizing this provision as proposed, except that we have added a specific reference to § 155.120(c) to the new regulation text at § 155.420(g) to clarify the precise nondiscrimination standards that are applicable to an Exchange's process for granting exceptions to pre-enrollment verification for special enrollment periods.

We summarize and respond to public comments received on the special enrollment period verification proposal.

Comment: The majority of commenters supported HHS' proposal. Many commenters agreed that this policy helps minimize barriers to enrollment while still maintaining program integrity. Most also agreed that this policy will advance health equity by alleviating barriers to enrollment for historically disadvantaged and marginalized communities. Several commenters mentioned that pre-enrollment special enrollment period verification can be especially burdensome for low-income individuals, since they are more likely to have inadequate internet access at home and are more likely to use a primary language other than English. Commenters also noted additional groups that would benefit from this policy: Immigrants, Native Americans, and those living in rural areas who may not have high-quality internet access.

Several commenters agreed that special enrollment period verification requirements can cause gaps in coverage and stated that reducing these barriers will encourage continuous coverage. Commenters mentioned that it can be difficult to verify life events, such as proving a change in household size when someone becomes a tax dependent. One commenter noted that pre-enrollment verification is not only time consuming for consumers, but also for brokers who could be using that time to help more clients enroll in coverage. Many commenters agreed that this proposal will encourage younger and healthier consumers who are eligible for a special enrollment period to enroll and that this will be good for the risk pool. Several commenters highlighted that concerns from issuers about scaling back pre-enrollment verification for special enrollment periods harming market stability have not been proven.

Response: We appreciate the comments highlighting that this policy will have a positive impact on consumers from historically disadvantaged and marginalized communities. We agree that this policy will decrease consumer burden and barriers to enrollment for eligible consumers, while still supporting program integrity. We also agree that this policy will increase enrollments among younger and healthier consumers and that this will have a positive impact on the risk pool.

Comment: Several commenters mentioned that, as written, this proposal would still pose a barrier for consumers, particularly those who face disproportionately high rates of being uninsured, such as immigrants and Black and African American consumers. Some commenters explained accessing documents from past employers to prove loss of minimum essential coverage can be challenging, especially for immigrants or those who are more likely to have unstable employment or work in the informal economy. One commenter also raised concern that losing coverage can place significant stress on a household and consumers may not have the bandwidth to complete a pre-enrollment verification process for a special enrollment period. Several commenters recommended that HHS further act to reduce consumer burden and barriers to enrollment by eliminating pre-enrollment verification for all special enrollment period types. A few commenters advocated for self-attestation in lieu of document verification and mentioned that many other Federal programs rely on self-attestation.

Response: We appreciate commenters' concerns related to health equity and consumer burden. We believe that by scaling back pre-enrollment verification for special enrollment periods, this policy will decrease consumer burden and barriers to enrolling through a special enrollment period. At this time, we believe that pre-enrollment verification for special enrollment periods is appropriate for the most commonly used special enrollment period type in order to support program integrity. HHS works to reduce consumer burden imposed by pre-enrollment verification for special enrollment periods based on loss of minimum essential coverage while still supporting program integrity by using available data to automatically verify loss of minimum essential coverage for a large portion of consumers requesting a loss of minimum essential coverage

[259] See 45 CFR 155.420(d)(1)(i).

special enrollment period, which requires no additional consumer action and does not delay enrollment. We will continue to evaluate whether additional changes are appropriate.

Comment: Some commenters supported the clarified flexibility for State Exchanges. Commenters stated that this change will enable State Exchanges to implement pre-enrollment special enrollment period verification processes that are tailored to their respective Exchanges and consumer populations. One commenter also appreciated that Exchanges may provide an exception to pre-enrollment special enrollment period verification for special circumstances. A couple of commenters highlighted that the new paragraph (g) language is redundant since State Exchanges already have flexibility to exercise discretion under current rules.

Many commenters expressed concern that State Exchanges may conduct pre-enrollment verification for additional special enrollment period types—outside of loss of minimum essential coverage—which could cause barriers to enrollment in those States, particularly for younger and Black and African American consumers. Due to this concern, these commenters recommended that HHS should not permit State Exchanges to have broader pre-enrollment verification of eligibility for special enrollment periods than the FFEs.

One commenter urged HHS to monitor how State Exchanges implement pre-enrollment verification for special enrollment periods to ensure their processes are not discriminatory. Another commenter suggested that HHS prohibit State Exchanges from implementing pre-enrollment verification that differs from that of the FFEs, unless the State Exchange can prove that pre-enrollment verification for special enrollment periods will not have a disproportionate impact on communities of color in their State.

Response: We agree that the new paragraph (g) allows State Exchanges to continue to implement pre-enrollment verification processes for special enrollment periods that are tailored to their respective populations and needs. We also agree that clarifying that Exchanges may provide an exception for pre-enrollment special enrollment period verification for special circumstances will enable Exchanges to be flexible so that eligible consumers can easily enroll in coverage when they may need it most, such as during the current COVID–19 PHE unwinding period. HHS is committed to equity in health care and plans to monitor use of SEP pre-enrollment verification in State Exchanges to ensure that they are following the non-discrimination standards under § 155.120(c).

Comment: Several commenters, particularly issuers, opposed this proposal due to concerns that scaling back pre-enrollment verification for special enrollment periods would lead to an increase in fraud and abuse that would negatively impact market stability and premium costs. A few of these commenters mentioned concerns about consumers temporarily relocating to a State for medical care, which could lead to increased costs in areas with renowned medical centers. Commenters stated that HHS should encourage year-long continuous coverage. One commenter cautioned that this policy, combined with other recent policy changes such as a longer open enrollment period and the special enrollment period for individuals with incomes under 150 percent of the Federal poverty level, will harm market stability.

Several commenters stated that before the 2017 Market Stabilization final rule (82 FR 18346), the market was unstable and costs were higher due to fraud and abuse in consumers' use of special enrollment periods as consumers would wait to enroll until they needed care. One commenter noted that data from a 2018 CMS report showed that most consumers with special enrollment period verification issues submitted the necessary documents to resolve their issue.[260] In addition, the report revealed that fewer consumers enrolled through an exceptional circumstance SEP (suggesting less abuse), and that the average age of special enrollment period enrollees was younger than that of open enrollment period enrollees.

Commenters also stated that risk adjustment data suggests that consumers with chronic conditions are abusing special enrollment periods and are waiting to enroll until they need care. One commenter highlighted that the loss ratios after risk adjustment for special enrollment period enrollments, relative to open enrollment period enrollments, has increased for some of their plans since 2019. They stated that this is likely due to Exchanges relaxing pre-enrollment verification for special enrollment periods during the PHE.

Response: We disagree that this policy will destabilize the market and cause large increases in premium costs. We believe that while pre-enrollment special enrollment period verification can decrease the risk of adverse selection and improve program integrity, it can also deter eligible consumers from enrolling in coverage through a special enrollment period because of the barrier of document verification. By verifying eligibility for the most commonly used special enrollment period type and removing verification for other special enrollment periods, we believe that the Exchanges on the Federal platform will successfully mitigate the negative impacts of special enrollment period verification without substantially sacrificing program integrity or market stability.

We acknowledge the data from the 2018 CMS report regarding special enrollment period verification. While most SEP verification issues have been resolved, current HHS data shows that younger consumers submit acceptable documentation to verify their special enrollment period eligibility at much lower rates than older consumers, which can negatively impact the risk pool as younger consumers are often healthier. We believe that improving access for younger and healthier eligible consumers will be good for the risk pool and offset the effect of potential increased adverse selection. Current HHS data also shows that Black and African American consumers submit acceptable documentation at much lower rates than White consumers. This suggests that pre-enrollment verification may be a barrier to enrollment for eligible Black and African American consumers. This policy change may improve health equity, and access to affordable, quality coverage for all.

Comment: Many commenters who opposed this proposal, agreed that document verification for special enrollment periods can be a barrier to enrollment for some eligible consumers. Therefore, they expressed support for more automation of special enrollment period verification. One commenter also encouraged HHS to evaluate why some consumers submit acceptable documents at lower rates and recommended redesigning the document collection process accordingly.

Response: We acknowledge these concerns and will continue to conduct automated, pre-enrollment verification when possible for the loss of minimum essential coverage SEP type. We note that automated verification is not always possible. However, we continue to believe that the approach we are adopting balances the priorities of reducing consumer burden with supporting program integrity. HHS

[260] The Exchanges Trends Report (2018, July 2). CMS. *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2018-07-02-Trends-Report-3.pdf.*

continues to evaluate document submission rates and consumer outcomes to inform process and policy improvements for successful SEP verification.

11. General Program Integrity and Oversight Requirements (§ 155.1200)

The Payment Integrity Information Act of 2019 (PIIA) [261] requires Federal agencies to annually identify, review, measure, and report on the programs they administer that are considered susceptible to significant improper payments. Pursuant to the Payment Integrity Information Act of 2019 (PIIA),[262] HHS is in the planning phase of establishing a State Exchange Improper Payment Measurement (SEIPM) program, as HHS has determined that APTC payments may be susceptible to significant improper payments and are subject to additional oversight.

State Exchanges must meet specific program integrity and oversight requirements specified at section 1313(a) of the ACA, as well as §§ 155.1200 and 155.1210. These requirements provide HHS with the authority to oversee the Exchanges after their establishment. Under § 155.1200(c), each State Exchange is required to engage or contract with an independent qualified auditing entity that follows generally accepted government auditing standards (GAGAS) to perform annual independent external financial and programmatic audits.

We proposed to add new § 155.1200(e) to permit a State Exchange to meet the requirement to conduct an annual independent external programmatic audit, as described at § 155.1200(c), by completing the required annual SEIPM program process. Therefore, under the proposal, HHS would generally accept a State Exchange's completion of the SEIPM process for a given benefit year as acceptable to meet the annual programmatic audit requirement for that benefit year. We had also proposed to amend § 155.1200(c) to cross-reference proposed § 155.1200(e) to ensure the coordination of these two requirements. Please see the proposed rule preamble for a complete description of the proposed policy and the SEIPM program.[263]

We sought comment on these proposals.

After reviewing the public comments, we are not finalizing this proposed provision at this time as it is interrelated with the SEIPM program proposal, which will not be finalized at this time through this final rule. HHS will continue to engage with the State Exchanges as we continue to develop the SEIPM program, which we plan to codify in future rulemaking. Please refer to section 12 for further details.

We summarize and respond to public comments received on general program integrity and oversight requirements (§ 155.1200) below.

Comment: Several commenters generally opposed the amendment to the programmatic audit requirement to permit a State Exchange to meet the requirement under § 155.1200(c) by completing the SEIPM program process, as proposed under subpart P. Commenters noted that the proposed change is duplicative because the existing programmatic audit requirement under § 155.1200(d) already addresses eligibility and enrollment compliance. One commenter explained that imposing a new audit requirement under SEIPM creates additional burden that is not offset by the amendment to the programmatic audit requirement under § 155.1200(e). Another commenter stated that while HHS is permitting a State Exchange to meet the programmatic audit requirement under § 155.1200(c) by completing the SEIPM program process, State Exchanges will need to spend substantial time and resources to prepare for SEIPM. Commenters noted that State Exchanges are already subject to extensive oversight under §§ 155.1200 and 155.1210 and requested HHS clarify how the SEIPM will impact the SMART for Plan Years 2023–2025. Another commenter requested that HHS grant programmatic audit relief while State Exchanges prepare to comply with the SEIPM program and also consider how the existing programmatic audit requirement may be able to meet SEIPM goals. A few commenters requested that HHS consider alternative approaches to the implementation of the proposed SEIPM program, such as enhancing the current programmatic audit requirement under § 155.1200 to review for improper payments or maintain the programmatic audit requirement intact, as it permits flexibility and does not add undue burden. One commenter recommended that HHS use onsite audits to reduce burden on the State Exchanges resulting from the SEIPM program.

Response: HHS will continue to evaluate how to minimize duplicative requirements and reduce burden on State Exchanges as we work toward implementation of the proposed SEIPM program. After considering the comments received, we are not finalizing this provision at this time, as it is interrelated with the SEIPM program proposal, which will not be finalized through this final rule. We clarify that the existing oversight and audit requirements under §§ 155.1200 and 155.1210 were not intended to be a part of any measurement program that may have been required under the Improper Payments Elimination and Recovery Act of 2010, and updated through PIIA. The maintenance of records requirement under § 155.1210 requires that State Exchanges keep eligibility and enrollment records, but it does not establish requirements specific to improper payments. The independent external programmatic audits required under 155.1200(c) do not review, estimate, or report the amounts or rates of improper payments and do not allow for standardized comparison or analysis across State Exchanges. In order to comply with the PIIA, HHS will continue to develop the SEIPM program and plans to engage in future rulemaking to codify the SEIPM program.

Regarding the SMART, we clarify that State Exchanges will continue to report on Exchange compliance through the annual SMART process, as required under § 155.1200(b)(2).

12. State Exchange Improper Payment Measurement Program (§§ 155.1500 Through 155.1540)

In 2016, HHS completed a risk assessment of the APTC program. Similar to other public-facing benefit programs, HHS determined that the APTC program is susceptible to significant improper payments, and as a result, HHS announced plans to increase the oversight of the APTC program through the development and reporting of annual improper payment estimates, and facilitating corrective actions.[264] At that time, we also announced that we would undertake rulemaking before implementing the improper payment measurement methodology.

In line with our prior announcement,[265] and as mentioned in section 11 of the preamble, HHS proposed regulations governing HHS' SEIPM program.

As noted in the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 655), current regulations found at 45 CFR 155.1200 and 155.1210 require that a State

[261] Public Law 116–117 (2020, March 2).

[262] Public Law 116–117 (2020, March 2).

[263] 87 FR 654 through 660.

[264] Presentation and materials provided to the then operational State Exchanges as part of 'All States' meeting held on February 21, 2019.

[265] Ibid.

Exchange have financial and operational safeguards in place to avoid making inaccurate eligibility determinations, including those related to APTC, CSR, and enrollments. The regulations at § 155.1200(c) require State Exchanges to hire an independent qualified auditing entity and submit the external audit results to HHS. The programmatic audits do not review, estimate, or report on the amounts or rates of improper payments as the result of eligibility determination errors made by State Exchanges. To meet the requirements of PIIA, to reduce burden on State Exchanges, and to ensure consistency across State Exchanges in terms of our review methodology, we proposed to update programmatic auditing requirements such that the completion of the annual SEIPM program would satisfy the current auditing requirements prescribed in § 155.1200(c). Therefore, we proposed to establish a new subpart P under 45 CFR part 155 (containing §§ 155.1500 through 155.1540) to codify the SEIPM program requirements. Please see the proposed rule preamble (87 FR 654 through 655) for a complete description of the proposed policy.

After reviewing and considering the public comments, we will not finalize the SEIPM proposals at this time due to commenters' concerns surrounding the proposed implementation timeline and other burdens that would be imposed by the proposed SEIPM program.

We summarize and respond to public comments received on the State Exchange Improper Payment Measurement Program (§§ 155.1500 through 1540) below.

Comment: Several commenters addressed the implementation timeline for the SEIPM program. One commenter expressed concerns with the relatively short implementation time frame and questioned whether it was operationally, fiscally, and technologically feasible for State Exchanges to comply with the program's requirement by the proposed PY 2023 effective date. A few commenters characterized the timeline for SEIPM implementation as inadequate. One commenter recommended several years of implementation in a pilot before HHS publishes error rates to ensure the data accurately reflect errors. One commenter characterized the implementation timeline as administratively and financially burdensome and unrealistic because State Exchanges would need to implement new processes and possibly technology changes by the end of 2022 to meet the proposed 2024 reporting requirements. One commenter proposed an effective date of plan year 2024 rather than 2023. One commenter requested extending the deadline for SEIPM.

Response: Given the additional burden that was placed upon State Exchange resources during the PHE, we agree that additional time should be provided for implementation and consequently we are not finalizing the provision at this time to allow for a longer implementation timeline. We also generally agree with the commenter who stated that additional piloting is needed. Because piloting efforts have also been hindered by the PHE, HHS will consider more robust piloting options in which the State Exchanges can participate prior to HHS publishing estimates of improper payment rates.

Comment: Several commenters supported the need for review of eligibility determinations that result in improper payments of APTC and encouraged HHS to collect more detailed documentation of eligibility denials.

Response: We thank the commenters for their support of the SEIPM program and we will consider this feedback as we continue to develop the program. We address the commenters' specific suggestions in the data collection section below.

Comment: One commenter indicated that it was neutral as to the establishment of the SEIPM program. The commenter noted that there are obvious potential benefits to the Federal oversight model instead of the programmatic audit model currently in use by State Exchanges, and the commenter also noted that it is currently too early to fully assess whether the tradeoffs regarding the cost and work related to the audit model will be more or less than the cost and work to meet the reporting requirements of the proposed Federal oversight model.

Response: We thank the commenter for sharing its view of the SEIPM program.

Comment: Many commenters expressed opposition regarding the SEIPM proposal noting it is duplicative because the existing SMART and programmatic audit requirements under § 155.1200 address eligibility and enrollment compliance.

Response: We address these comments under section 11 of the preamble.

Comment: A few commenters stated that the SEIPM program is duplicative because consumers already reconcile APTC on their tax returns.

Response: We appreciate the commenters' observation, but note that the APTC reconciliation process on the tax return only addresses the APTC calculation and not the accuracy of the eligibility determination. The IRS uses the annual enrollment data and monthly reconciliation data provided by HHS to calculate the PTC and to verify reconciliation of APTC made to the QHP issuers on enrollees' individual tax returns. However, the IRS does not address other issues related to the APTC calculation, particularly in examining the eligibility and enrollment processes including the verification of citizenship, social security number, residency, minimum essential coverage, special enrollment period circumstance, income, family size, and data matching issues related to document authenticity. Examination of these areas would be necessary to identify any underlying issues that could lead to improper payments, and therefore may need to be addressed through corrective action as stipulated under the PIIA.

Comment: A few commenters stated that the data HHS is proposing to collect are already available to HHS through the Federal Data Services Hub (FDSH), the State-based Marketplace Inbound (SBMI), or enrollment and disenrollment reports, making the additional SEIPM collection effort burdensome and duplicative.

Response: We appreciate the feedback regarding the potential duplication of Federal requirements and increased burden. As we continue to develop the SEIPM program, we intend to work collaboratively with State Exchanges to continue to evaluate how to best minimize duplicate requirements and reduce burden on the State Exchanges, as well as how HHS can use data submitted by State Exchanges under existing Federal requirements to help streamline SEIPM processes. We note that as of this writing, HHS does not collect data regarding verification and eligibility determination, enrollment reconciliation, or plan management from the State Exchanges to determine whether they comply with existing regulations. While the FDSH does provide applicant verification information, it does not provide evidence that the State Exchange used FDSH data to conduct verifications or whether verification inconsistencies were resolved properly. Moreover, the FDSH does not provide the information needed to determine whether a State Exchange evaluated the verified information properly to determine an applicant's eligibility for enrollment in a QHP and receipt of APTC. We recognize that the State-Based Marketplace Inbound (SBMI) data provides the policies and payments for an applicant, however, that data cannot

be matched to a specific application submission, which prevents HHS from using the data to verify that eligibility determinations and associated APTC payments were made correctly. Further, the SBMI data does not include the reconciliation that occurs with the State Exchange and its issuers to provide evidence that the State Exchange resolved any data discrepancies with the issuers that may result in incorrect APTC payments being made. Additionally, the SBMI data does not indicate whether policies were certified as QHPs. HHS currently uses this data to understand the sampling of policies from each State Exchange and to determine an appropriate sample that would be selected to reflect the State Exchange's applicant population. We will continue to evaluate this and other data that HHS currently collects and will use it to the maximum extent feasible as we continue to develop the SEIPM program.

Comment: A few commenters expressed concern that the proposed rule does not provide enough information to assess the SEIPM program proposal or to evaluate the tradeoffs related to the current Federal programmatic audit requirements under § 155.1200(c) compared to the proposed audit processes under the SEIPM program.

Response: Although commenters did not specify what additional information would have been helpful in assessing the program, HHS believes that this concern is related to potential duplication of effort and whether current requirements under § 155.1200(d) are consistent with SEIPM requirements. Though we are not finalizing this proposed provision, we will consider these comments as we continue to develop the SEIPM program.

Comment: One commenter requested that the SEIPM program not collect data from the State Exchanges during the annual individual market Exchange Open Enrollment Period (OEP) timeframe, which is from the end of October (final preparation for annual OEP) to the end of January (distribution of Forms 1095–A).

Response: We will consider this feedback as we continue to develop the SEIPM program. As we continue to develop the program, we aim to coordinate with State Exchanges to offer maximum flexibility to account for State's enhanced workloads during the OEP.

Comment: One commenter noted that despite the provision allowing completion of the SEIPM requirements to satisfy the existing independent external programmatic audit requirement under § 155.1200(c), State Exchanges would have to spend time and resources to prepare for and procure a separate audit when participating in the SEIPM program.

Response: We appreciate the feedback around potential duplication of Federal requirements and increased burden. We address these concerns in section 11 of the preamble.

Comment: One commenter suggested that HHS convene an HHS and State Exchanges working group to identify approaches to the specific areas that HHS wants to address through current Federal audit requirements.

Response: We appreciate the commenter's suggestion and value the feedback we have received from the State Exchanges during the SEIPM pilot process. We have been engaging in discussions regarding the SEIPM with the State Exchanges since 2019 and we continue to meet with State Exchanges individually to gather feedback on the SEIPM approach. We will continue these efforts as we move forward in the development of the SEIPM program.

Comment: One commenter recommended that the SEIPM program operate as a minimum threshold for State Exchanges to meet the proposed SEIPM requirements and to allow flexibility for any individual State Exchange to create more stringent auditing criteria above and beyond what is required in the proposed SEIPM program. The commenter suggested allowing State Exchanges to meet their independent external programmatic audit requirements by complying with the SEIPM program. In cases where the State Exchange has more stringent auditing criteria than the SEIPM program, the commenter suggested that the State Exchange should be able to maintain its criteria.

Response: We understand that the State Exchanges may expand on the Federal regulations to create more stringent policies and procedures. In addition to evaluating compliance with Federal requirements during the planned SEIPM review process, our goal is to also measure compliance with State Exchange specific policies and procedures to the extent that State Exchange specific policies and procedures do not conflict with Federal requirements. As we continue to develop the SEIPM program, we will collaborate with each State Exchange to modify the review criteria so that each State Exchange is evaluated against their own policies and procedures.

Comment: One commenter encouraged HHS to take a risk-based approach that focused on reviews of a specific area or areas that have a higher risk of over-payments. The commenter suggested HHS use a more proactive approach that used test scenarios to demonstrate APTC accuracy.

Response: We appreciate the feedback and recognize that certain State Exchange system functions may have more risk than others in implementing Federal regulations. We appreciate the recommendation to use test scenarios and have begun to do so, in some instances, as we engage with State Exchanges on SEIPM pilot and preparatory activities. We will consider this comment as we continue to develop the SEIPM program.

Comment: One commenter recommended modifying the SEIPM's scope to focus on APTC in addition to the SEIPM process replacing the annual programmatic audit requirement.

Response: As we continue to develop the SEIPM program, we plan for the SEIPM review process to focus on identifying, measuring, estimating, and reporting errors made in determining eligibility for APTC greater than $0 that resulted in improper payments. We plan for this to include the examination of eligibility and enrollment processes, which consists of verifications of citizenship, social security number, residency, minimum essential coverage, special enrollment period circumstance, income, family size, and data matching issues related to document authenticity. Examination of these areas would be necessary to identify any underlying issues that could lead to improper payments, and therefore would need to be addressed through corrective action, as stipulated under the PIIA.

Comment: One commenter suggested that HHS observe trends that emerge during SEIPM implementation and propose Corrective Action Plan parameters in future rulemaking, and then release the first improper payment report in November 2025, at the earliest.

Response: We appreciate the comments offering support to defer the CAP parameters. We plan to engage in future rulemaking to codify the SEIPM program and will solicit comments regarding the CAP at that time.

a. Purpose and Definitions (§ 155.1500)

We proposed to add new § 155.1500 to convey the purpose of subpart P and definitions that are relevant to the SEIPM program.

- At paragraph (a), we proposed the purpose of subpart P as setting forth the requirements of the SEIPM program for State Exchanges.
- At paragraph (b), we proposed to codify the definitions that are specific to the SEIPM program and key to

understanding the process requirements.

• We proposed the definition of ''Appeal of redetermination decision (or appeal decision)'' to mean HHS' appeal decision resulting from a State Exchange's appeal of a redetermination decision.

• We proposed the definition of ''Corrective action plan (CAP)'' to mean the plan a State Exchange develops to correct errors resulting in improper payments.

• We proposed the definition of ''Error'' to mean a finding by HHS that a State Exchange did not correctly apply a requirement in subparts D and E of part 155 regarding eligibility for and enrollment in a QHP; APTC, including the calculation of APTC; redeterminations of eligibility determinations during a benefit year; or annual eligibility redeterminations.

• We proposed the definition of ''Error findings decision'' to mean HHS' enumeration of errors made by a State Exchange, including a determination of how the enumerated errors inform improper payment estimation and reporting requirements.

• We proposed the definition of ''Redetermination of an error findings decision (or redetermination decision)'' to mean HHS' decision resulting from a State Exchange's request for a redetermination of HHS' error findings decision.

• We proposed the definition of ''Review'' to mean the process of analyzing and assessing data submitted by a State Exchange to HHS in order for HHS to determine a State Exchange's compliance with subparts D and E of part 155 as it relates to improper payments.

• We proposed the definition of ''State Exchange improper payment measurement (SEIPM) program'' to mean the process for determining estimated improper payments and other information required under the PIIA, and implementing guidance, for APTC, which includes a review of a State Exchange's determinations regarding eligibility for and enrollment in a QHP; the calculation of APTC; redeterminations of eligibility determinations during a benefit year; and annual eligibility redeterminations.

After reviewing the public comments, we are not finalizing this provision at this time. We summarize and respond to public comments received on purpose and definitions (§ 155.1500) below.

Comment: One commenter recommended that HHS also define the following terms: (1) Annual Program Schedule, (2) Measurement Cycle, (3) Measurement Year, and (4) Reporting Year. The commenter also recommended clarifying the meaning of two statistical terms: (1) Pre-sampling Data and (2) Sampled Unit Data.

Response: HHS agrees that the defining these additional terms would provide greater clarity to State Exchanges regarding SEIPM program requirements. We will consider defining these terms in future rulemaking.

b. Program Notification and Planning Process (§ 155.1505)

We proposed to add new § 155.1505 to outline the annual program notification requirements related to the SEIPM program.

• At paragraph (a), we proposed the requirements associated with HHS' responsibility to notify the State Exchanges prior to the start of the measurement year regarding information pertinent to the SEIPM program and the program's upcoming measurement cycle, which may include but would not be limited to review criteria; key changes from prior measurement cycles, where applicable; or other modifications regarding specific SEIPM activities. This proposed notification would occur during the benefit year (that is, the year under review for which data would be collected), which immediately precedes the proposed measurement year (that is, the year in which the measurement will be completed). The proposed measurement cycle would conclude with the reporting year during which all data issues would be resolved and the improper payment rate would be calculated and published.

• At paragraph (b), we proposed the requirements associated with HHS' responsibility to notify the State Exchanges prior to the proposed measurement year regarding SEIPM schedules, which will include relevant timelines. For example, among other things, the proposed SEIPM annual program schedule would detail the time period during which HHS would provide the proposed SEIPM data request form to State Exchanges with instructions regarding how to complete each part of the form. The proposed SEIPM annual program schedule would also provide the deadlines prescribed for State Exchanges to complete each part of the form.

• At paragraph (c), we proposed the requirements associated with information to be provided by State Exchanges to HHS regarding the operations and policies of the State Exchange, and changes that have been made by the State Exchange which could impact the proposed SEIPM review process such as changes to business rules, business practices, policies, and information systems (for example, data elements and table relationships), which are used to review the State Exchange's execution of consumer verifications, verification inconsistency resolutions, eligibility determinations, enrollment management, and APTC calculations. Please see the proposed rule preamble (87 FR 656) for a complete description of the proposed policy.

We did not receive any comments in response to the proposals on the program notification and planning process.

As previously stated, we are not finalizing this provision at this time.

c. Data Collection (§ 155.1510)

We proposed to add new § 155.1510 to address the data collection requirements to support the SEIPM process.

• At paragraph (a)(1), we proposed the requirement that the State Exchange annually provide pre-sampling data to HHS by the deadline provided in the annual program schedule. The proposed pre-sampling data request would provide HHS with essential information about the composition of the State Exchange's application population to appropriately stratify and sample the population.

Please see the proposed rule preamble for a complete description of the sampling methodology for this proposal (87 FR 656).

• At paragraph (a)(2) we proposed annual requirement that the State Exchange provide sampled unit data to HHS. To meet this requirement under the proposal, a State Exchange can submit consumer-submitted documentation in one or more batches so long as all of the batches are provided to HHS within the deadline specified in the annual program schedule. The proposed sampled unit data request would include the list of sampled units and the associated information specific to each unit. The information required under the proposal for the sampled units would include data and supporting documentation regarding various State Exchange functions, for example, electronic verifications, manual reviews of data matching inconsistencies, special enrollment period verifications, eligibility determinations, redeterminations, enrollment reconciliation, and plan management.

• At paragraph (b), we proposed the State Exchange submit the pre-sampling and sampled unit data specified in paragraph (a) to be submitted to HHS in a manner and within a deadline

specified in the annual program schedule. We also proposed language regarding requests for extension which may be submitted by State Exchanges. Given the importance of the time frames associated with the measurement process, through this proposal, we did not anticipate granting extensions in most situations. Rather, the approval of extension requests was envisioned to be reserved for extreme circumstances that would directly impact operations of the particular State Exchange. Such situations might include natural disasters, interruptions in business operations such as major system failures, or other extenuating circumstances.

• At paragraph (c), we proposed language regarding potential consequences as a result of a State Exchange's failure to timely provide the information in accordance with the schedule and deadlines detailed in the annual program schedule, or in response to a request for extension in paragraph (b). Under the proposal, as a result of not timely providing required data, we may have cited errors due to lack of documentation to support the State's eligibility or payment decisions.

After reviewing the public comments, we are not finalizing this provision at this time.

We summarize and respond to public comments received on data collection (§ 155.1510) below.

Comment: A few commenters pointed out that there may be differences between State Exchanges in terms of database structures, data fields, and reporting. A few commenters stated that implementing the SEIPM data requirements will create a financial and operational burden as it will require them to change their information technology systems, and they will need to employ new staff or forgo other activities such as standing up other programs.

Response: We appreciate these comments and will take them into consideration as we continue to develop the SEIPM program. However, we emphasize that it was not the intention of the proposed SEIPM program to drive changes to a State Exchange's information technology systems. One goal of HHS is to reduce burden by requesting State Exchanges to populate the information elements of the data request form by using existing data elements from their current IT system. Still, we recognize there is a cost burden related to the employment of staff resources required to conduct data analysis, perform data mapping activities, and extract data to support submission requirements. We will consider these costs in future rulemaking to codify the SEIPM program.

Comment: A few commenters noted a desire for flexibility in the data fields they provide to HHS. One commenter appreciated that under the pilot program, State Exchanges were allowed flexibility in what data fields could be provided.

Response: We recognize that State Exchange systems and business processes may vary in the way that data is used and stored. For this reason, we are conducting information review sessions with State Exchanges to address State Exchange-specific needs. There are many complex elements that must be met for any applicant who is deemed eligible for APTC. Because of the complexity and breadth of those elements, a very structured review methodology is required. To meet that need, certain data fields have been identified that are required for the purposes of conducting a review of this nature. The data request form was designed to aid in the matching of information fields that are needed by HHS with the States' data in order to conduct the required measurement in a consistent manner across all State Exchanges. The ongoing review sessions will allow opportunities to identify the most efficient means for collecting the information that is ultimately deemed necessary. We will continue to engage with State Exchanges through such sessions as we continue to develop the SEIPM program.

Comment: A few commenters suggested changes to the program sample size. One commenter recommended that the sample size be from 100–1,000 tax households to account for the variation in State Exchange populations. One commenter suggested that HHS choose a different method for sampling and auditing eligibility and enrollment data to instead allow a State Exchange to pull data records for a ''reasonable'' sample size, which it did not further define, and work with an HHS auditor for data review.

Response: We appreciate and thank commenters for their suggestions regarding sample size. We clarify that the PIIA and OMB Circular A–123, Appendix C require HHS to produce a statistically valid point estimate of the improper payment rate aggregated across all State Exchanges. This requires determining the sample size that is necessary for meeting the targeted margin of error to estimate a total improper payment rate across all State Exchanges and determining the sample sizes for the individual State Exchanges under that parameter. To reduce State burden, we plan to assess various stratification variables which may optimize the sample size and will continue to assess the benefits and deficiencies of various other sampling methodologies.

Comment: A few commenters suggested that HHS require State Exchanges to collect additional information such as data on erroneous coverage denials and incorrect financial assistance allocations.

Response: We appreciate the commenters' suggestions to expand the scope of CMS data collection to include erroneous coverage denials and incorrect financial assistance allocations. The focus of the planned SEIPM program, however, is to identify, measure, estimate, and report on erroneous determinations of eligibility for APTC payments in an amount greater than $0 that result in improper payments. We continue to assess and identify improvements to the planned SEIPM review process with a focus on the statutory and regulatory requirements and compliance with OMB guidance.

Comment: A few commenters suggested requiring State Exchanges to disaggregate eligibility and enrollment data by race and ethnicity. One commenter also suggested disaggregating data by primary language, sex, sexual orientation, gender identity, and disabilities. One commenter suggested disaggregating data by applicants who indicate their primary language is other than English.

Response: We will consider the commenters' suggestions as we continue to develop the SEIPM program. We also respectfully remind commenters that the focus of the planned SEIPM program is to identify, measure, estimate, and report on erroneous determinations of eligibility for APTC payments in an amount greater than $0 that result in improper payments. As we continue to develop the SEIPM program, we plan to audit State Exchanges in compliance with the PIIA and OMB guidance to estimate improper payments.

Comment: One commenter suggested that HHS explicitly require any protected health information (PHI) or personally identifying information (PII) shared with HHS or contractors be transmitted using a secure file transfer mechanism such as Secure File Transfer Protocol (SFTP).

Response: HHS will consider how to establish a secure file transfer mechanism between the State Exchanges and HHS to support the exchange of files that may contain PII and PHI data.

Comment: A few commenters noted that they had worked in pilots of the SEIPM program with CMS and that the process was difficult either because the program based its effort to standardize audits across State Exchanges on the FFE data model or because the program required manual review of records.

Response: We recognize that State Exchange systems and business processes may vary in the way that data is used and stored. For this reason, we are conducting information review sessions with State Exchanges to address State Exchange-specific needs. The data request form was designed to aid in the matching of information fields that are needed by HHS in order to conduct the required measurement in a consistent manner across all State Exchanges. The information review sessions allow opportunities to identify the most efficient means for collecting this information from each State Exchange. We will continue to engage with State Exchanges through such sessions as we continue to develop the SEIPM program. HHS developed a review modules document (RMD) to establish the baseline set of review criteria that will be applied across all State Exchanges. Each review criterion is based on specific Federal regulations or on a State Exchange's own policies that may expand on how a regulation is implemented in their State Exchange. In support of the review criteria in the RMD, CMS developed the data request form detailed above. We note that CMS developed the data request form to define a set of generalized data elements that are not specific to the FFE data model. These data elements should be common to all State Exchanges as they would be needed to execute general Federal regulation requirements established for the enrollment and eligibility process.

Comment: One commenter noted that there are not clear standards for the data that would satisfy an SEIPM audit. The commenter noted that the State Exchanges may not have the requested data available where self-attestation is accepted.

Response: We recognize the need for clear standards for data to satisfy an SEIPM review. As we continue to develop the SEIPM program, we will continue with our current communications with State Exchanges to address State Exchange-specific needs and to convey planned standards and data requirements that can be found in the corresponding PRA package, including the pre-sampling and sampled unit data request. State Exchanges that have voluntarily chosen to participate in the current engagement process will continue to benefit from receiving guidance regarding planned standards and data requirements. HHS encourages all State Exchanges to voluntarily engage with HHS to better understand the planned data collection requirements. During these engagement sessions, HHS can better understand the unique business rules and environment the State Exchange is operating within and make appropriate modifications to the review criteria and data that is requested to evaluate the State Exchange against those criteria. In addition, HHS recognizes that utilization of self-attestation may limit the availability of certain data and is taking this into account as we continue to develop the SEIPM program. Finally, we note that additional detail regarding the proposed SEIPM data request form is provided above in the preamble to the data collection process.

d. Review Process and Improper Payment Rate Determination (§ 155.1515)

We proposed to add new § 155.1515 to address the review process and the determination of the improper payment rate.

- At paragraph (a), we proposed that HHS would keep a record of the status of receipt for information requested from each State Exchange for a minimum of 10 years.
- At paragraph (b), we proposed to review the following for compliance with subparts D and E of part 155: A State Exchange's determinations regarding eligibility for and enrollment in a QHP; APTC, including the calculation of APTC; redeterminations of eligibility determinations during a benefit year; and annual eligibility redeterminations. As part of the proposed review process, HHS would issue error findings decisions and render redeterminations of error findings decisions within the timeframe specified in the annual program schedule.
- At paragraph (c), we proposed to notify each State Exchange of HHS' error findings decisions for that State Exchange and HHS' calculation of that State Exchange's improper payment rate.

We did not receive any comments in response to the proposals on the review process and improper payment rate determination.

As previously stated, we are not finalizing this provision at this time.

e. Error Findings Decisions (§ 155.1520)

We proposed to add new § 155.1520 to address the issuance of error findings decisions and the content of error findings decisions.

- At paragraph (a), we proposed that HHS will issue error findings decisions to each State Exchange. While we anticipate that error findings decisions would be issued at regular and recurring points of time within the measurement year during each review cycle under the proposal, we recognize that certain events could result in necessary delays, for example, public health emergencies, natural disasters, interruptions in business practices, or other extenuating circumstances. Thus, we proposed that, should these types of events warrant the additional time, we would notify State Exchanges of the delay via the CMS website. In the situation where no errors are found during the course of the review, HHS would still issue an error findings decision to the State Exchange indicating that no errors were identified. As proposed, the error findings decisions are intended to be communicated to each respective State Exchange only and would not be published publicly.
- At paragraph (b), we proposed language regarding the specific information that would be included in error findings decisions. We proposed that, at a minimum, error findings decisions will include HHS' findings regarding errors made by the State Exchange and information about the State Exchange's right to request a redetermination of the error findings decision in accordance with proposed § 155.1525.

After reviewing the public comments, we are not finalizing this provision at this time.

Comment: One commenter expressed concern that each State Exchange's error findings decision would not be made easily accessible to the public and requested that HHS post each State Exchange's error findings decision on the HHS website to ensure transparency.

Response: We thank the commenter for the recommendation to make each State Exchange's error findings decisions easily accessible to the public by posting each State Exchange's error findings decision on the HHS website to ensure transparency. We will take the recommendation into consideration as we continue to develop the SEIPM program.

f. Redetermination of Error Findings Decisions (§ 155.1525)

We proposed to add new § 155.1525 to address a State Exchange's request for a redetermination, as well as HHS' issuance of the redetermination decision and the content of that decision.

• At paragraph (a), we proposed language indicating a State Exchange's ability to request a redetermination of the error findings decision within the deadline prescribed in the annual program schedule. As proposed, during the period for a State Exchange to request a redetermination of the error findings decision, HHS would consider a request for an extension in extreme circumstances, which includes but is not limited to situations such as natural disasters, interruptions in business operations such as major system failures, or other extreme circumstances. While we recognize that each State Exchange has a multitude of responsibilities, as proposed, HHS would not otherwise accept any request for a redetermination received after the expiration of the deadline prescribed by the annual program schedule, which is designed to enable HHS to meet deadlines for the publication of the improper payment rate.

• At paragraph (a)(1), we proposed language requiring that the State Exchange identify the specific error(s) for which the State Exchange would be requesting a redetermination. As proposed, this identification may pertain to a single individual's application or to a type of error affecting a class of applications. As proposed, a redetermination would constitute a review of the initial decision and not a de novo investigation. Thus, we proposed that the State Exchange would base its request on documentation and other information already submitted to HHS (for example, we proposed that if the application lacked income information, the State Exchange may not retrospectively seek this documentation and add it to the record). As proposed, any issues unrelated to an error identified by HHS in the initial error findings decision would not be addressed.

• At paragraph (a)(2), we proposed language that the State Exchange must include all data and information that support the State Exchange's request for a redetermination. Note that, as proposed, while State Exchanges can submit data and information in requesting a redetermination, new information submitted as part of the request for redetermination should supplement data previously submitted as part of the SEIPM data request form for the benefit year under review and would be accepted at HHS' discretion. In the proposal, we explained that State Exchanges may not use the redetermination process as a means to circumvent prior deadlines for submitting data or information to HHS.

• At paragraph (a)(3), we proposed language that would require a State Exchange to provide an explanation of how the data and information submitted under paragraph (a)(2) pertains to the error(s) specified in paragraph (a)(1). In the proposal, we stated that the State Exchange should clearly articulate how the data and information is related to HHS' findings, and how it impacts HHS findings. We proposed that if a State Exchange did not provide this explanation, HHS would not anticipate or assume a State Exchange's reasoning in requesting a redetermination on a particular error.

• At paragraph (b), we proposed language regarding the issuance of redetermination decision. As proposed, the redetermination of an error findings decision would be issued within the deadline prescribed in the annual program schedule. The goal of this proposal was to ensure that each State Exchange has ample time to assess the error findings decision, give HHS adequate time to thoroughly evaluate a State Exchange's request for a redetermination, and calculate an improper payment rate in adequate time to publish aggregate findings across all State Exchanges in the Agency Financial Report. Thus, we also proposed that if circumstances like natural disasters or other extenuating circumstance resulted in HHS needing additional time to render the redetermination decisions, a State Exchange would be notified of the delay.

• At paragraph (c), we proposed language conveying the minimum content requirements for HHS' redetermination decision.

• At paragraph (c)(1), we proposed language specifying that HHS' decision must address its findings regarding the impact of any additional data and information provided by the State Exchange on the error(s) for which the State Exchange requested a redetermination.

• At paragraph (c)(2), we proposed language that would establish HHS' responsibility to give a State Exchange information about the right to request an appeal of the redetermination of error findings decision in accordance with proposed § 155.1530.

After reviewing the public comments, we are not finalizing this provision at this time.

We summarize and respond to public comments received on redetermination of error findings decisions (§ 155.1525) below.

Comment: A few commenters expressed concern that HHS would consider only the initial data submitted in response to the data request form when a State Exchange requests redetermination of an error findings decision. These commenters requested that HHS allow State Exchanges to introduce new information that could help clarify the process used by a State Exchange and possibly negate the need for an error findings decision.

Response: We will take this feedback into consideration as we continue to evaluate any adjustments that may be needed to the redetermination process as State Exchanges participate in the pilot program, prior to SEIPM implementation.

g. Appeal of Redetermination Decision (§ 155.1530)

We proposed to add a new § 155.1530 to address a State Exchange's ability to request an appeal of the redetermination decision. Appeals will be administered by HHS.

• At paragraph (a), we proposed language regarding a State Exchange's right to request an appeal of a redetermination within the deadline prescribed in the annual program schedule. Moreover, we proposed that, in the request for an appeal, the State Exchange must indicate the specific error(s) identified in the redetermination decision for which the State Exchange is requesting an appeal.

• At paragraph (b), we proposed language that conveys the appeal entity's review would be an on-the-record review, meaning that the appeal entity would only review data and information provided at the time of a State Exchange's redetermination request. As proposed, no additional new data or information submitted in support of the request for appeal would be considered.

• At paragraph (c), we proposed language that the appeal decision would be issued within the deadline prescribed in the annual program schedule unless there is a delay, and that the State Exchange will be notified in the event of any delay in the appeal entity's ability to reach a decision.

• At paragraph (d), we proposed the content of the appeal decision.

• At paragraph (d)(1), we proposed that the appeal decision would include the findings on the error for which an appeal was requested and that those findings would be limited to the errors that were identified in the request for appeal.

• At paragraph (d)(2), we proposed that the appeal decision would include the final disposition of the appeal request.

• At paragraph (e), we proposed that upon completion of the review and the closure of all appeals, HHS may issue to

each individual State Exchange, a report containing the error findings and the estimated improper payment rate for their respective program. As proposed, that report would not be made public. Additionally, through the proposal, it was described that the estimated improper payment rates for each State Exchange would be used to estimate an aggregate improper payment rate across all State Exchanges and that the aggregate rate would be published in the agency's Annual Financial Report.

After reviewing the public comments, we are not finalizing this provision at this time.

We summarize and respond to public comments received on the appeal of the redetermination decision (§ 155.1530) below.

Comment: One commenter requested that HHS provide more detail regarding the effects of a fully adjudicated error and specifically asks whether an enrollee would be retroactively impacted by a fully adjudicated error or whether the IRS would require changes through Form 1095–A reporting.

Response: At this time, HHS has not determined to what extent, if at all, fully adjudicated error findings decisions may impact an enrollee. HHS, in collaboration with IRS, the Department of the Treasury, and other agencies as required, will make this decision based on further research and evaluation of how recoveries could be implemented, including the authority to pursue any such recoveries. Further, any decision relating to the recovery will be communicated through future rulemaking. HHS is not aware of any intended changes in Form 1095–A reporting to support the planned SEIPM program.

Comment: One commenter expressed concern that publishing aggregate error rates across all State Exchanges rather than publishing error rates for each State Exchange could negatively reflect on higher-performing State Exchanges. The commenter also stated that SEIPM design flaws could result in a higher assessed rate of improper payments.

Response: We appreciate the comment. As we continue to develop the SEIPM program, HHS will consider methodologies for identifying errors with the goal of determining an accurate estimate of improper payments that meet OMB criteria. With regard to SEIPM design flaws, HHS is continuing to engage State Exchanges in order to test the planned SEIPM data collection, sampling, and review processes to determine if any adjustments are needed.

h. Corrective Action Plan (§ 155.1535)

Under the proposed rule, we proposed to add a new § 155.1535 to address the scenario in which a State Exchange's improper payment rate for a given benefit year, in HHS' reasonable discretion, necessitates a CAP to correct the causes of any payment errors. With regard to the CAP process, we proposed the minimum set of requirements with the intent to define full CAP parameters in future rulemaking, using the standards provided under Appendix C to OMB Circular No. A–123, to support State Exchanges in satisfying the requirement of developing, implementing, and monitoring a CAP.

As we gather additional information and data, and observe trends based on experience with implementing the SEIPM program, we will detail CAP parameters or requirements in future rulemaking.

- At paragraph (a), we proposed that, depending on a State Exchange's error rate for a given benefit year, we would require the State Exchange to develop and submit a CAP to HHS to correct errors resulting in improper payments.
- At paragraph (b), we proposed that Appendix C to OMB Circular No. A–123 would serve as a minimum set of guidelines to any State Exchange that is developing a CAP.
- At paragraph (c), we proposed that a State Exchange would be required to develop an implementation schedule to accompany its CAP, and implement any CAP initiatives in accordance with that schedule.
- At paragraph (d), we proposed the recourse HHS has in the event that a State Exchange that is required to submit a CAP fails to timely do so by stating that HHS may take actions consistent with § 155.1540.

After reviewing the public comments, we are not finalizing this provision at this time.

We summarize and respond to public comments received on the corrective action plan (§ 155.1535) below.

Comment: A few commenters supported the proposal to implement CAP under § 155.1535. One commenter supported deferring the CAP parameters to future rulemaking to observe trends that emerge from the SEIPM implementation. One commenter requested that all State Exchange CAPs be made public. Another commenter stated that State Exchanges are already subject to CAPs to remedy eligibility and enrollment errors.

Response: We appreciate the comments offering support to defer the CAP parameters to future rulemaking. Based on the public comments received, we are not finalizing this provision at this time.

i. Failure To Comply (§ 155.1540)

We proposed to add a new § 155.1540 that would address failures to comply with SEIPM requirements. At paragraph (a), we proposed that if a State Exchange fails to substantially comply with the SEIPM collection requirements or CAP provisions and HHS determines such failures undermine or prohibit HHS' efficient administration of improper payment measurement activities of the State Exchange, HHS would have the discretion to address failures of compliance with audit data submission and CAP requirements contained in subpart P under paragraph (a)(1), and consistent with authorities HHS possesses under title I of the ACA or any other Federal law as proposed under paragraph (a)(2).

HHS considered exercising its authority under § 1313(a)(5) of the ACA to ensure State Exchange compliance with SEIPM program data collection and CAP requirements. For instance, upon a State Exchange's failure to substantially comply with data collection requirements, HHS could require the State Exchange to provide on-site access to required data and State Exchange personnel capable of displaying requested data directly to HHS personnel or contractors.[266] If a State Exchange failed to substantially comply with requirements under an existing CAP, HHS could require the State Exchange to revise the CAP and its related implementation plan to contain revised or additional requirements specifically designed to address the State Exchange's compliance failures and ensure the State Exchange's future compliance with CAP requirements. We sought comment on these measures and invited suggestions for other measures HHS might undertake in relation to State Exchanges to incentivize compliance with data collection and CAP requirements (or cure non-compliance) and to ensure the efficient administration of APTC.

Please see the proposed rule preamble (87 FR 658 through 659) for a complete description of the proposed policy. After reviewing the public comments, we are not finalizing this provision at this time.

[266] See, for example, section 1313(a)(2) of the ACA (HHS may investigate the affairs of an Exchange, may examine the properties and records of an Exchange, and may require periodic reports in relation to activities undertaken by an Exchange, and an Exchange must fully cooperate in any investigation conducted under this paragraph).

We summarize and respond to public comments received on failure to comply (§ 155.1540) below.

Comment: One commenter expressed support for the failure to comply with provisions that allow HHS to require a State Exchange to revise their corrective action plan and implementation plan where there is a compliance failure to curtail flawed eligibility processes and ensure CAP compliance in a timely fashion.

Response: We clarify that the purpose of this proposed provision was to incentivize compliance with the planned data collection and CAP requirements. As we continue to develop the SEIPM program, we do not anticipate broad or willful noncompliance with planned requirements.

E. 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 2023 Benefit Year (§ 156.50)

Section 1311(d)(5)(A) of the ACA permits an Exchange to charge assessments or user fees on health insurance issuers offering a QHP through an FFE or SBE–FP 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 specified that an 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 No. A–25 established Federal policy regarding user fees; 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 2023 Benefit Year

Based on estimated costs, enrollment, and premiums for the 2023 benefit year, in the HHS Notice of Benefit and Payment Parameters proposed rule (87 FR 584, 660), we proposed a 2023 benefit year user fee rate for all issuers offering a plan through an FFE of 2.75 percent of monthly premiums charged by the issuer for each policy under the plan where enrollment is through an FFE. This is the same user fee rate that we established for the 2022 benefit year (86 FR 53412). We stated that we believe the proposed 2023 user fee rate would not result in a substantial increase to consumer premiums from prior years, and would also ensure adequate funding for Federal Exchange operations. We refer readers to the proposed rule (87 FR 660) for further discussion of this proposal and a description of the cost, premium, and enrollment projections that went into calculating the proposed 2023 FFE user fee rates.

As we explained in the proposed rule (87 FR 660), activities performed by the Federal government that do not provide issuers offering a plan in an FFE with a special benefit are not covered by the FFE user fee. As in benefit years 2014 through 2022, issuers seeking to participate in an FFE in the 2023 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 2023 benefit year, issuers offering a plan 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).

b. SBE–FP User Fee Rates for the 2023 Benefit Year

SBE–FPs enter into a Federal platform agreement with HHS to leverage the systems established for the FFEs to perform certain Exchange functions, and to enhance efficiency and coordination between State and Federal programs. Accordingly, in § 156.50(c)(2), we specified 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.

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 2023 benefit year, we used the same assumptions on contract costs, enrollment, and premiums as the proposed FFE user fee rates. We calculated the SBE–FP user fee rate based on the proportion of all FFE functions that are also conducted for SBE–FPs. The final SBE–FP user fee rate for the 2022 benefit year of 2.25 percent of premiums was based on HHS' calculation of the percent of costs of the total FFE functions utilized by SBE–FPs—the costs associated with the information technology, call center infrastructure, and eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs, which we estimate to be approximately 80 percent. Based on this methodology, in the proposed rule (87 FR 661), we proposed to charge issuers offering QHPs through an SBE–FP a user fee rate of 2.25 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE–FP for the 2023 benefit year. This is the same user fee rate that we established for the 2022 benefit year. We sought comment on these proposed user fee rates. We refer readers to the proposed rule (87 FR 660 through 661) for a complete description of the proposal and calculation methodology.

After reviewing the public comments, for the reasons discussed in this rule and the proposed rule, we are finalizing for the 2023 benefit year, as proposed, a user fee rate for all issuers offering QHPs through an FFE of 2.75 percent of the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE, and a user fee rate for all issuers offering QHPs through an SBE–FP of 2.25 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE–FP.

We summarize and respond to public comments received on FFE and SBE–FP user fee rates for the 2023 benefit year (§ 156.50).

Comment: Several commenters supported the proposed user fee rates and appreciated the rates being held constant with 2022. One supporting commenter stated that avoiding an increase in user fees may help to

incentivize additional issuers to participate in the Exchanges, providing consumers with additional choice. Another commenter noted that maintaining the user fee level has the benefit of steady administrative costs to issuers, which translates to stable premiums for consumers.

Other commenters disagreed with the proposed user fee rates, asking HHS to either increase or decrease the user fee rates. One commenter encouraged HHS to lower user fee rates based on decreasing technology costs. Another suggested decreasing the user fee rates noting that higher rates raise premiums and are unnecessary due to user fee collections that could have carried over from prior years. Other commenters requested that HHS increase the user fee rates in order to improve Exchange functions, and requested that HHS increase funding for Navigators, *HealthCare.gov,* appeals, investments in technology, investments in language services, investments in disability accessibility, and access to back-end data with approval from clients.

Response: We appreciate the support for the proposed user fee rates of 2.75 percent of monthly premiums charged by FFE issuers and 2.25 percent of monthly premiums charged by SBE–FP issuers and are finalizing the user fee rates as proposed. We will continue to examine cost estimates for the special benefits provided to issuers offering QHPs on the FFEs and SBE–FPs for future benefit years, and will continue to establish the user fee rates that are reasonable and necessary to fully fund user fee eligible Exchange operation costs.

As we discussed in the proposal to maintain the user fee rates for the 2023 benefit year (87 FR 660), we developed the user fee rates based upon estimated costs, enrollment, and premiums. We specifically noted that the user fee rates incorporate our estimates of premium and enrollment changes for the 2023 benefit year, and are not solely a reflection of the total expenses estimated to operate and maintain the Federal platform and FFE operations. Finally, we noted that technology upgrades and maintenance efforts will continue to be evaluated annually and funded at levels appropriate to ensure a smooth enrollee experience. We do not believe that a decrease in user fee rates is appropriate as HHS remains committed to providing a seamless enrollment experience for Federal platform consumers and applying resources to cost-effective, high-impact enrollment activities that offer the highest return on investment. While we did not anticipate any new services or contracts to require the expenditure of additional FFE user fees for the 2023 benefit year, we believe that we have estimated adequate funding for these services in the 2023 benefit year user fees.

As for commenters requesting increased funding for language services and disability accessibility, we note that under § 155.205(c)(2)(i)(A), HHS currently provides telephonic interpreter services in at least 150 languages at no cost to applicants and enrollees. Translation services are provided telephonically and for written communications at no cost to the consumer. HHS additionally notes that under § 155.205(c)(1), information must be provided to applicants and enrollees in plain language and in a manner that is accessible and timely to individuals living with disabilities including accessible websites and the provision of auxiliary aids and services at no cost to the individual in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act. We have included the costs of these services in the estimates used in setting the 2023 benefit year user fees.

For the request that we increase funding for Navigators, *HealthCare.gov,* and access to back-end data, we anticipate spending on the management of a Navigator program and consumer assistance tools will be similar to what was estimated for the 2022 benefit year, as we believe that was an adequate level of funding for these activities, and thus we do not believe it is necessary to increase user fees for these purposes. As discussed in the proposed rule (87 FR 660), for the 2023 benefit year, we anticipate that spending on consumer outreach and education, eligibility determinations, and enrollment process activities will increase above the 2022 benefit year level.

Comment: Some commenters believed that changes should be made to how user fees are charged. Specifically, several commenters requested that HHS explore a PMPM user fee structure.

Response: HHS did not propose any changes to the user fee structure, as such the user fee rates will continue to be set as a percent of the premium. However, HHS will continue to engage with stakeholders regarding how the FFE and SBE–FP user fee policies can best support consumer access to affordable, quality health insurance coverage through the Exchanges that use the Federal platform.

Comment: Some commenters requested additional transparency into user fees; specifically, one commenter requested a report reflecting how much of the user fee is used for the Navigator program. Other commenters requested additional information about how funds generated by the user fees are allocated across Exchange functions, as well as greater transparency regarding the cost of the Federal platform, call center, other programs associated with running the Exchanges, individual State usage of Federal resources, allocated costs, and how State user fees compare with each State's applicable costs. To further transparency of the development of the SBE–FP user fee rates, one commenter urged HHS to provide the enumeration and specific calculation of costs associated with FFE infrastructure and services provided to each State.

Response: HHS provided additional information in the proposed rule (87 FR 660 through 661) to show how we expect costs to grow under certain categories. We are limited by two main constraints when it comes to projecting costs. First, we are projecting contracts and costs into the future. Second, we are projecting revenues against these costs, which are based on estimated enrollments and premiums. Additionally, HHS is not permitted to publicly provide information that is confidential due to trade secrets associated with contracting. As such, we believe that providing a range of premium and enrollment projections in setting the 2023 benefit year FFE and SBE–FP user fee rates is sufficient to project revenues for user fee rate setting purposes. The weighted average premium projections that we considered ranged from $618 to $625 per month. The annual enrollment percentage change projections that we considered ranged from –1 percent to 2 percent. We took a number of factors into consideration in choosing which premium and enrollment projections should inform the 2023 FFE and SBE–FP user fee rates. The assumption that the enhanced PTC subsidies in section 9661 of the ARP will expire after the 2022 benefit year significantly influenced our development of the 2023 enrollment and premium projections. We expected the expiration of this provision of the ARP to revert enrollment and premium projections to the pre-ARP level observed in the 2020 benefit year. Our 2023 enrollment estimates also account for the 2021 benefit year transition (and projected transitions through the 2023 benefit year) of States from FFEs or SBE–FPs to State Exchanges, as well as the enrollment impacts of section 1332 waivers. We projected that 2023 benefit year premiums will generally increase at the rate of medical inflation after expiration of the enhanced PTC

subsidies in section 9661 of the ARP. After considering the range of costs, premium and enrollment projections, we proposed a 2023 user fee rate that will not result in a substantial increase in consumer premiums from prior years, and that also ensures adequate funding for Federal Exchange operations.

As for transparency in the Navigator program, the Navigator program makes the most recent awards public.[267] We anticipate spending on consumer assistance tools, management of a Navigator program, regulation of agents and brokers, and certification of QHPs will be similar to what was estimated for the 2022 benefit year, as we believe that was an adequate level of funding for these activities.

FFE and SBE–FP user fee costs are not allocated to or provided to each State. User fees cover activities performed by the Federal government that provide issuers offering a plan in an FFE or SBE–FP with a special benefit. As stated, these services are generally IT, eligibility, enrollment, and QHP certification services that are more efficiently conducted in a consolidated manner across the Federal platform, rather than by State, so that the services, service delivery, and infrastructure can be the same for all issuers in the FFEs and SBE–FPs. For example, all FFE and SBE–FP issuers send their 834 enrollment transactions to the Federal platform database, which are processed consistently regardless of State. Contracts are acquired to provide services for the Federal platform. The services do not differ by State, and therefore, we do not calculate costs on a State-by-State basis.

As we explained in the proposed rule (87 FR 660 through 661), to calculate the SBE–FP rates for the 2023 benefit year, we used the same assumptions on contract costs, enrollment, and premiums as we use to develop the proposed FFE user fee rates. We calculated the SBE–FP user fee rate based on the proportion of all FFE functions that are also conducted for SBE–FPs. The benefits provided to issuers in SBE–FPs by the Federal government include the use of the Federal Exchange information technology and call center infrastructure 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.

The final SBE–FP user fee rate for the 2022 benefit year of 2.25 percent of premiums was based on HHS' calculation of the percent of costs of the total FFE functions utilized by SBE–FPs (the costs associated with the information technology, call center infrastructure, and eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs), which we estimate to be approximately 80 percent.

2. User Fees for FFE–DE and SBE–FP–DE States

Consistent with the removal of § 155.221(j) and the repeal of the Exchange DE option in part 3 of the 2022 Payment Notice (86 FR 53412, 53424 through 53429, 53445),[268] in the HHS Notice of Payment and Benefit Parameters for 2023 proposed rule (87 FR 584, 661), we proposed a technical correction to remove from § 156.50 all references to the Exchange DE option and cross-references to § 155.221(j). In part 3 of the 2022 Payment Notice (86 FR 53429), we also finalized the repeal of the accompanying user fee rate for FFE–DE and SBE–FP–DE States for 2023; however, HHS inadvertently did not amend the accompanying regulatory text in § 156.50 related to the Exchange DE option user fees. As such, in the proposed rule (87 FR 661), we proposed to make conforming changes to §§ 156.50(c) and (d) to remove all references to the Exchange DE option and 155.221(j). Specifically, we proposed to remove § 156.50(c)(3), and amend §§ 156.50(d)(1), (d)(2)(i)(A) and (B), (d)(2)(ii), (d)(2)(iii)(B), (d)(3), (d)(4), (d)(6), and (d)(7) to remove the references to the Exchange DE option. We sought comment on these proposed technical amendments.

We received one comment offering general support for these technical amendments. After consideration of this comment, for the reasons set forth in this rule and in the proposed rule, we are finalizing, as proposed, the amendments to § 156.50(c) and (d) to remove all references to the Exchange DE option and § 155.221(j); specifically, we are removing § 156.50(c)(3), and amending §§ 156.50(d)(1), (d)(2)(i)(A) and (B), (d)(2)(ii), (d)(2)(iii)(B), (d)(3), (d)(4), (d)(6), and (d)(7) to remove the references to the Exchange DE option.

3. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

a. States' EHB-Benchmark Plan Options

At § 156.111(a), we allow a State to modify its EHB-benchmark plan by: (1) Selecting the EHB-benchmark plan that another State used for PY 2017; (2) replacing one or more EHB categories of benefits in its EHB-benchmark plan used for PY 2017 with the same categories of benefits from another State's EHB-benchmark plan used for PY 2017; or (3) otherwise selecting a set of benefits that would become the State's EHB-benchmark plan. In implementing this section, we stated in the 2019 Payment Notice that we would propose EHB-benchmark plan submission deadlines in the HHS annual Notice of Benefit and Payment Parameters.

Accordingly, in the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 661), we proposed that the first Wednesday in May that is 2 years before the effective date of the new EHB-benchmark plan to be the deadline for States to submit the required documents for the State's EHB-benchmark plan selection for that PY. For example, under this proposal, the deadline for PY 2025 would be May 3, 2023, and the deadline for PY 2026 would be May 4, 2024. We proposed corresponding edits to § 156.111(d) and (e) to reflect the proposed deadline. We stated in the proposed rule that we believe that it is in the interest of States and issuers that we formalize a consistent, permanent annual deadline in early-May for EHB-benchmark submissions. We refer readers to the proposed rule (87 FR 661) for further background and information regarding this proposal. We invited comments on this approach, including whether there are any unforeseen consequences to establishing this perpetual deadline.

After reviewing the public comments, for the reasons set forth in this rule and in the proposed rule, we are finalizing the proposal with minor edits to the language for clarity. Specifically, in the proposed rule, we proposed the first Wednesday in May that is two years before the effective date of the new EHB-benchmark plan to be the deadline for States to submit the required documents for the State's EHB-

[267] *CMS Navigator Cooperative Agreement Awardees.* (2021). CMS. *https://www.cms.gov/files/document/2021-navigator-grant-recipients.pdf.*

[268] We also clarified that the repeal of the Exchange DE option is specific to removing the Exchange DE option codified at § 155.221(j) and the accompanying FFE–DE and SBE–FP–DE user fees, and that the other Federal requirements applicable to the FFE DE Pathways, as outlined in §§ 155.220, 155.221, and 156.1230, remain intact. See 86 FR 53427.

benchmark plan selection for that PY, and we gave the example that the deadline for PY 2025 would be May 3, 2023, and the deadline for PY 2026 would be May 4, 2024. To more clearly reflect the examples provided in the proposed rule, we are finalizing minor edits to the proposed regulation text to establish the permanent deadline for States to submit the required documents for the State's EHB-benchmark plan selection as the first Wednesday in May ''of the year'' that is 2 years before the effective date of the new EHB-benchmark plan. Moving forward, we will not be proposing deadlines for the process in annual Notices of Benefit and Payment Parameters. We summarize and respond to public comments received on States' EHB-benchmark plan options below.

Comment: All commenters expressed support for the proposed deadline. Some noted that the set deadline would make the process more predictable for both States and stakeholders involved with EHB-benchmark development. Others noted that the proposed timeline should give States and HHS sufficient time to solicit comments and opinions on proposed benchmarks while also enabling issuers to determine how they will provide EHB consistent with the new EHB-benchmark plan.

Response: We agree with commenters that the permanent deadline will provide more predictability to the EHB-benchmark plan selection process for all parties involved. Since we finalized the 2019 Payment Notice, we have set an early-May deadline for the submission of EHB-benchmark plans by States for each year from PY 2021–2024.[269] We believe that requiring these submissions in the first week of May of the year that is two years before the effective date of the new EHB-benchmark plan has worked well. The feedback received from States that have submitted new EHB-benchmark plans indicates that this timeframe provides the States with enough time to prepare EHB-benchmark plan submissions. It also provides us with sufficient time to review and respond to these submissions in advance of issuers needing to make changes to plan design to conform with EHB-benchmark plan changes.

Comment: We also received several comments that were outside the scope of the proposal. One commenter noted that most States currently have no established process for updating their EHB-benchmark plans and could add benefits to address unmet health care needs in their States without exceeding generosity limits. They urged HHS to identify best practices in EHB-benchmark plan selection and provide additional guidance and training for States to update their EHB-benchmark plans. Several commenters urged HHS to strengthen the transparency of the public comment process for EHB-benchmark plan selection to ensure that stakeholders and other interested parties have ample opportunity to provide meaningful input. A commenter suggested that HHS should require States to adopt standards for public commenting that mirror those specified by HHS for States requesting demonstration projects through section 1115 of the Act. One commenter expressed support for the flexibility provided to States under the EHB-benchmark plan selection policy. Another commenter cautioned HHS to remain vigilant that any changes in a State's EHB-benchmark plan do not result in a decreased availability of EHB. The commenter requested that HHS collect and report data on States that utilize flexibility under the policy to allow consumers, advocates, and other stakeholders to better identify and understand any trends with regard to EHB-benchmark plans.

Response: Although these comments are outside the scope of HHS' proposal regarding the deadline for EHB-benchmark plan submissions, we note that HHS is committed to ensuring access to EHB while providing States with flexibility under the EHB-benchmark plan selection policy. We will consider these comments and requests for future guidance or proposals. However, as they are out-of-scope with regard to this specific proposal, we decline to comment further on them at this time.

b. Annual Reporting of State-Required Benefits

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 662), we proposed to eliminate the requirement at § 156.111(d) and (f) to require States to annually notify HHS of any State-required benefits applicable to QHPs in the individual or small group market that are considered to be ''in addition to EHB'' and any benefits the State has identified as not in addition to EHB and not subject to defrayal. We also proposed to revise the section heading to § 156.111 to reflect the proposed removal of the annual reporting requirements such that it would instead read, ''State selection of EHB-benchmark plan for PYs beginning on or after January 1, 2020.'' As we explained in the proposed rule, since finalizing the annual reporting requirement in the 2021 Payment Notice, we have received consistent feedback from States and stakeholders restating the concerns raised by the majority of commenters on the annual reporting requirement in the 2021 and 2022 Payment Notices. Although some commenters agreed that this policy is important to ensure States are defraying State benefit requirements consistently, most commenters objected to the policy as unnecessary, burdensome on States, and without adequate justification. We refer readers to the proposed rule (87 FR 661 through 662) for further information and background regarding this proposal. We solicited comment on this proposal, including on whether we should retain the reporting requirement or make it voluntary.

After considering the public comments, for the reasons set forth in this rule and in the proposed rule, we are finalizing, as proposed, repeal of the annual reporting requirement at § 156.111(d) and (f), including revising the section heading to § 156.111 to instead read, ''State selection of EHB-benchmark plan for PYs beginning on or after January 1, 2020.'' Thus, States will no longer be required to annually notify HHS of any State-required benefits applicable to QHPs in the individual or small group market that are considered to be ''in addition to EHB'' or any benefits the State has identified as not in addition to EHB and not subject to defrayal. We note that we will continue to engage in technical assistance with States to help ensure State understanding of when a State-benefit requirement is in addition to EHB and requires defrayal and will provide additional written technical assistance and outreach to clarify the defrayal policy more generally and to provide States with a more precise understanding of how HHS analyzes and expects States to analyze whether a State-required benefit is in addition to EHB pursuant to § 155.170. We also note that, although this policy will relieve States of the annual reporting requirements, it will not pend or otherwise impact the defrayal requirements under section 1311(d)(3)(B) of the ACA, as implemented at § 155.170.

We summarize and respond to public comments on the proposal to eliminate the annual reporting of State-required benefits.

Comment: The majority of commenters supported the repeal of the annual reporting policy at § 156.111(d) and (f), reiterating many of the same

[269] For PY 2021, the deadline was May 6, 2019 (see 84 FR 17534); for PY 2022, it was May 8, 2020 (84 FR 17534); for PY 2023, it was May 7, 2021 (85 FR 29226); for PY 2024 it is May 6, 2022 (86 FR 24232).

objections and concerns raised by commenters on the initial proposal for this policy in the 2021 Payment Notice and echoed by States and stakeholders since the finalization of the policy. Many commenters stated that the annual reporting policy is unnecessary and overly burdensome as the requirements already in regulation at § 155.170 are sufficient at instructing States and issuers on how to comply with the defrayal requirement. Many commenters supporting repeal of the policy also noted the policy was an unjustified new administrative burden and duplicative of State efforts, as many States already engage in in-depth processes with their State legislatures to evaluate State defrayal obligations, make actuarially sound analyses regarding State benefit requirements, and subsequently make defrayal payments if necessary in compliance with § 155.170. These commenters stated that the reporting requirement would unnecessarily burden both State and Federal officials, requiring State officials to either procure consultants or divert existing staff from other work to comply with an entirely new reporting process.

One commenter expressed that States are the primary regulators of the individual and small group markets, and therefore, maintain the authority to mandate benefits in those markets and monitor issuer compliance, which is at odds with the duplicative oversight required through the annual reporting requirement.

Many commenters stated that HHS already has the requisite authority to investigate States that the agency believes are not in compliance with the defrayal requirement. Such commenters emphasized that there is therefore no demonstrated need to require States to report all State mandates on an annual basis to show compliance and that this is particularly true for States that do not have any State-required benefits that are in addition to EHB. Other commenters supporting repeal of the policy stated HHS had not demonstrated evidence of widespread State noncompliance with defrayal requirements to warrant the policy and expressed concern regarding ambiguity around how HHS would enforce the annual reporting policy.

Some commenters expressed support for repealing the annual reporting policy because they believe it was designed to discourage States from expanding upon EHB in their State to improve benefit coverage, which one commenter explained is concerning as enhanced EHB benefits are particularly beneficial for people with chronic conditions and disabilities, who are disproportionately women, LGBTQI+ people, and people of color. As an example, one commenter explained that Colorado's enhanced EHB-benchmark plan effective beginning in plan year 2023 includes coverage of an annual mental wellness exam, services related to substance use disorder, and comprehensive gender-affirming care.

Commenters objecting to the repeal of the annual reporting policy expressed that the policy was justified to protect Federal expenditures as only a small number of States have actually identified State-required benefits that are in addition to EHB and have transparent processes in place to identify and defray costs as required by section 1311(d)(3)(B) of the ACA. Commenters objecting to repeal further explained that the policy would have supported transparency and increased understanding of the costs of State-required benefits and promoted uniformity in the application of the ACA. Commenters also stated that the policy would have promoted accountability and helped to ensure that benefit packages remain affordable. Some commenters noted that requiring States to report in this manner would have made issuer compliance with defrayal requirements easier to manage and others explained it would have promoted a more consistent understanding of new benefit mandates that a State enacts to better inform policymaking. One commenter noted that absent State reporting, it is unclear how the defrayal requirement may be enforced.

Commenters objecting to the repeal of the annual reporting policy also challenged claims that the policy was overly burdensome. Such commenters noted that States should already have determined the status and cost of State-required benefits and that, therefore, the reporting requirement should not place a burden on States of conducting new analyses. Commenters further noted that the minimal administrative burden on States would decrease further after the initial reporting cycle.

Response: We continue to believe that repealing the annual reporting policy at § 156.111(d) and (f) is warranted and would not weaken State compliance with the defrayal requirement. Therefore, we are finalizing the repeal of the policy, as proposed, including revising the section heading to § 156.111 to instead read, ''State selection of EHB-benchmark plan for PYs beginning on or after January 1, 2020.''

We understand the frustration expressed by States that already may appropriately identify which State-required benefits are in addition to EHB and provide defrayal, for which reporting this information to HHS on an annual basis would have added burden without increasing compliance. However, we acknowledge the concerns of many commenters that emphasized the importance of the annual reporting policy to address inconsistent State compliance and application of the defrayal requirements at § 155.170. Although we continue to share concerns that some States may not be properly identifying all State-required benefits that are in addition to EHB, we also believe alternative approaches to the annual reporting policy—such as expanded technical assistance and issuing clarifying guidance—can achieve improved State adherence with § 155.170 without imposing a requirement on States to submit detailed annual reports on State-required benefits.

We acknowledge that the information States would have submitted through annual reporting would have supported increased oversight over whether States are appropriately identifying which State benefit requirements are in addition to EHB and promoted increased transparency for stakeholders. We further acknowledge that receipt of such reports by HHS would have been helpful for identifying noncompliant States, although this would not have been accomplished without also requiring already compliant States to submit reports. However, after carefully considering the comments, we believe that a more targeted approach where HHS provides written guidance on how to assess State-required benefits, paired with continued individualized technical assistance and outreach to States better balances the goal of increased State compliance with the competing priority of preserving State resources and reaffirming State authority as the entity responsible for identifying which State-required benefits are in addition to EHB.

We reiterate that the obligation for a State to defray the cost of QHP coverage of State-required benefits in addition to EHB is a statutory requirement independent from the annual reporting policy we are now repealing at § 156.111(d) and (f). Therefore, even with the repeal of the annual reporting policy, States remain responsible for identifying which State-required benefits are in addition to EHB and require defrayal, making payments to defray the cost of additional required benefits to either the issuer or the enrollee, and note that issuers are still responsible for quantifying the cost of these benefits and reporting the cost to the State. With regard to future HHS enforcement of the defrayal policy in

instances where we have State compliance concerns, we intend to work closely with any such State to monitor compliance and address any areas of confusion through continued outreach and technical assistance.

Even though defrayal is a statutory requirement, we understand the critique that it can function as a restriction on States in mandating coverage of benefits in addition to EHB by requiring States to absorb new State expenditures. We are very supportive of States making improvements to the scope of EHB in their markets within the limits imposed by the generosity and typicality standards at § 156.111(b)(2) and encourage State utilization of any of the three methods available to States for selecting a new EHB-benchmark plan at § 156.111, a process Colorado used to select a new EHB-benchmark plan that will be effective for the 2023 plan year and many other States utilized in years past. We note as a reminder that the act of selecting a new EHB-benchmark plan does not alone create new State mandates, but it also does not relieve the State of its obligation to continue defraying the cost of QHPs covering any State-mandated benefits that are in addition to EHB. The annual reporting policy would not have changed that standard, nor does repeal of the annual reporting policy.

Although we are finalizing the repeal of the annual reporting policy, we maintain that it would have imposed a minimal burden on States as the information that States would have been required to report to HHS should already be readily accessible to States, as every State should already be identifying which State-required benefits are in addition to EHB and should be defraying any such costs. However, even if the State burden from the annual reporting policy would have been minimal, we still believe it is appropriate to repeal the annual reporting policy and instead take a more targeted approach of engaging with individual States on questions of compliance with the defrayal requirement. We believe this modified approach will yield similar results to the annual reporting policy without requiring all States, including compliant States, to expend additional time and resources submitting a report with this detailed information.

Comment: The majority of all commenters—both those supporting and those objecting to repeal of the annual reporting policy—encouraged HHS to issue additional technical assistance and guidance clarifying the defrayal policy. Commenters supporting repeal expressed gratitude for the existing technical assistance HHS provides. Such commenters further agreed it would be helpful for HHS to issue additional written guidance paired with additional outreach regarding how HHS analyzes and expects States to analyze whether a State mandate is in addition to EHB, especially given how often questions regarding defrayal arise in States.

Commenters objecting to the repeal of the annual reporting policy stated that if the policy is ultimately rescinded, HHS should still take the alternative, but a less effective step, of publishing technical guidance. Such commenters urged HHS to include guidance on the standards, including required actuarial analyses, to determine if a benefit exceeds EHB and, if so, the cost of the mandated benefit, to ensure States and issuers have a consistent understanding of whether a State-mandated benefit will actually increase health care costs. Other commenters acknowledged that there are other ways to achieve the oversight goals of the annual reporting policy if the reporting requirement is removed, such as providing additional written guidance or performing targeted audits of States. Other commenters stated that, although technical assistance and outreach are important, the periodic reporting that would have been required under the annual reporting policy would have had a valuable sentinel effect that cannot be duplicated through simple outreach and assistance.

Response: We agree that engaging in technical assistance with States to help ensure State understanding of when a State-benefit requirement is in addition to EHB and requires defrayal will bolster State compliance with defrayal requirements in the absence of the annual reporting policy. We also reaffirm our intent to provide additional written guidance and outreach to clarify the defrayal policy more generally and to provide States with a more precise understanding of how HHS analyzes and expects States to analyze whether a State-required benefit is in addition to EHB pursuant to § 155.170.

We believe that a more targeted approach where HHS provides written guidance on how to assess State-required benefits, paired with continued individualized technical assistance and outreach to States will still effectively promote State compliance with the defrayal requirement. It will enable us to instead concentrate HHS efforts on providing better, more tailored technical assistance to States rather than reviewing detailed reports for compliance across all States, even those that are already compliant. Although we acknowledge that the annual reporting policy may have ultimately had a sentinel effect on State adherence to the defrayal policy, we also believe continued ad hoc monitoring of States will yield similar compliance results without requiring all States to report each year. We believe our future technical assistance and guidance will ultimately facilitate an environment where States are more confident that their analysis of State-required benefits aligns with § 155.170 and will be instructive for States that need to subsequently make any necessary adjustments to State policy to comply with the defrayal policy.

Comment: Many commenters that supported issuing additional technical assistance provided policy recommendations with regard to the content of such guidance that are not within the scope of HHS' proposal regarding annual reporting of State-required benefits, such as requesting that HHS interpret the defrayal policy to be more lenient for States (for example, interpreting more State mandates to fall within the ''benefit delivery method'' exception that would not require defrayal or otherwise allowing States to change their benefit requirements to keep up with medical advancements without being required to defray). Other commenters urged HHS to include additional guidance on the defrayal requirements for habilitative services. One commenter urged HHS to require that State calculations for defrayal also be performed by a member of the American Academy of Actuaries.

Response: Although such comments are out-of-scope, we will consider such recommendations as we continue to develop guidance and conduct outreach. We encourage States to reach out to CMS with specific defrayal questions in the interim.

4. Provision of EHB (§ 156.115)

In the 2019 Payment Notice, we finalized flexibility through which States may opt to permit issuers to substitute benefits between EHB categories. In the preamble to that rule, we stated that this option would promote greater flexibility, consumer choice, and plan innovation through coverage and plan design options.

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 662 through 663), we proposed to withdraw this flexibility by amending § 156.115 to no longer allow States to permit issuers to substitute benefits between EHB categories.

In addition, in the event we did not finalize the proposal to eliminate the State option for between-category

substitution, we proposed to establish a static, permanent annual deadline for States to notify HHS that they wish to permit issuers to substitute benefits between EHB categories.

We sought comment on these proposals. We refer readers to the proposed rule for further discussion of these proposals and our rationale (87 FR 662 through 663).

After reviewing the public comments, for the reasons set forth in this rule and in the proposed rule, we are finalizing, as proposed, an amendment to § 156.115 to no longer allow States to permit issuers to substitute benefits between EHB categories. We are therefore not establishing a static, permanent annual deadline for States to notify HHS that they wish to permit issuers to substitute benefits between EHB categories.

We summarize and respond to public comments regarding the proposal to eliminate substitution of benefits between EHB categories.

Comment: The majority of the commenters supported the proposal to amend § 156.115 to no longer allow States to permit issuers to substitute benefits between EHB categories. Many of the commenters opposed the between-category substitution when it was proposed in the 2019 Payment Notice. Some of these commenters noted that Congress expressly included each EHB category in the ACA to ensure a comprehensive and appropriate range of benefits to meet patients' needs across their lifespan. They added that Congress selected those benefits because they were not often covered by private insurance prior to the ACA and recognized that they were not interchangeable. A few commenters expressed concerns that substitution of benefits between EHB categories would result in issuers creating narrowed plans that would not ensure access to and would increase out-of-pocket costs for the items and services consumers need to manage their health conditions, particularly for consumers with chronic conditions and disabilities. They added that between-category substitution could lead to adverse selection and discrimination by allowing issuers to cut benefits needed by people with significant health needs and substituting them with benefits meant to attract healthier enrollees.

One commenter noted that the argument that benefit substitution will allow consumers to find a plan that is better tailored to their needs is based on the false assumption that consumers can accurately predict their health needs. The commenter noted that this rationale undercuts the purpose of health insurance: To ensure access to affordable and comprehensive coverage even when one enters a period of unanticipated, increased health care need.

Commenters noted that if a State were to permit issuers to substitute benefits between EHB categories, it would make it difficult for regulators to ensure that issuers are actually covering the EHBs they are required to provide and confusing for consumers who expect to have coverage for all EHBs in ACA plans. Many commenters noted that any potential benefit of flexibility to States in selecting EHB-benchmark plans does not justify the policy given the potential harm to consumers.

Response: We agree with commenters that the negative effects on consumers of allowing States to permit issuers to substitute benefits between EHB categories outweigh any flexibility it could have afforded to States and issuers. For example, we agree with commenters that allowing States to permit issuers to substitute benefits between EHB categories could negatively affect access to and increase out-of-pocket costs for the items and services consumers need to manage their health conditions, and could lead to adverse selection and discrimination by allowing issuers to substitute benefits needed by people with significant health needs with benefits meant to attract healthier enrollees. In addition, we agree that allowing such substitution would make it difficult for regulators to ensure that issuers are actually covering the EHBs they are required to provide and could be confusing for consumers.

As we stated in the proposed rule (87 FR 662), to date, no State has ever notified HHS that it would permit issuers to substitute benefits between EHB categories. Given that this policy has never been utilized, it has not promoted greater flexibility, consumer choice, or plan innovation through coverage and plan design options as intended. Rather, as we explained in the proposed rule (87 FR 662), HHS is of the view that it may only create potential harm for consumers with chronic conditions and disabilities and that whatever theoretical flexibility this policy could have afforded to States is not justified given the potential negative effects on consumers.

Comment: One commenter opposed eliminating the option for States to permit issuers to substitute benefits across categories and stated that theoretical harm from allowing substitution of benefits between EHB categories and the fact that this option has not been used are not sufficient justifications for withdrawing the policy. The commenter noted that States' use of other flexibilities to make changes to their EHB-benchmark plans is an indication of their continued interest in exploring flexibilities and that States may have been too overwhelmed with the COVID–19 PHE to avail themselves of this particular flexibility. They requested that HHS leave the flexibility in place.

Response: We do not agree with the commenters that opposed eliminating the option for States to permit issuers to substitute benefits across categories. HHS is of the view that whatever untapped theoretical flexibility this policy could have afforded to States is not justified given the potential negative effects on consumers, including increased out-of-pocket costs for consumers with chronic conditions and disabilities and adverse selection and discrimination of consumers with significant health needs. We note that States continue to be able to use existing flexibilities to make changes to their EHB-benchmark plans.

Comment: Several of the supportive commenters included additional points that were outside the scope of the proposal. Many commenters urged HHS to prohibit substitution within EHB categories. They noted that the potential harm to consumers with chronic conditions and disabilities that may arise from substitution between EHB categories may also arise from substitution within EHB categories. Commenters noted that benefit components are not interchangeable within EHB categories that list multiple components, such as the ''mental health and substance use disorder services including behavioral health treatment,'' the ''preventive and wellness services and chronic disease management,'' and the ''rehabilitative and habilitative services and devices'' categories.

One commenter expressed concerns that the flexibility to adopt benchmark plans from other States and replace EHB categories with categories of benefits from another State's less generous benchmark plan could lead to a ''race to the bottom'' and erode EHB benefits. The commenter noted the effect could be even more damaging if a State chose the least generous coverage categories from various EHB-benchmark plans around the country to aggregate as their new EHB-benchmark plan. One commenter requested that CMS collect and publish data on State EHB-benchmark plan substitution so that interested parties can better assess the coverage of specific services.

Response: Although these comments are outside the scope of the proposal, we will consider these comments and suggestions and also note that benefit

designs that are discriminatory or intended to discourage enrollment by certain populations or individuals with significant health needs are prohibited under 45 CFR 156.125(b). In addition, we note that States may collect data on EHB benefit substitution. However, as the comments are outside the scope of this specific proposal, we decline to comment further on them at this time.

5. Prohibition on Discrimination (§ 156.125)

Section 156.125(b) states that an issuer providing EHB must comply with the requirements of § 156.200(e), which currently states that a QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex. In the proposed rule (87 FR 584, 671), we proposed to amend § 156.200(e) to explicitly prohibit different forms of discrimination based on sex—specifically, discrimination based on sexual orientation and gender identity. As explained in the **SUPPLEMENTARY INFORMATION** section earlier in this preamble, HHS will address this policy, as well as the public comments submitted in response to this proposal, in a future rulemaking.

6. Refine EHB Nondiscrimination Policy for Health Plan Designs (§ 156.125)

We proposed to refine HHS' EHB nondiscrimination policy under § 156.125 and proposed a regulatory framework for entities that are required to comply with the EHB nondiscrimination policy.

Under § 156.125(a), an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.[270] Section 156.125(b) requires that issuers must also comply with § 156.200(e), which provides that a QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex.[271] Section 156.110(d) states that an EHB-benchmark plan may not include a discriminatory benefit design that contravenes § 156.125. In the 2016 Payment Notice (80 FR 10750, 10822), we provided examples of potentially discriminatory practices,[272] and in the 2017 Payment Notice (81 FR 12244), we noted that we would consider providing further guidance regarding discriminatory benefit designs in the future.

In the proposed rule, we first proposed to revise § 156.125(a) to provide that a nondiscriminatory benefit design that provides EHB is one that is clinically based, incorporates evidence-based guidelines into coverage and programmatic decisions, and relies on current and relevant peer-reviewed medical journal article(s), practice guidelines, recommendations from reputable governing bodies, or similar sources.

Second, we proposed examples of health plan designs and practices that HHS would deem to be presumptively discriminatory. HHS identified these examples as presumptively discriminatory practices based on whether the issuer's benefit design or coverage decisions were adequately supported by appropriate clinical evidence relevant to each circumstance. Through these examples, HHS sought to further clarify its EHB nondiscrimination policy to better ensure that unlawful discrimination does not impede consumers' ability to access benefits for medically necessary treatment.

Third, we proposed to further refine our EHB nondiscrimination policy by describing and identifying examples of guidelines and resources (such as medical journals) that HHS would deem appropriate to counter a claim that an issuer's benefit design or its implementation of the design is discriminatory. We proposed that unscientific[273] evidence, disreputable sources, and other bases or justifications that lack the support of relevant, clinically-based evidence would be an unacceptable basis upon which to dispute a claim that an issuer's benefit design is discriminatory. We stated that we did not intend to limit the scope of acceptable peer-reviewed journal articles to those authored by persons who have earned the degree Doctor of Medicine (or M.D.). Rather, we proposed that HHS would consider sufficient peer-reviewed articles authored by other relevant, licensed health professionals, including, for example, doctors of osteopathy, chiropractors, optometrists, nurses, occupational therapists, pharmacists, and dentists. Notwithstanding, we also proposed that articles that are not peer-reviewed or that are written primarily for a lay audience would be insufficient to dispute a claim that an issuer's benefit design is discriminatory. We proposed that we would not consider sufficient a peer-reviewed journal article that has not been accepted for publication in a reputable medical publication.

We further sought comment on the types of clinically-based justifications and the level of clinical evidence that should be acceptable. Specifically, we sought comment on whether we should further define the types of acceptable clinical evidence.

We stated in the proposed rule that presumptively discriminatory practice examples may point to a State's EHB-benchmark plan, State law, or an issuer's application of a State's benchmark plan or law as being the source of the discriminatory benefit design. We stated that a benefit design that is discriminatory and inconsistent with § 156.125 must be cured regardless of how it originated. For example, if a State EHB-benchmark plan has a discriminatory benefit design, we explained that a State may issue guidance to issuers in the State explaining that to be compliant, plans providing benefits that are substantially equal to the EHB-benchmark plan must not replicate this discriminatory design. Similarly, if a State-mandated benefit has a discriminatory benefit design, the State may attempt to remedy this by revising the mandate or issuing guidance. Regardless, we stated that plans required to provide EHB would need to alter the benefit design or justify their approach with clinical evidence when designing plans that meet EHB standards. We sought comment on whether there are any unforeseen barriers in the ability to remedy inconsistencies with this refined EHB nondiscrimination policy.

We also stated in the proposed rule that, in ensuring that benefit designs are not discriminatory, issuers should also consider the method in which EHBs are delivered and not inadvertently discriminate based on the service delivery model. Accessibility to EHB delivered virtually has significantly

[270] ACA section 1302(b)(4) prohibits discrimination based on age, disability, or expected length of life, and requires that benefits not be subject to denial based on age or expected length of life, present or predicted disability, degree of medical dependency, or quality of life.

[271] 45 CFR 156.200(e) states that a QHP issuer may not discriminate based on ''race, color, national origin, disability, age, or sex.''

[272] The examples of potentially discriminatory practices were: (1) Attempting to circumvent coverage of medically necessary benefits by labeling the benefit as a ''pediatric service,'' thereby excluding adults; (2) refusing to cover a single-tablet drug regimen or extended release product that is customarily prescribed and is just as effective as a multi-tablet regimen, absent an appropriate reason for such refusal; and (3) placing most or all drugs that treat a specific condition on the highest cost tiers. 80 FR 10750, 10822.

[273] *Merriam-Webster.com* Dictionary, s.v. ''unscientific,'' Retrieved November 5, 2021, from *https://www.merriam-webster.com/dictionary/unscientific* (defining 'unscientific' as ''not based on or exhibiting scientific knowledge or scientific methodology: Not in accord with the principles and methods of science'').

increased during the COVID–19 PHE as enrollees had limited options for in-person health care visits. We noted that some issuers have designed health plans that deliver services virtually with no copay, compared to in-person health care services with a copay. We stated that this type of health plan design could inadvertently incentivize enrollees to access EHB using a certain delivery method. We further stated that although this approach may not amount to a discriminatory practice under § 156.125, such a health plan design could influence whether an enrollee seeks medically necessary in-person care due to the variation in the amount of copayment, potentially leading to adverse health outcomes. We noted that we intend to monitor the issue and remind issuers that while we encouraged expanded use of EHB virtually, it should be done in a nondiscriminatory manner.

In relation to the proposed refinements of the nondiscrimination standard under § 156.125, we proposed that the policy would become effective 60 days after the publication of the final rule in the **Federal Register**. We sought comments regarding whether the proposed effective date would be sufficient to allow issuers to come into compliance with our proposed refinements to our EHB nondiscrimination policy.

In addition, we recognized that other nondiscrimination and civil rights law may apply. These laws are distinct from the nondiscrimination requirements in CMS regulations, and compliance with § 156.125 is not determinative of compliance with any other applicable requirements, nor is additional enforcement precluded. Section 156.125 does not apply to the Medicaid and CHIP programs generally, but a parallel provision applies to EHB furnished by Medicaid Alternative Benefit Plans.[274] We sought comment on the examples of presumptively discriminatory benefit designs.

After reviewing the public comments, we are finalizing the proposed revisions to § 156.125(a) to provide that a nondiscriminatory health plan design that provides EHB is one that is clinically based, but we do not finalize the proposed regulation text that would have provided that a nondiscriminatory health plan design that provides EHB is one that incorporates evidence-based guidelines into coverage and programmatic decisions, and relies on a current and relevant peer-reviewed medical journal article(s), practice guidelines, recommendations from reputable governing bodies, or similar sources. We also do not finalize our proposal to further refine our EHB nondiscrimination policy by describing and identifying examples of guidelines and resources (such as medical journals) that HHS would deem appropriate to counter a claim that an issuer's benefit design or its implementation of the design is discriminatory. Rather, under § 156.125(a), we finalize only that an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions; and that a non-discriminatory benefit design that provides EHB is one that is clinically based. As we explain in further detail in the comment responses later in this section, we credit commenter concerns that information relevant to whether a benefit design is unlawfully discriminatory could appear in reputable publications or come from sources that are not peer-reviewed medical journals or those that are otherwise dissimilar to the sources and information HHS discussed in the proposed rule's preamble discussion on § 156.125(a). Although we do not finalize the proposal to specifically define the evidence and sources that would be sufficient to counter a claim that a plan's benefit design is discriminatory, this should not be construed to mean that HHS will deem unscientific[275] evidence, disreputable sources, or other bases or justifications that lack the support of relevant, clinically-based evidence as sufficient to dispute a claim that an issuer's benefit design is discriminatory.

We are also providing final versions of the examples of presumptively discriminatory benefit designs outlined in the proposed rule, except that we do not address the example related to gender-affirming care. For the reasons explained in the Supplementary Information section earlier in the preamble, HHS will address the gender-affirming care example, including the public comments that addressed this example, in future rulemaking.

For the final examples included in this final rule, we have revised the examples in response to commenter questions and concerns to clarify key points in relation to HHS' refined EHB nondiscrimination policy. First, we clarify that the requirement § 156.125 and HHS' refined EHB nondiscrimination policy apply only to services that are covered as EHB under a plan and do not require a plan to cover services that the plan does not already cover as EHB. Second, we clarify that neither § 156.125 nor the examples reflecting HHS' refined EHB nondiscrimination policy require health care professionals to perform services outside of their normal specialty area or scope of practice.

Lastly, we do not finalize the proposed applicability date of HHS' refined EHB nondiscrimination policy. Instead, to allow issuers sufficient time to come into compliance with our refined nondiscrimination policy and to better align with the ability of plans to make uniform modifications of coverage at the time of renewal, we are finalizing that the refined EHB nondiscrimination policy will be applicable starting on the earlier of January 1, 2023 (the start of PY 2023) or upon renewal of any plan subject to the EHB requirements. We have added text to § 156.125(a) to reflect this applicability date.

General Comments on the Proposal To Refine EHB Nondiscrimination Policy for Health Plan Designs (§ 156.125)

Comment: Many commenters broadly supported the proposals to refine the EHB nondiscrimination policy, implement a clinical evidence framework, and provide discriminatory benefit design examples in an effort to reduce discriminatory benefit designs and safeguard consumers who depend on nondiscrimination protections. Such commenters recognized the need for such safeguards and stated that many aspects of health plan design may be arbitrary, not clinically based, and have discriminatory impacts. These commenters noted that these proposals would reduce the incidents of discriminatory benefit design, which still occur despite the ACA's nondiscrimination protections. One commenter provided feedback that, by implementing consistent requirements under § 156.125, the proposal ensures that enrollees can fairly access covered benefits.

Response: We agree with commenters that despite current EHB nondiscrimination protections, enrollees may be harmed by discriminatory health plan designs. We also agree with commenters that requiring nondiscriminatory benefit designs to be clinically based will help ensure that plan limitations on benefits covered as EHB will not discriminate on the bases prohibited under § 156.125.

[274] See 42 CFR 440.347(e).

[275] *Merriam-Webster.com* Dictionary, s.v. ''unscientific,'' Retrieved November 5, 2021, from *https://www.merriam-webster.com/dictionary/unscientific* (defining 'unscientific' as ''not based on or exhibiting scientific knowledge or scientific methodology: Not in accord with the principles and methods of science'').

Specifically, § 156.125(a) prohibits plans from discriminating in their benefit design, or the implementation of its benefit design, based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. Further, § 156.125(c) requires that an issuer providing EHB must comply with the requirements of § 156.200(e). Section 156.200(e) currently prohibits discrimination on the basis of race, color, national origin, disability, age, and sex. Thus, any limitation on coverage of an EHB in a plan (that is subject to EHB standards) based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, other health conditions, race, color, national origin, disability, age, or sex, must be based on clinical evidence. We believe that the clinical evidence standard that we are finalizing at § 156.125 in this rule will reduce incidents of discriminatory benefit design of EHBs by ensuring that any plan design limiting coverage of an EHB on a protected basis in § 156.125 is clinically based, better safeguarding all consumers' access to medically necessary care.

We emphasize that issuers of EHB-compliant plans may continue to utilize reasonable medical management techniques in accordance with § 156.125(c). Further, our refined EHB nondiscrimination policy does not require issuers subject to § 156.125 to cover services under a health plan that are not already covered by the plan as EHB; and it does not create a general requirement that a health plan cover any and all medically necessary services.

Even when not intended, health plan designs that limit coverage of EHBs on the basis of characteristics protected from discrimination in § 156.125 can lead to negative health outcomes when such limitations lack clinical justification. We believe the refinements to our EHB nondiscrimination policy will improve issuer compliance with the nondiscrimination standards at § 156.125 and help ensure that enrollees can fairly and more easily access benefits covered as EHB, ultimately promoting improved health outcomes.

Comments on the Impact on Issuers and States

Comment: One commenter expressed concern that the proposal would require States to update their EHB-benchmark plans to remove unjustifiable discriminatory benefit designs, like age limitations and limitations based on health conditions. Some commenters requested that HHS clarify whether issuers modifying existing plan designs to conform with nondiscriminatory benefit design requirements would meet uniform modification exceptions to uniformly modify the benefits in their plans.

Response: As we stated in the proposed rule, a plan's benefit design that is discriminatory and inconsistent with § 156.125 must be cured regardless of how it originated. The nondiscrimination requirements at § 156.125, including the clinical evidence standard we are finalizing, apply to an issuer's benefit design or implementation of a benefit design for all benefits the issuer covers as EHB. Because some current EHB-benchmark plans continue to be based on plan year 2014 plans, some of the EHB-benchmark plan designs may not comply with current Federal requirements such as nondiscrimination requirements at § 156.125. Therefore, when designing plans that are substantially equal to the EHB-benchmark plan, issuers may need to further conform plan benefits, including coverage and limitations, to comply with current Federal requirements, such as the nondiscrimination requirement of § 156.125. This requirement is not new. Plans subject to the EHB requirement have always been required to comply with the nondiscrimination requirements in § 156.125 regardless of the presence of any noncompliant discriminatory language in the relevant EHB-benchmark plan.

Under the guaranteed renewability provision at 45 CFR 147.106, a health insurance issuer offering non-grandfathered health insurance coverage in the individual, small group, or large group market is required to renew or continue in force the coverage at the option of the plan sponsor or the individual, unless the issuer discontinues all coverage, the product is discontinued, or the issuer's action is otherwise excepted from this requirement. One such exception is for the modification of coverage made uniformly and solely pursuant to applicable Federal or State requirements, as described at § 147.106(e)(2). This allows an issuer to, at the time of renewal, modify its plans uniformly if the modification is made within a reasonable time period after the imposition or modification of a Federal or State requirement and the modification is directly related to the imposition or modification of the Federal or State requirement. An issuer revising its benefit design to conform with these nondiscrimination requirements could constitute a modification under a Federal requirement; thus, issuers may exercise the exception at § 147.106(e)(2) to uniformly modify their plans in accordance with guaranteed renewability requirements. As explained later in this section, we are finalizing that the refined EHB nondiscrimination policy at § 156.125 will be applicable on the earlier of PY 2023 or upon renewal of any plan subject to the EHB requirements and, therefore, this policy should not conflict with uniform modification requirements.

To address State EHB-benchmark plan compliance with the non-discrimination standards, we further stated in the proposed rule that, if a state EHB-benchmark plan has a discriminatory benefit design, the State may issue guidance to issuers in the State explaining that plans providing benefits that are substantially equal to the EHB-benchmark must not replicate that discriminatory benefit design. We clarify that we will not consider State EHB-benchmark plan designs to be out of compliance with § 156.110(d) or § 156.111(b)(2)(v) if the State provides such guidance or otherwise directs issuers to comply with these refined nondiscrimination standards, notwithstanding any aspects of the EHB-benchmark plan that are not consistent with these refined nondiscrimination standards. Under this approach, States are not required at this time to go through the formal process at § 156.111 to update their EHB-benchmark plans solely for the purpose of removing any such discriminatory benefit designs. But States that do elect to update their EHB-benchmark plans at any point going forward will be expected to ensure their new EHB-benchmark plans are compliant with Federal discrimination law and policy.

Comment: Several commenters asserted that the proposed rule violates the Administrative Procedure Act (APA). Some commenters expressed concern that the lack of a cost-benefit analysis in the proposed rule could be a violation of the APA, noting HHS did not cite how many plans already cover the procedures specified in the examples in a nondiscriminatory manner, how the refined EHB policy will impact utilization, and any premium impact. Other commenters asserted that the proposed changes to § 156.125 are overly broad. Some of these commenters expressed concerns that the proposed rule may impede States' ability to regulate and put forth benefit packages that are affordable and best meet the needs of their residents and recommended that HHS should

alternatively continue to work with States and issuers to develop sufficient coverage for enrollees while applying protections against discrimination. Other commenters expressed concern that issuers may see increased utilization of benefits and therefore higher costs. Some commenters recommended that HHS should conduct and publish the results of a detailed cost study demonstrating premium impacts for consumers prior to finalizing the proposal.

Response: We do not agree with commenters that our proposals under § 156.125 violate the APA. Additionally, the revisions we are finalizing in this rule do not impose an unreasonable burden on States, are not overly broad, and do not impede States' ability to regulate or put forth benefit packages that are affordable and meet the needs of consumers. The revisions to § 156.125 clarify existing Federal regulation regarding the prohibition on discriminatory benefit designs for plans subject to the requirement to provide EHB.

Specifically, this final rule affirms the existing requirement that an issuer provides EHB when its benefit design or implementation of its benefit design does not discriminate on bases prohibited under § 156.125. This final rule further clarifies that a plan design that includes limitations on EHB on a basis prohibited under § 156.125 must be clinically based in order to be considered nondiscriminatory. We reiterate that these nondiscrimination requirements at § 156.125 apply to any benefit design or implementation of a benefit design to the extent that the issuer covers benefits as EHB. This does not substantively alter or broaden the regulatory requirements under this section, as issuers of non-grandfathered individual and small group health insurance are already prohibited from offering plans with discriminatory benefit designs under § 156.125 in the provision of EHB.

We explained in the proposed rule the potential that there would be administrative burden on States and issuers when coming into compliance with the proposal to require clinical evidence to support EHB limitations that may otherwise be considered discriminatory under § 156.125. However, we clarify that States are not required at this time to formally update their EHB-benchmark plans through § 156.111 solely for the purpose of removing any such discriminatory benefit designs. Therefore, any such administrative burden on the part of States would be limited to instances where, at the State's discretion, the State updates its EHB-benchmark plans to remove discriminatory benefit designs or otherwise issues guidance to issuers on how to comply with § 156.125 in spite of any discriminatory limits that may be present in the State's EHB-benchmark plan. The examples in the final rule of presumptively discriminatory plan designs do not substantively change the existing regulatory EHB nondiscrimination requirements, but provide further guidance for plans to design benefit limitations that follow those requirements. Accordingly, we are unable to isolate and identify the burdens of providing those additional examples as a tool to guide issuers' efforts to comply with the existing requirements.

We disagree with commenters that suggest that the proposals we are finalizing in this rule will result in increased utilization and higher costs due to an unintended adverse impact on issuers' ability to administer packages that are safe and clinically effective. We stated in the proposed rule that, based on our experience with States updating benefits [276] covered as EHB in their EHB-benchmark plans under § 156.111, any actions necessary to come into compliance with the requirement to justify potentially discriminatory benefit limitations with clinical evidence will cause only a minimal increase in premiums. Thus, we do not find credible those assertions that the policy finalized in this rule will have a significant cumulative effect on issuers' ability to administer packages of benefits that are affordable.

We acknowledge that States are generally the primary enforcers of EHB requirements and HHS will continue to provide technical assistance to assist States as applicable. HHS will also consider whether additional guidance is necessary as we monitor issuer compliance with EHB nondiscrimination requirements and States' oversight and enforcement activities.

Comments on the Requirement That Health Plan Designs Be Supported by Clinical Evidence

Comment: Many commenters were broadly supportive of including a clinical evidence standard at § 156.125, but disagreed with or had recommendations regarding the appropriate scope of such a standard. For example, many commenters noted that the clinical evidence required under § 156.125 should not be limited to evidence provided by doctors of medicine and that HHS should allow evidence provided by other qualified, licensed health professionals, including nurses. Such commenters also urged HHS to include the relevant ''standard of care'' within the list of appropriate clinical evidence to rely upon as standards of care are the leading guide for treatment. Other commenters urged HHS to clarify that the list of reputable sources is only illustrative and recommended that HHS add more peer-reviewed journals to the sources list in the preamble. One commenter noted the concern of overlapping or potentially inconsistent standards as issuers already use clinical evidence in plan designs.

Other commenters strongly supported the incorporation of evidence-based guidelines and recommendations from appropriate governing bodies into coverage decisions, but recommend that HHS not further define the acceptable types of clinical evidence. Some commenters recommended that the opinion of recognized, disease-specific experts be included as additional appropriate evidence sources.

Response: In light of the myriad comments we received regarding the appropriate scope of clinical evidence to include at § 156.125, we have reconsidered whether the proposed clinical evidence standard appropriately reflects the breadth and types of clinical evidence that issuers may rely upon to demonstrate that a plan design limitation is not discriminatory under § 156.125. We are therefore finalizing § 156.125 only to require that a nondiscriminatory benefit design that provides EHB be one that is clinically based. We are declining to finalize that a nondiscriminatory benefit design that provides EHB must incorporate evidence-based guidelines into coverage and programmatic decisions, and rely on current and relevant peer-reviewed medical journal articles, practice guidelines, recommendations from reputable governing bodies, or similar sources, or the related examples of acceptable sources included in the preamble of the proposed rule. We believe that requiring plan designs providing EHB to be clinically based, without these additional requirements, is sufficient to protect consumers from discriminatory benefit designs. We will reassess whether refining this standard in future rulemaking is warranted as we continue to monitor issuer compliance with the nondiscrimination standards at § 156.125.

[276] See, for example, Colorado 2023 EHB-Benchmark Plan Actuarial Report. CMS. *https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb* Suite of Gender-affirming care benefits to treat gender dysphoria resulted cost estimate was 0.04 percent of the total allowed claims assuming utilization would be for adults.

We did not propose a requirement that clinically-based benefit designs be supported by evidence provided by individuals with specific credentials or areas of expertise, and we do not finalize any such requirement in this final rule. The presence or absence of any specific degree by the individual(s) that develops resources for clinical evidence is not by itself sufficient to satisfy or preclude compliance under this rule, nor is inclusion of particular types of expert.

When designing nondiscriminatory plan designs and ensuring that any limitations on EHB on a basis prohibited under § 156.125 are clinically indicated, we encourage issuers to seek current and relevant clinical evidence, rather than utilizing standards that tend to overlap or are potentially inconsistent with the scope of the plan design. However, we also acknowledge that limitations in medical research may restrict availability of such clinical evidence. Since we are not finalizing our proposal to specify sources of acceptable clinical information an issuer may use to show that a coverage limitation or a benefit design is not discriminatory, we also decline to include any specific ''standard of care'' within a list of appropriate clinical evidence that issuers may rely upon. HHS is of the view that the requirements of this rule and the guidance provided are sufficient to enable issuers to set coverage limitations that comply with the EHB requirements. We will continue to assess issuer compliance under this rule and will consider if future rulemaking is warranted.

We also clarify that HHS would not consider a plan design subject to § 156.125 to be discriminatory when the plan design limits coverage of an EHB on a basis that is prohibited under the regulation, but the limitation is a direct result of the issuer's compliance with other applicable Federal coverage requirements. For example, Federal law requires issuers of plans that must meet EHB standards to cover all evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force (USPSTF).[277] [278] However, evidence-based items and services with A or B ratings in effect by USPSTF often contain age limits. We would not consider a plan design subject to § 156.125 to be discriminatory when the plan design limits an EHB on a prohibited basis under § 156.125 but such limitation is due to compliance with an otherwise applicable Federal requirement. As explained in greater detail later in this final rule in relation to the finalized example of discrimination based on age, this policy is not meant to conflict with or supersede the policy at § 156.115(d), which prohibits coverage of, among other things, routine non-pediatric dental services and eye exam services as EHB.

Comment: Many commenters supported the proposal to require clinical evidence for health plan designs. Some commenters who supported the proposal cautioned HHS that clinical evidence used to defend plan designs may itself be discriminatory due to embedded systemic racism and bias in medical research.

Response: We recognize that embedded systemic racism and bias are pervasive and limit many aspects of medical research. HHS is committed to reducing the effects of such racism and bias on consumers and consumer health outcomes, which is why we are finalizing that a nondiscriminatory plan design that provides EHB is one that is clinically based, without specifying that the plan design must rely on current and relevant peer-reviewed medical journal article(s), practice guidelines, recommendations from reputable governing bodies, or similar sources. Overall, we are working to advance health equity by designing, implementing, and operationalizing policies and programs that promote and support health coverage that provides fair access to covered health care services for all person who purchase (or would purchase) the plan, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing access to the care and support that enrollees need to thrive.

Finalizing this proposal is another step towards achieving that goal, but we recognize that this policy, by itself, is insufficient to address broader concerns that the existing clinical evidence on which issuers may design nondiscriminatory benefit limitations cannot be cured of the effects of embedded systemic racism, bias, and limits in available medical research. We expect issuers to work cooperatively with States to design nondiscriminatory plans and expect States to evaluate the clinical evidence for plan designs while conducting form reviews and issuing guidance.

Comment: Some commenters expressed concern that clinical evidence may be used by issuers as justification to perpetuate discriminatory plan designs and urged HHS to clarify that lack of clinical evidence does not provide the license to deny access to new innovations or therapies that are difficult to research. They noted that some services and treatments that may be beneficial may not be conducive to conventional methodologies for developing a clinical evidence-base, such as some treatments for rare diseases.

Response: The policy finalized in this final rule at § 156.125(a) provides mandatory guidelines to issuers to support their design and implementation of benefit packages that conform to EHB nondiscrimination requirements. Under § 156.115, plans subject to the requirement to provide EHB must provide benefits that are substantially equal to the EHB-benchmark plan, including covered benefits; limitations on coverage, including benefit amount, duration, and scope; and prescription drug benefits. Thus, issuers cannot omit coverage of an EHB by asserting a lack of clinical evidence to support a discriminatory limitation on that EHB. However, separate from the policy finalized in this rule, issuers continue to have the ability to substitute benefits provided in the EHB-benchmark plan under § 156.115(b). In fact, utilizing the flexibility available under § 156.115(b) to substitute benefits may be a way for issuers to cover new and innovative benefits.

Comment: Some commenters expressed concern that the new proposed policy will unintentionally limit plan designs that strive to address health disparities. They noted that HHS should clarify that actions taken to reduce health disparities would not violate EHB nondiscrimination requirements. They expressed concern that limitations in clinical evidence may hinder innovative plan designs and issuers' ability to respond to a public health emergency.

Response: We disagree with commenters that assert this policy will inhibit efforts to advance health equity or efforts to address public health emergencies. We also do not find credible any assertion that the pursuit of sound clinical evidence in coverage decisions will in any way hinder the creation of innovative plan designs. We believe that requiring issuers to ensure their plan designs are clinically based is essential to achieving health equity and reducing health disparities.

[277] 45 CFR 156.115(a)(4).

[278] U.S. Preventative Services Task Force (n.d.) *USPSTF A & B Recommendations. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations.*

Comment: One commenter expressed concern that relying on clinical guidelines exclusively to determine discriminatory design may lead to issuers using clinical evidence or research as a shield to escape valid claims of discriminatory benefit. The commenter noted that if issuers begin to counter enrollee's arguments with clinical evidence, it may be hard to evaluate the validity of their sources as there is often a lack of transparency about the data or underlying assumptions in research. The commenter suggested that HHS should continue to employ other tools such as outlier analyses to reveal problematic plan design and consider approaches to compliance borrowed from mental health parity enforcement, such as disclosure requirements.

Response: We appreciate these recommendations and are exploring ways to improve our nondiscrimination reviews and develop new tools to detect discriminatory practices. In addition, we note that previously awarded State grants have focused on enhancing policy filing review processes to enhance enforcement of nondiscrimination (among several others).

Comments on Unforeseen Barriers and Remedying Inconsistencies With the EHB Nondiscrimination Policy

Comment: Some commenters expressed concern that the proposed changes may preempt State benefit mandates, which could create inconsistencies and impact health care affordability and accessibility. One commenter expressed concerns that State legislatures may enact mandates that are limited to a specific sub-population, as they often balance expanding coverage with the potential additional cost to those purchasing health insurance and their defrayal obligations pursuant to § 155.170. As such, this commenter noted that it is not appropriate for HHS to designate benefits being offered in accordance with State law as presumptively discriminatory. The commenter further stated that HHS should clarify that benefits offered in accordance with a duly enacted State law would not be considered presumptively discriminatory and that HHS finalize a process by which a health insurer could rebut any allegations that a benefit design is discriminatory. Another commenter urged HHS to provide additional compliance resources to allow plans and States to assess both what State mandates may not be allowed under this proposal, and how plans and States can work together to ensure consistent benefit coverage. Some commenters expressed concern that it is premature and inappropriate for HHS to include the examples given in the proposed rule without further analysis of how the examples relate to existing State and Federal nondiscrimination policies.

Response: We disagree with the premise that it is inappropriate to apply this policy to issuer plan designs that are the result of State-required benefits. We also clarify that § 156.125 would only apply to State-required benefits that are considered EHB. For example, benefits required by a State mandate enacted on or after January 1, 2012, are generally not considered EHB pursuant to § 155.170. Therefore, an issuer covering a State-required benefit that is not EHB would not be required to modify the benefit in its plan design to comply with the nondiscrimination standards under § 156.125. A State-required benefit enacted on or before December 31, 2011, is considered EHB, and issuers covering that State-required benefit would therefore be required to comply with the nondiscrimination standards in § 156.125 when including that State-required benefit in their plan designs.

If a State-mandated benefit that is considered EHB is discriminatory under this policy, the State may attempt to remedy this through various ways, including revising the mandate, issuing guidance as described earlier in this section of the preamble, or otherwise furthering issuer compliance such as by amending form filing checklists or providing technical assistance to issuers. Regardless, issuers subject to § 156.125 would need to modify any discriminatory benefit designs for benefits the issuer is covering as EHB or be prepared to justify their approach with clinical evidence when designing plans that meet EHB nondiscrimination requirements. We would expect an issuer to be able to rebut a presumption of discriminatory plan design by demonstrating that such plan designs are clinically based.[279] This policy does not disallow any benefit mandates required under State law, but does require issuers to comply with the non-discrimination provisions if benefits mandated by the State are EHB.

The preceding clarifications should address the concerns raised by commenters regarding how this policy impacts State mandates and potential defrayal implications. As noted in relation to the policy we are finalizing to repeal the annual reporting requirement for State benefit requirements at § 156.111, we intend to provide additional guidance regarding the defrayal of State-required benefits in the future. We encourage States to reach out to HHS when regulatory concerns arise in this area in the interim. We further note that, under defrayal regulations at § 155.170, State mandates imposed for purposes of coming into compliance with Federal requirements are not 'in addition to EHB' and do not require defrayal.

Comments on Telehealth Oversight

Comment: Many commenters supported oversight to ensure that telehealth is not being utilized in a discriminatory fashion. They noted that telehealth utilization is often preferred for clinical reasons or to increase convenience. One commenter recommended that HHS continue to monitor this issue closely and ensure that the decision for an in-person or virtual visit is made between the health care provider and the patient, based on medical necessity and convenience, and not based on preferential plan structuring. Another commenter noted that telehealth is best utilized when it is provided within the context of the medical home and utilized as a component of, and coordinated with, longitudinal care. Some commenters noted that some issuers have arbitrarily terminated coverage of telehealth services which they noted is not based on any clinical rationale. Further, some commenters stated that the arbitrary and inconsistent coverage impedes care coordination and transition care planning, and adds to the stress on the patient, their family, and the treatment team. Some commenters provided consumer survey information related to patients' concerns that telehealth coverage may be denied as an available option upon the expiration of the COVID–19 PHE. They urged HHS to not define plan designs that incentivize the use of virtual services as discriminatory.

Response: We are aware that States have primary oversight of telehealth practices and coverage. We encourage the commenters to work with States to help ensure consistent coverage considering the increased availability of telehealth services experienced during the COVID–19 PHE. As we noted in the proposed rule, we do not currently believe that the practice of health plans

[279] *See* proposed example of Age Limits for Infertility which provides a rationale when plans include age limitation due to variations in clinical effectiveness of treatment for infertility, defined as not being able to achieve pregnancy after 1 year of having regular, unprotected intercourse, or after 6 months if the woman is older than 35 years. *Infertility and Fertility.* (2017, January 31). NIH. *https://www.nichd.nih.gov/health/topics/infertility.*

covering services delivered virtually with no copay while requiring a copay for in-person health care services amounts to be a discriminatory practice under § 156.125. However, we intend to monitor telehealth utilization as it pertains to the delivery of benefits and how the utilization of telehealth may impact nondiscriminatory access to EHB.

General Comments Relating to Examples of Presumptively Discriminatory Benefit Designs

As noted earlier, we made some clarifying changes to the examples of presumptively discriminatory benefit designs after considering public comments, and the final examples follow later in this section of this preamble. Our explanations and rationale for the changes are noted in this response to comments section.

Comment: Several commenters supportive of the examples of presumptively discriminatory plan designs asked HHS to include additional specific examples or provided their own examples of what they believed to be presumptively discriminatory plan designs.

Response: We acknowledge and appreciate the additional examples from the commenters. As discussed in the proposed rule, we provided examples that illustrate presumptively discriminatory practices that HHS believes amount to prohibited discrimination under § 156.125. However, it is not the intent of HHS to imply that any of the services or specific benefits noted in the examples are always EHB, as that can vary among States. We also do not plan at this time to add additional examples. The examples provided are non-exhaustive and provide adequate guidance for setting coverage limitations that comply with existing regulatory requirements prohibiting discriminatory benefit design. We emphasize that it is not the intent of HHS to list every possible instance of presumptively discriminatory plan design and that the absence of a specific plan design practice within these examples does not mean it does not constitute a presumptively discriminatory practice. Rather, the refined policy provides guidance to issuers on the kind of evidence that we would find acceptable to justify limitations to benefits, to the extent they are EHB.

Comments on the Example Illustrating a Discriminatory Benefit Design Based on Age

Comment: One commenter supporting the age limitation example asserted that labeling certain benefits as ''pediatric'' should be considered age discrimination as this labeling could potentially exclude coverage for adults with chronic health conditions.

Response: As finalized at § 156.125, plan designs may include age limitations on coverage for EHB so long as those limitations are supported by or consistent with relevant clinical guidelines or standards. We also recognize that in defining the EHB package at section 1302(b) of the ACA, Congress included pediatric services among the items and services that must be covered as EHB. As such, in implementing this section, we recognize that the statute explicitly requires certain medically necessary services to be covered as EHBs, such as those services required under the preventive services and pediatric service category. Therefore, plan designs may be limited to pediatric enrollees without running afoul of discriminatory benefit design concerns when such limitations are permitted under Federal law. Further, the policy is not meant to conflict with or supersede the policy at § 156.115(d), which prohibits coverage of, among other things, routine non-pediatric dental services and eye exam services as EHB. However, to the extent an issuer's plan provides coverage of an EHB other than oral and vision care only for pediatric enrollees and no applicable Federal requirement only requires covering such EHB for that limited age group, the issuer will be held to the clinically based standard finalized at § 156.125. HHS will continue to monitor issuer compliance with EHB nondiscrimination requirements to discern whether additional assistance, policy changes, or rulemaking is necessary.

Finalized Examples: Discrimination Based on Age

We are finalizing these examples as proposed, but with minor clarifications to the conclusion of each example to clarify that these examples apply and are presumptively discriminatory to the extent issuers cover benefits as EHB.

1. Limitation on Hearing Aid Coverage Based on Age

a. Background: The National Institute on Deafness and Other Communication Disorders (NIDCD) defines a hearing aid as a small electronic device that you wear in or behind the ear. It makes some sounds louder so that a person with hearing loss can listen, communicate, and participate more fully in daily activities.[280] The FDA defines a hearing aid as ''any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.''[281]

b. *Circumstance:* Some States have included age limits in their benefit mandates that require coverage for hearing aids by specifying in the mandate that such coverage applies only to enrollees in a certain age group. For example, a State has required hearing aid coverage for enrollees only up to age 21 with certain cost-sharing conditions.

c. *Rationale:* Individuals can experience hearing loss at any stage of life, and therefore, the limitation in coverage would impact an individual in a different age group who has impaired hearing. Neither the FDA definition of a hearing aid nor NIDCD specifies an age when individuals need hearing aids. However, the definitions explain that a hearing aid is for ''a person with hearing loss'' and is for ''aiding persons with or compensating for, impaired hearing.'' Access to hearing aids can positively affect an individual's communication abilities, quality of life, social participation, and health.[282]

d. *Conclusion:* Age limits are presumptively discriminatory under § 156.125 when applied to EHB and there is no clinical basis for the age limitation. A plan subject to § 156.125 that covers medically necessary hearing aids as an EHB, but limits such coverage based on age is presumptively discriminatory under § 156.125 unless the limitation is clinically based. For example, it would be presumptively discriminatory for an issuer subject to § 156.125 to cover medically necessary hearing aids as EHB under its plan, but limit such coverage to a subset of individuals, such as enrollees who are 6 years of age or younger, since hearing aids may be medically necessary for enrollees over the age of 6.[283] The

[280] National Institute on Deafness and Other Communication Disorders FAQ on Hearing Aids (2017). NIH. *https://www.nidcd.nih.gov/health/hearing-aids#hearingaid_01.*

[281] 21 CFR 801.420(a)(1). Please note that this provision is subject to a pending rulemaking. See 86 FR 58150.

[282] Blazer, D.G., Domnitz, S., & Liverman, C.T. (2016). *Hearing Health Care for Adults: Priorities for Improving Access and Affordability.* National Academies of Sciences, Engineering, and Medicine. National Academies Press (US). *https://doi.org/10.17226/23446.*

[283] In the 2016 Payment Notice proposed rule, we cautioned both issuers and States that age limits are discriminatory when applied to services that have been found clinically effective at all ages. For example, it would be arbitrary to limit a hearing aid to enrollees who are 6 years of age and younger since there may be some older enrollees for whom a hearing aid is medically necessary.

policy reflected in this example does not apply to benefits that are not covered by a plan as EHB. For example, pursuant to § 155.170, a health benefit an issuer covers under a plan pursuant to a State mandate adopted on or after January 1, 2012, other than for purposes of compliance with Federal requirements, is not considered EHB and would not be subject to the policy reflected in this example.

2. Autism Spectrum Disorder (ASD) Coverage Limitations Based on Age

a. *Background:* According to the American Psychiatric Association, ''[p]eople with ASD may have communication deficits, such as responding inappropriately in conversations, misreading nonverbal interactions, or having difficulty building friendships appropriate to their age. In addition, people with ASD may be overly dependent on routines, highly sensitive to changes in their environment, or intensely focused on inappropriate items.'' [284]

b. *Circumstance:* We noted that some States have mandated coverage for the diagnosis and treatment for of ASD up to a certain age. For example, a State has required coverage for enrollees up to age 18 with certain cost-sharing conditions. Similarly, some States' EHB-benchmark plans that cover applied behavior analysis (ABA therapy) include age limits.

c. *Rationale:* The CDC recognizes the American Psychiatric Association's fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM–5) as standardized criteria to help diagnose ASD.[285] Under the DSM–5 criteria, individuals with ASD must show symptoms from early childhood, but may not be fully recognized until later in life.[286] We noted that screening for ASD is usually done at a young age although an individual may not be diagnosed until later in life. The CDC estimates that 2.21 percent of adults in the U.S. have ASD.[287]

d. *Conclusion:* Age limits are presumptively discriminatory under § 156.125 when applied to services that are covered as EHB and there is no clinical basis for the age limitation. A plan subject to § 156.125 that covers diagnoses and treatment of ASD as an EHB, but limits such coverage in its plan benefit design based on age is presumptively discriminatory under § 156.125 unless the limitation is clinically based. This example does not apply to benefits that are not EHB. For example, pursuant to § 155.170, a benefit required by State action taking place on or after January 1, 2012, other than for purposes of compliance with federal requirements, is not considered EHB, and this example would not apply.

3. Age Limits for Infertility Treatment Coverage When Treatment Is Clinically Effective for the Age Group

a. *Background:* The National Center for Health Statistics reported that 8.8 percent of couples in the U.S. have experienced infertility issues while 9.5 percent have received infertility services (for example, medical assistance, counseling, testing for the woman and man, ovulation drugs, fallopian tube surgery, artificial insemination, assisted reproductive technology, and miscarriage preventive services).[288]

b. *Circumstance:* We noted that some States have defined ''infertility'' in State law, which impacts insurance companies, hospitals, medical service corporations, and health care centers providing coverage for medically necessary expenses of the diagnosis and treatment of infertility. For example, a State restricted coverage for treatment of infertility to individuals who are ''presumably healthy,'' thus excluding from coverage of treatment for infertility those who are not presumably healthy.

c. *Rationale:* We noted that an individual's age is an important factor for reproductive health and development. Fertility, especially in women, declines with age, which makes natural conception more unlikely as women get older.[289] However, we also noted that the mean age for individuals experiencing their first childbirth has increased in recent years.[290] We also understand that not all individuals would be eligible for infertility treatment if they are not at the stage of development for reproduction or have certain medical conditions. Younger individuals, for example, who are not at the stage of reproductive development would reasonably not require treatment for infertility. Older adults as well would not need treatment for infertility, for example women who have reached post-menopause.

d. *Conclusion:* Age limits are presumptively discriminatory under § 156.125 when applied to EHB services and there is no clinical basis for the age limitation. A plan subject to § 156.125 that covers treatment of infertility as an EHB but limits such coverage in its plan benefit design based on age is presumptively discriminatory under § 156.125 unless the limitation is clinically based. An issuer could rebut the presumption that the plan's age limit on the coverage for treatment of infertility is discriminatory by demonstrating clinical evidence that infertility treatments have low efficacy for the excluded age groups and/or are not clinically indicated for the excluded age groups. This example does not apply to benefits that are not EHB. For example, pursuant to § 155.170, a benefit required by State action taking place on or after January 1, 2012, other than for purposes of compliance with federal requirements, is not considered EHB and this example would not apply.[291]

Comments on the Example Illustrating a Discriminatory Benefit Design Based on Health Conditions

We did not receive substantive comments related to the example, Limitations on Foot Care Coverage Based on Diagnosis (Whether Diabetes or Another Underlying Medical Condition).

Finalized Example: Discrimination Based on Health Conditions

4. Limitation on Foot Care Coverage Based on Diagnosis (Whether Diabetes or Another Underlying Medical Condition)

a. *Background:* Routine foot care includes cutting or removing corns and calluses; trimming, cutting, or clipping or debriding of nails; and hygienic or other preventive maintenance care, such as using skin creams, cleaning, and soaking the feet.[292] Although basic foot care is part of an individual's personal self-care, a health care provider in

[284] *Autism Spectrum Disorder.* (2013). American Psychiatric Association. *https://www.psychiatry.org/File%20Library/Psychiatrists/Practice/DSM/APA_DSM-5-Autism-Spectrum-Disorder.pdf.*

[285] *Autism Spectrum Disorder (ASD).* (2020, June 29). CDC. *https://www.cdc.gov/ncbddd/autism/hcp-dsm.html.*

[286] American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 5th ed. Arlington, VA: American Psychiatric Association; 2013.

[287] *Key Findings: CDC Releases First Estimates of the Number of Adults Living with Autism Spectrum Disorder in the United States.* (2020, April 27). CDC. *https://www.cdc.gov/ncbddd/autism/features/adults-living-with-autism-spectrum-disorder.html.*

[288] Infertility Statistics. (2021, December 20). CDC. *https://www.cdc.gov/nchs/fastats/infertility.htm.*

[289] *Having a Baby After Age 35: How Aging Affects Fertility and Pregnancy.* (2020). American College of Obstetricians and Gynecologists. *https://www.acog.org/womens-health/faqs/having-a-baby-after-age-35-how-aging-affects-fertility-and-pregnancy.*

[290] Mean Age of Mothers is on the Rise: United States, 2000–2014. (2016, January 14). CDC. *https://www.cdc.gov/nchs/products/databriefs/db232.htm.*

[291] *Key Statistics from the National Survey of Family Growth.* (2017, June 20). CDC. *https://www.cdc.gov/nchs/nsfg/key_statistics/i.htm.*

[292] Routine Foot Care. *Medicare Benefit Policy Manual* (pp. 265). CMS. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

certain situations may perform routine foot care for a patient to the degree that is medically necessary to prevent the perpetuation of chronic conditions.

b. *Circumstance:* We noted that some issuers have restricted coverage for routine foot care to individuals diagnosed with diabetes. For example, several issuers have limited coverage for routine foot care to diabetes care only.

c. *Rationale:* The American Diabetes Association estimates that over 10 percent of the American population has diabetes, which costs $237 billion for direct medical costs.[293] The annual cost of diabetic foot ulcer treatment, for example, is significantly greater than non-diabetic foot ulcer treatment, estimated at $1.38 billion versus $0.13 billion.[294]

Although diabetes is a vast medical expenditure in the United States, individuals may need routine foot care to treat other conditions associated with metabolic, neurologic, or peripheral vascular disease.[295]

d. *Conclusion:* Benefit designs that restrict coverage on the basis of health condition are presumptively discriminatory under § 156.125 when applied to EHB services and there is no clinical basis for the limitation. A plan subject to § 156.125 that covers routine foot care as EHB in its health plan but limits such coverage on the basis of health condition to only apply to individuals diagnosed with diabetes despite clinical evidence demonstrating that routine foot care may also be medically necessary for treatment of other conditions, such as metabolic, neurologic, or peripheral vascular disease, is presumed to be discriminatory under § 156.125. This example does not apply to benefits that are not EHB. For example, pursuant to § 155.170, a benefit required by State action taking place on or after January 1, 2012, other than for purposes of compliance with federal requirements, is not considered EHB and this example would not apply.

Comments on the Example Illustrating a Discriminatory Benefit Design Based on Adverse Tiering of Prescription Drugs

After reviewing the public comments for the Adverse Tiering example (87 FR 667 through 668), we are finalizing this proposed example in our EHB nondiscrimination policy for health plan benefit designs under § 156.125 as proposed with some minor clarifications. We clarify that this example applies to benefits that are EHB. This example does not apply to benefits that are not EHB; for example, under § 155.170, coverage of a specific drug that a State mandated on or after January 1, 2012 be covered does generally not qualify as EHB and this example does not apply.

Comment: Many commenters supported the example related to discrimination in accessing prescription drugs for chronic health conditions and adverse tiering, as the further emphasis on the existing prohibition against adverse tiering would only further expand access to care and improve health outcomes. One commenter noted that the prohibition of adverse tiering under § 156.125 is consistent with Medicare Part D and emerging State practices. Commenters agreed with the application of § 156.125 to adverse tiering because using cost as the primary factor in formulary decisions can cause tangible patient harm including nonadherence and negative health outcomes.

Response: We agree with commenters that the inclusion of the Adverse Tiering example clarifies our existing position that adverse tiering, which occurs when an issuer assigns all or the majority of drugs for certain medical conditions to a high-cost prescription drug tier to discourage enrollment by people with those medical conditions, is presumptively discriminatory under § 156.125. Allowing this practice would allow issuers to discourage enrollment for entire segments of the population with a particular medical condition by placing all or the majority of drugs for that medical condition on a high-cost tier.

To be clear, and as reiterated below, in finalizing this example, we are not prohibiting issuers from considering drug cost in setting drug formularies. On the contrary, we believe that it is prudent for a plan to consider a drug's cost in determining on which tier to place a particular drug. For example, if there are two effective drugs available to treat a particular condition, and one drug is less expensive than the other, it may be appropriate for the issuer to place the less expensive drug on a lower tier to incentivize usage of the less expensive drug. However, under this example, it is presumptively discriminatory for an issuer to place both of these drugs on a high-cost prescription drug tier in order to actively discourage enrollment by those with that condition in the plan. HHS or the State, in determining whether the issuer has rebutted this presumption that a formulary that places all drugs for a particular condition on a high-cost tier is discriminatory, will look at the totality of the circumstances, including whether the issuer demonstrated that neutral principles were used in assigning tiers to drugs and that those principles were consistently applied across types of drugs, particularly as related to other drugs in the same class (for example, demonstrating that the issuer or pharmacy benefit manager (PBM) weighed both cost and clinical guidelines in setting tiers).

Thus, we urge issuers and PBMs to pay close attention to any instance where all or the majority of drugs to treat a particular condition are placed on the highest-cost tiers. As we noted in the proposed rule, a generic drug requiring no special handling that is inexpensive to obtain might be rightly placed on a generic tier or the lowest tier, whereas a specialty drug requiring special handling and counseling, and that is also very costly, might be rightly placed on a specialty tier that has the highest cost sharing. We acknowledge that cost is often an important factor in how issuers and PBMs that service issuers tier their drugs and note that plans and issuers are permitted to use reasonable medical management practices and consider cost in structuring plan designs and cost sharing.

We believe finalizing this example is consistent with the requirement finalized in this rule at § 156.125 to justify limitations on EHBs with clinical guidelines. As explained in the proposed rule and in more detail below, this example and the existing pharmacy and therapeutics (P&T) committee requirements at § 156.122(a)(3) operate together to require issuers to base their drug formulary tier decisions on clinically indicated evidence.

Comment: Some commenters recommended that HHS allow individual plan P&T committees to determine formularies, as P&T committee recommendations are flexible in the face of constant change in the clinical evidence and other industry considerations. These commenters stated that formulary plan designs developed through the P&T committee process should not be deemed

[293] *Statistics About Diabetes.* (2022, February 4). American Diabetes Association. *https://www.diabetes.org/resources/statistics/statistics-about-diabetes.*

[294] Hicks, C.W., Selvarajah, S., Mathioudakis, N., Sherman, R.E., Hines, K.F., Black, J.H., 3rd, & Abularrage, C.J. (2016). Burden of Infected Diabetic Foot Ulcers on Hospital Admissions and Costs. *Annals of vascular surgery, 33,* 149–158. *https://doi.org/10.1016/j.avsg.2015.11.025.*

[295] *Foot Care Coverage Guidelines.* (2010). CMS. *https://wayback.archive-it.org/2744/20191012061156/https:/www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1113.pdf.*

discriminatory simply because the formularies place higher cost drugs in higher drug tiers. They noted that the proposed EHB policy would not only undermine the role of the P&T committee, but would also impact the ability of issuers to develop cost-effective formulary plan designs and may compel plans to include at least some high-cost specialty drugs in lower tiers, contrary to clinical evidence. In addition, they asserted that the proposed EHB policy would encourage manufacturers of these drugs to impose higher drug prices, which will drive up premiums.

Response: We acknowledge the importance of P&T committees in setting clinically indicated, non-discriminatory drug formularies; since 2017, we have required plans subject to the requirement to provide EHB to utilize P&T committees that meet the standards at § 156.122(a)(3). Based in part on those standards, we expect that P&T committees for issuers of such plans provide recommendations consistent with the most current and relevant clinical evidence for their respective service area.

Formulary plan designs are not discriminatory simply because formularies place higher cost drugs in higher drug tiers. Under this finalized example, formularies are presumptively discriminatory when all or a majority of drugs for a particular condition are placed on a high-cost prescription drug tier to discourage enrollment by those with that condition. As we noted in the proposed rule, HHS or the State may determine that an issuer can rebut this presumption by a totality of the circumstances, including by showing that neutral principles were applied consistently across the entire formulary in assigning all or a majority of drugs for a particular condition on a high-cost prescription drug tier. These principles harmonize with the existing requirements for P&T committees at § 156.122(a)(3)(iii) in establishing and managing an EHB-compliant formulary drug list. In this way, this example places even greater importance on the independent nature and clinically-based endeavors of P&T committees. Further, we do not agree that a P&T committee's input would likely compel plans to include at least some high-cost specialty drugs in lower tiers. We do not agree with commenters who asserted that this example will encourage manufacturers of these drugs to impose higher drug prices, which will drive up premiums. We believe this example will contribute to controlling the costs of drugs by ensuring that issuers do not inappropriately place additional drugs on higher cost drug tiers.

Comment: Some commenters suggested that HHS needs to promulgate clear parameters of what is considered discriminatory, including a tool for QHP issuers to perform their own verification that their formularies meet the new non-discrimination requirements in advance of their plan submission. One commenter urged HHS to monitor issuers for compliance with nondiscrimination requirements, and to assist States with oversight and enforcement. One commenter recommended HHS should review issuers' internal coverage guidelines for discriminatory benefit designs as part of the QHP certification process.

Response: We believe that this final rule provides issuers clear guidance regarding the EHB nondiscrimination policy and encourage issuers to utilize tools that are appropriate for their own practices to aid with meeting EHB nondiscrimination requirements. For example, HHS currently uses and makes available a non-discrimination cost sharing review tool to identify and analyze outlier plans seeking certification as QHPs on the FFEs, as a means to identify potentially discriminatory benefit designs and strives to enhance such techniques. In the proposed rule, we stated that we will continue to monitor issuer compliance with EHB nondiscrimination requirements and States' oversight and enforcement activities to discern whether additional guidance, policy changes, or rulemaking are necessary. HHS will also consider whether additional guidance is necessary as we monitor issuer compliance with EHB nondiscrimination requirements and States' oversight and enforcement activities.

Finalized Example: Discrimination Based on Health Conditions

5. Access to Prescription Drugs for Chronic Health Conditions (Adverse Tiering)

a. *Background:* QHP issuers are allowed to structure and offer tiered prescription drug formularies. As a result, QHPs will have different tier structures depending on decisions that issuers make about their formulary structure, including decisions made on the basis of cost. However, there is concern that formulary tiers may also be structured to discourage enrollment by consumers with certain chronic conditions. One approach to this, called adverse tiering, occurs when plans structure the formulary by assigning all or the majority of drugs for certain medical conditions to a high-cost prescription drug tier.[296]

b. *Circumstance:* Individuals with certain chronic health conditions, for example, have reported that the majority of their prescription drugs have been designated as specialty drugs and placed in the highest cost tier. Individuals have also seen most or all prescription drugs in the same therapeutic class, used to treat their chronic health condition, placed on the highest cost tiers.

c. *Rationale:* More than half of U.S. adults are diagnosed with a chronic condition. In 2018, the prevalence of multiple chronic conditions was higher among women, non-Hispanic white adults, older adults, adults aged 18–64 enrolled in Medicaid, adults dually eligible for Medicare and Medicaid, and adults in rural areas.[297] Adults with certain high-cost chronic conditions require long-term treatment to manage their chronic health conditions. Health benefit designs with adverse tiering may discriminate based on an individual's present or predicted disability or other health conditions in a manner prohibited by § 156.125(a).

d. *Conclusion:* It is presumptively discriminatory under § 156.125 for an issuer providing EHB to place all drugs for a particular condition on a high-cost tier to discourage enrollment by those with that condition. To rebut the presumption that a formulary that places all drugs for a particular condition on a high-cost tier is discriminatory, HHS or the State will consider the totality of the circumstances, including whether the issuer has demonstrated that neutral principles were used in assigning tiers to drugs and that those principles were consistently applied across types of drugs, particularly as related to other drugs in the same class (for example, demonstrating that the issuer or PBM weighed both cost and clinical guidelines in setting tiers).

The 2016 Payment Notice provides that if an issuer places most or all drugs that treat a specific condition on the highest cost tiers, that such plan designs could be found to discriminate against individuals who have those chronic high-cost conditions under the § 156.125(a) standard. We clarified that

[296] Jacobs, D.B., & Sommers, B.D. (2015). Using drugs to discriminate—adverse selection in the insurance marketplace. *The New England journal of medicine,* 372(5), 399–402. *https://doi.org/10.1056/NEJMp1411376.*

[297] Boersma, P., Black, L.I., & Ward, B.W. (2020). Prevalence of Multiple Chronic Conditions Among US Adults, 2018. *Preventing chronic disease,* 17, E106. *https://doi.org/10.5888/pcd17.200130.*

such instances of adverse tiering are presumptively discriminatory and that issuers and PBMs assigning tiers to drugs should weigh the cost of drugs on their formulary with clinical guidelines for any such drugs used to treat high-cost chronic health conditions to avoid tiering such drugs in a manner that would discriminate based on an individual's present or predicted disability or other health conditions in a manner prohibited by § 156.125(a).

In addition, we indicated in the 2016 Payment Notice and the 2014 Letter to Issuers that we will notify an issuer when we see an indication of a reduction in the generosity of a benefit in some manner for subsets of individuals that is are not based on clinically indicated, reasonable medical management practices.[298] [299] Issuers should expect to cover and provide sufficient access to treatment recommendations that have the highest degree of clinical consensus based on available data, such as professional clinical practice guidelines.

Comments on Implementing the Refined EHB Nondiscrimination Policy 60 Days After Final Rule Publication

Comment: One commenter supported the proposed effective date of 60 days after the publication of the final rule, given the negative effects that discriminatory benefit designs can have on enrollees with chronic conditions, especially during a public health emergency. Another commenter supported the 60-day effective date, noting that since the proposed clinical standards framework is consistent with HHS' earlier rulemaking and plan compliance reviews, it should not unduly burden issuers to review and update their plans for compliance.

Many commenters objected to the proposed implementation timeframe as too immediate. Commenters requested that HHS extend the effective date until one year after the publication of this final rule to allow time for review of benefits coverage and making necessary adjustments. Other commenters recommended implementation of the policy no earlier than the 2024 plan year, while two other commenters recommended that the policy become effective at the beginning of a plan year so that formularies do not change in the middle of a plan year. Commenters explained that issuers will need to work with States to assess this requirement and administrative changes while reviewing existing networks and any new benefits. Commenters also noted they need adequate implementation time to prevent duplicative health plan designs and potential inconsistent standards as many health plans already use clinical evidence-based guidelines.

Response: We recognize that issuers subject to § 156.125 requirements may choose to carefully review the refined EHB nondiscrimination final rule. We recognize that such reviews may take time and that issuers may experience added burden to the extent that issuers make additional changes to their EHB plan designs in response to those reviews. While we expect that issuers are already compliant with current § 156.125 requirements, we recognize that in reviewing and implementing the refined EHB nondiscrimination policy, issuers may still have to make changes to benefits covered as EHB to ensure compliance, which may not always be done mid-plan year. Therefore, the refined EHB nondiscrimination policy will be applicable starting on the earlier of PY 2023 or upon renewal of any plan subject to the EHB requirements. We encourage issuers to promptly update their practices to more immediately reduce the impact of presumptively discriminatory practices, consistent with applicable State and Federal requirements. HHS intends to work collaboratively to address compliance issues with issuers that are acting in good faith to comply with the refined EHB nondiscrimination policy.

7. Publication of the 2023 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, and maximum annual limitations on cost sharing and reduced maximum annual limitation on cost sharing in guidance annually starting with the 2023 benefit year. In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 668), we noted that these parameters were not included in the proposed rule, as HHS did not propose to change the methodology for these parameters for the 2023 benefit year, and therefore, HHS published these parameters in guidance on December 28, 2021 (Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage for the 2023 Benefit Year).[300]

8. Levels of Coverage (Actuarial Value) (§§ 156.140, 156.200, 156.400)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 668), HHS proposed to change the *de minimis* ranges at § 156.140(c) beginning in PY 2023 to +2/−2 percentage points for all individual and small group market plans subject to the AV requirements under the EHB package, other than for expanded bronze plans,[301] for which HHS proposed a *de minimis* range of +5/−2. Under § 156.200, HHS proposed, as a condition of QHP certification, to limit the *de minimis* range to +2/0 percentage points for individual market silver QHPs; HHS also proposed under § 156.400 to specify a *de minimis* range of +1/0 percentage points for income-based silver CSR plan variations.

Section 2707(a) of the PHS Act and section 1302 of the ACA direct issuers of non-grandfathered individual and small group health insurance plans (including QHPs) to ensure that these plans adhere to the levels of coverage specified in section 1302(d)(1) of the ACA. A plan's level of coverage, or AV, is determined based on its coverage of the EHB for a standard population. Section 1302(d)(1) of the ACA requires a bronze plan to have an AV of 60 percent, a silver plan to have an AV of 70 percent, a gold plan to have an AV of 80 percent, and a platinum plan to have an AV of 90 percent. Section 1302(d)(2) of the ACA directs the Secretary of HHS to issue regulations on the calculation of AV and its application to the levels of coverage. Section 1302(d)(3) of the ACA authorizes the Secretary to develop guidelines to provide for a *de minimis* variation in the actuarial valuations used in determining the level of coverage of a plan to account for differences in actuarial estimates.

[51] Letter to Issuers on Federally-facilitated and State Partnership Exchanges (pp.15). (2013, April 5). CMS. *https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/2014_letter_to_issuers_04052013.pdf.*

[299] 2015 Letter to Issuers in the Federally facilitated Marketplaces (pp.29). (2014, March 14). CMS. *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf.*

[300] Letter for Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage for the 2023 Benefit Year (2021, December 28). CMS. *https://www.cms.gov/files/document/2023-papi-parameters-guidance-v4-final-12-27-21-508.pdf.*

[301] Expanded bronze plans are bronze plans currently referenced in § 156.140(c) that cover and pay for at least one major service, other than preventive services, before the deductible or meet the requirements to be a high deductible health plan within the meaning of section 223(c)(2) of the Code.

We sought comments on this proposal. We refer readers to the proposed rule (87 FR 668 through 671) for further discussion of these proposals and our rationale.

After reviewing the public comments, for the reasons set forth in this rule and in the proposed rule, we are finalizing the proposed changes to the *de minimis* ranges at §§ 156.140(c), 156.200, and 156.400 as proposed.

First, beginning in PY 2023, we are finalizing that all individual and small group market plans subject to the AV requirements under the EHB package will be subject to a *de minimis* range of +2/−2 percentage points, except for expanded bronze plans, for which we finalize a *de minimis* range of +5/−2 percentage points.

As we explained in the proposed rule (87 FR 668), since we finalized these *de minimis* ranges in the 2018 Payment Notice (81 FR 94058, 94142) and the 2017 Market Stabilization final rule (82 FR 18346, 18368), we have observed an increasing percentage of bronze plans offered on *HealthCare.gov* with AVs in the upper end of the current *de minimis* range. In PY 2018, 8.45 percent of all bronze plans offered on *HealthCare.gov* had an AV between 64 and 65 percent. In PYs 2019 and 2020, this number grew to 14.29 percent and 24.44 percent, respectively. For PY 2021, 67.55 percent of bronze plans offered on *HealthCare.gov* had an AV between 64 and 65 percent. As the cost of health care services continues to increase, we expect more bronze plans to have an AV of at least 64 percent in future PYs.

TABLE 6: Distribution of Bronze Plans by Actuarial Value Percentage, PY 2018-2021

PY	< 60%	60.00 to 61.99%	62.00 to 63.99%	64.00 to 65.00%
2018	19.41%	61.50%	10.64%	8.45%
2019	26.64%	43.20%	15.87%	14.29%
2020	16.98%	22.64%	35.93%	24.44%
2021	0.00%	20.41%	12.04%	67.55%

During PYs 2018 through 2021, as the percentage of bronze plans within the upper limit of the +5/−4 percentage point range increased, the percentage of silver plans offered on *HealthCare.gov* within the lower end of the current +2/−4 percentage point range remained consistent, with less than a third of silver plans having an AV between 66 and 68 percent.

TABLE 7: Distribution of Silver Plans by Actuarial Value Percentage, PY 2018-2021

PY	66.00 to 67.99%	68.00 to 69.99%	70.00 to 71.99%
2018	25.65%	29.47%	44.88%
2019	30.59%	17.59%	51.82%
2020	26.27%	23.44%	50.28%
2021	28.43%	34.20%	37.37%

Despite the consistency of silver plan distribution by AV percentage, the number of enrollees in silver plans on *HealthCare.gov* within the lower end of the current +2/−4 percentage point range has decreased each year since 2018, while the number of enrollees in bronze plans within the upper end of the current +5/−4 percentage point range has increased each year since 2018.

TABLE 8: Number of HealthCare.gov Enrollees in Plans by AV Percentage, PY 2018-2021

PY	62.00 to 63.99%	64.00 to 64.99%	66.00 to 67.99%	68.00 to 69.99%
2018	481,209	335,164	289,230	275,767
2019	511,823	514,874	197,918	160,841
2020	1,037,700	827,694	132,939	173,399
2021	395,175	2,184,483	102,878	144,818

As the availability of and enrollment in bronze plans within the upper end of the current *de minimis* range increases and the enrollment in silver plans within the lower end of the current *de minimis* range decreases, we believe it is increasingly important for consumers to be able to distinguish the levels of coverage between bronze plans and silver plans and be assured that the level of coverage of their plan corresponds to the relevant metal tier. We are not confident that, with current de minimis ranges, consumers can reliably distinguish plans that have similar AV percentages, but significantly different cost sharing. Despite their similar AVs, there is generally a 10-percentage point difference in median coinsurance per EHB between expanded bronze and base silver plans offered on *HealthCare.gov*. The difference between copayment amounts for the expanded bronze plan and the base silver plan is also apparent.

TABLE 9: Median Pre-Deductible Copays for Standard Silver and Expanded Bronze Plans on HealthCare.gov, PY 2021

Service	Expanded Bronze (56 to 65% AV)	Standard Silver (66 to 72% AV)
Primary Care Visit	$40	$30
Specialist Visit	$90	$65
Mental Health/ Substance Use Disorder Outpatient Office Visit	$50	$35
Generic Drugs	$25	$20
Preferred Brand Drugs	$165	$60
Non-Preferred Brand Drugs	$250	$150

Thus, we are no longer of the view that a silver *de minimis* range of +2/−4 percentage points ensures the meaningful comparison of plans between the silver and bronze levels of coverage. However, we continue to recognize the importance of permitting issuers to offer expanded bronze plans because the rationale for expanding the upper limit of the *de minimis* range for these plans to +5 still applies to the current market: Issuers continue to require greater flexibility for bronze plan design to assist with innovation, premium impact, and future impacts to the AV Calculator methodology, to ensure that bronze plans can continue to be more generous than catastrophic plans and to ensure that high deductible health plans (HDHPs) can be offered at the bronze level. At the same time, the 2017 Market Stabilization final rule also noted the narrow difference in bronze and silver QHPs and therefore, to improve a consumer's ability to meaningfully compare the bronze and silver levels of coverage, pursuant to our authority under sections 1302(d)(3) and 1321(a)(1)(A) and (D) of the ACA, and sections 2707 and 2792 of the PHS Act, we are changing the *de minimis* range for standard silver plans as proposed.

Additionally, as shown in Tables 10 and 11, we stated that we have observed a shift in enrollment for gold plans in 2021 and bronze plans since 2019 within the +2/−4 *de minimis* towards the center of the *de minimis* (+2/−2).

TABLE 10: Distribution of Gold Plan Enrollment by AV Percentage, PY 2018-2021

PY	76.00 to 77.99%	78.00 to 79.99%	80.00 to 81.99%
2018	155,725	237,202	135,160
2019	247,467	185,302	196,882
2020	273,623	68,308	271,174
2021	80,624	175,056	234,361

TABLE 11: Distribution of Bronze Plan Enrollment by AV Percentage, PY 2018-2021

PY	56.00 to 57.99%	58.00 to 59.99%	60.00 to 61.99%	62.00 to 63.99%	64.00 to 64.99%
2018	161,536	282,003	1,192,625	481,209	335,164
2019	159,121	410,260	952,680	511,823	514,874
2020	110,689	193,673	568,351	1,037,700	827,694
2021	0	0	450,022	395,175	2,184,483

Because of this shift, and for consistency across the metal levels, which would help reduce potential consumer confusion, we believed it is appropriate, starting with PYs beginning in 2023, to change the *de minimis* ranges for the standard bronze, gold, and platinum levels of coverage from +2/−4 percentage points to +/−2 percentage points. Likewise, we have observed a similar shift in enrollment for expanded bronze plans that currently utilize a +5/−4 *de minimis* range. Because of this shift, and to align with the change above, starting with PYs beginning in 2023, we are changing the *de minimis* range for expanded bronze plans from +5/−4 to +5/−2.

Further, States generally remain the primary enforcers of the requirement to meet AV requirements, including, to the extent required by § 156.135, the use of the Federal AV Calculator or an AV Calculator that utilizes State-specific data under § 156.135(e). In the 2017 Market Stabilization final rule (82 FR 18369), we stated that States are the primary enforcers of AV requirements and can apply stricter AV standards that are consistent with Federal law. We also stated that a State cannot require issuers to design plans that apply an AV range that is not consistent with our implementation of sections 1302(d)(1) and (d)(3) of the ACA (which defines the metal levels and *de minimis* ranges). We reiterate those statements here. Under this final rule, a State cannot apply an AV range that exceeds +2/−2 percentage points, except for under the expanded bronze range originally provided for in § 156.140(c).

In addition to the changes applicable to non-grandfathered individual and small group market health insurance coverage market-wide, we are also amending § 156.200(b)(3) to state that, beginning with year PY 2023, as a requirement for certification, the allowable variation in AV for individual market silver QHPs would be +2/0 percentage points. Through the authority granted to HHS in sections 1311(c) and 1321(a) of the ACA to establish minimum requirements for QHP certification, we are finalizing this narrower *de minimis* range for individual market silver QHPs to maximize PTC and APTC for subsidized enrollees. We believe that narrowing the

de minimis range of individual market silver QHPs will influence the generosity of the SLCSP, the benchmark plan used to determine an individual's PTC. We note that a subsidized enrollee who has an SLCSP that is currently below 70 percent AV will see the generosity of their current SLCSP increase, likely accompanied by a corresponding increase in premium, resulting in an increase in PTC. As shown in Table 8, since 2018, enrollment in 66.00 to 69.99 percent AV silver plans has decreased and enrollment in 62 to 64.99 percent AV bronze plans has increased; enrollees in such bronze plans now outnumber enrollees in such silver plans by more than ten to one.

In addition, as we stated in the proposed rule (87 FR 670), after the implementation of the ARP enhanced financial subsidies, there are even fewer enrollees remaining in silver QHPs with AVs between 66.00 and 69.99 percent offered through Exchanges that use the Federal platform. Approximately 248,000 enrollees remain, of which about 91,000 are unsubsidized. By comparison, enrollment for the income-based silver CSR variations corresponding to the above silver QHPs has increased to about 4.2 million. We believe the amendment we are finalizing to the *de minimis* range for individual market silver QHPs will reduce the cost of insurance coverage for an increasing population of subsidized enrollees. It will also mitigate the net burden of the additional cost to a decreasing population of unsubsidized enrollees by incentivizing healthier, subsidy-eligible enrollees to participate in the Exchanges.

Thus, we believe increasing PTC for all subsidized enrollees justifies a narrower *de minimis* range on individual market silver QHPs that have fewer enrollments each year.

Finally, we are changing the *de minimis* variation for individual market income-based silver CSR plan variations from +1/−1 to +1/0 with a revision to the definition of ''*De minimis* variation for a silver plan variation'' at § 156.400. Similar to the +2/0 *de minimis* change for individual market silver QHPs, we believe the change to the *de minimis* variation for individual market income-based silver CSR plan variations will deliver further subsidization of premiums via increased APTC and PTC for subsidized enrollees in the income-based silver CSR plan variations and increase the generosity of these plans. While there will be an expected increase to the premium for the CSR plan variations as a result of the increased generosity, it will be substantially offset by increases to the APTC and PTC.

We summarize and respond to public comments received on levels of coverage (actuarial value) (§§ 156.140, 156.200, 156.400).

Comment: Many commenters expressed general support for the proposed changes to the *de minimis* ranges, agreeing with the rationale from the proposed rule that narrowing the *de minimis* ranges would increase PTC and APTC, and make coverage more affordable for subsidized enrollees. Many other commenters did not support the proposal and expressed satisfaction with the current *de minimis* ranges, asserting that not every enrollee would be eligible for the increased subsidies that would offset any premium increases due to the narrowed *de minimis* ranges. These commenters noted that the expanded PTC under section 9661 of the ARP is set to expire after PY 2022.

Response: We agree with commenters that the proposed *de minimis* changes would increase PTC and APTC to make coverage more affordable for subsidized enrollees. As we noted in the proposed rule, after implementation of the ARP enhanced financial subsidies, there are even fewer enrollees remaining in silver QHPs with AVs between 66.00 and 69.99 percent offered through Exchanges that use the Federal platform, of which about 91,000 are unsubsidized. By comparison, enrollment for the income-based silver CSR variations corresponding to the above silver QHPs has increased to about 4.2 million.

We recognize that this change will increase premiums for enrollees in the individual and small group market. We estimated that the premiums would increase approximately 2 percent on average because of this change, which accounts for changes after the expiration of the expanded PTC under section 9661 of the ARP. We received no comments that addressed the accuracy of this estimate or its effects as a whole. While we recognize that not every enrollee in plans subject to the AV requirement is eligible for APTC and lives in an area with a SLCSP that is currently below 70 percent AV, we believe that the benefit of increased PTC and APTC for the majority of enrollees in the Exchanges outweighs the effects of wider *de minimis* ranges and the burden of premium increases.

Comment: Some commenters requested clarification on the applicability of uniform-modification-of-coverage rules should the narrower *de minimis* ranges be finalized. One such commenter requested clarification that plans within the current *de minimis* ranges, but outside of the proposed narrower ranges for PY 2023, will be allowed to renew within the same metal level of coverage under the Federal uniform-modification-of-coverage rules. These commenters generally contended that discontinued plans not subject to those rules would cause disruption for enrollees.

Response: Under the guaranteed renewability provision at 45 CFR 147.106(e), a health insurance issuer offering health insurance coverage in the individual, small group, or large group market is required to renew or continue in force the coverage at the option of the plan sponsor or the individual, unless the issuer discontinues all coverage, the product is discontinued, or the issuer's action is otherwise excepted from this requirement. One such exception that applies to individual and small group coverage is the modification of coverage at the time of renewal made consistent with State law, effective uniformly and solely pursuant to applicable Federal or State requirements, as described at § 147.106(e)(1)–(2). This allows an issuer to modify its plans uniformly if the modification is made within a reasonable time period after the imposition or modification of a Federal or State requirement and the modification is directly related to the imposition or modification of the Federal or State requirement. As finalizing these changes to the *de minimis* ranges constitutes a modification of a Federal requirement, issuers that, consistent with State law, uniformly modify their plans solely to bring the plans' AV levels into the narrower *de minimis* ranges to maintain the same metal level will be considered to have modified their plans consistent with the Federal uniform-modification-of-coverage rules outlined in 45 CFR 147.106(e). Such changes would not cause any product, or any plan within a product, to be a different product or plan, as explained in the definitions of product and plan in 45 CFR 144.103.

Comment: Many commenters opposed the proposed +2/0 *de minimis* range for individual market silver QHPs and +2/−2 *de minimis* range for other silver plans and recommended keeping the +2/−2 *de minimis* range consistent across the individual market. These commenters cited concerns about the effects of non-uniform *de minimis* ranges for silver plans across the individual market, asserting that applying different *de minimis* ranges on- and off-Exchange could destabilize the individual market. They further believe that the different *de minimis* ranges could adversely impact

consumers who choose to buy health coverage off-Exchange.

Response: We strive to maintain consistency for the *de minimis* ranges as much as possible. A consistent *de minimis* range allows for the most reliable determination of the differences between metal levels of coverage which, overall, improves the consumer shopping experience. We diverge from that goal only to the extent necessary to achieve compelling policy interests. For example, we previously regulated by this guideline in the 2017 Market Stabilization final rule, changing the *de minimis* ranges to +2/−4 from the original +2/−2 allowable AV variation finalized in the Final 2018 Payment Notice, in an attempt to achieve the compelling policy interest of improving plan variability and choice. In this rule, we believe it is appropriate to adopt separate *de minimis* ranges for individual market silver QHPs to achieve the compelling policy interest of addressing the rising costs of health insurance premiums by influencing the generosity of the SLCSP to increase the amounts of PTC and APTC.

Comment: Many commenters urged that we not finalize changes to *de minimis* ranges for small group market plans, asserting that the proposed rule's rationale for changing the *de minimis* ranges applies only to changes to individual market plans. These commenters pointed out that HHS did not describe similar shifts in enrollments in small group QHPs offered on *HealthCare.gov* that are towards the upper end of the expanded bronze *de minimis* range as done with enrollment in individual market QHPs offered on *HealthCare.gov,* and that enrollees in small group market plans would experience premium increases as a result of the proposal, without the benefit of increased PTC or APTC. Further, these commenters stated that, because small group enrollees purchase their coverage through employers, they are not involved with plan comparison in the same way as individual market enrollees and HHS' justification for maintaining the integrity between metal levels is inapplicable to the small group market. These commenters also asserted that sponsors of small group market plans prefer the variety of plan choices under a wider *de minimis* range, and explained that these employers would experience disruption to existing plans or decide to drop coverage entirely.

Response: We recognize the concern raised by commenters that the proposed *de minimis* changes will lead to increased premiums for small group market enrollees without any subsidies to offset the cost. We are of the view that the burden of small premium increases in the small group market does not outweigh the benefits of ensuring that all purchasers of health coverage, including small group employers and their employees, can discern the material differences in benefits provided under competing health insurance plans. In response to the assertion that sponsors of small group market plans prefer the variety of plan choices that wider *de minimis* ranges allow for, and that these employers would experience disruption to existing plans or decide to drop coverage entirely, we believe that the benefits of improved plan comparability outweigh the advantages of wider *de minimis* ranges.

We do not have sufficient data to confidently describe enrollment trends in small group market QHPs. However, enrollment trends were not the basis for proposing to change the *de minimis* range for small group market plans. As we explained in the proposed rule (87 FR 669 through 670), the rationale for making equivalent changes to the *de minimis* ranges across the individual and small group markets is to maintain consistency across the metal levels, as an effort to reduce potential consumer confusion. Maintaining consistency for the metal level *de minimis* ranges allows for the greatest degree of confidence that consumers can recognize and understand the differences between metal levels. We diverge from the standard +2/−2 *de minimis* range for expanded bronze plans (+5/−2) for the reasons described in the preamble of the proposed rule, and for individual market silver QHPs offered both on-Exchange and off-Exchange (+2/0) and income-based silver CSR plan variations (+1/0) only to further the compelling policy interests described elsewhere in this section.

Comment: Many commenters supported the proposed *de minimis* ranges by citing the expected improvement in consumers' ability to meaningfully compare plans and make informed decisions related to their health coverage. These commenters stated that the current *de minimis* ranges are too permissive and blur the distinction between the metal levels of coverage envisioned by the ACA, which makes the plan comparison process difficult for consumers. They noted that the proposed *de minimis* ranges would narrow the allowable variation in plan generosity per metal level and should improve the plan comparison process for consumers, leading to more informed decisions on effective health coverage. The commenters also stated that the proposed *de minimis* ranges could lead to higher enrollment, as consumers would better understand the difference between metal level QHPs and more efficiently choose their health coverage. Additionally, one of the commenters noted that narrowing the allowable levels of coverage would positively impact plan marketing and display practices across issuers and keep consistent thresholds across competitors. They particularly noted that the narrow *de minimis* ranges would end the ''race to the bottom'' of underbidding high generosity competitor plans by offering plans with lower generosity that still display under the same metal level of coverage within marketing.

Opposing commenters expressed a preference for the current *de minimis* ranges, asserting that the proposed ranges are too disruptive to the current market of plan offerings and could lead to more difficulty for consumers during plan selection. According to these commenters, consumer feedback indicates a preference for consistently similar plan offerings year-over-year. These commenters also generally asserted that the proposed ranges would cause fluctuations in available plan offerings, and could lead to consumers choosing coverage that is not in their best interests. These commenters also noted that the proposal may eliminate popular plan options at lower bound levels of coverage and that the gap in the allowable *de minimis* range could lead to limited plan design flexibility. Some commenters raised concerns about the effect of the proposed *de minimis* ranges on future plan designs as well, stating that narrowing the ranges for plans on and off the Exchanges would reduce issuers' ability to create plan designs that meet the specific needs of enrollees. These commenters further contended that popular plan designs would become non-compliant, with one State Exchange commenting that a standardized gold plan design, currently at 76 percent AV and accounting for 51 percent of the Exchange's gold metal level enrollment, would be non-compliant under this proposal. Some commenters also expressed general concerns about market disruption and requested a delay of any changes to the *de minimis* ranges to at least PY 2024.

Response: We agree with commenters that this policy will improve comparability, ensuring that consumers can more meaningfully distinguish between plans in different metal levels of coverage, and ensure consistency across metal levels. Increased recognition by consumers of the fundamental differences between the benefits offered under different health

plans means that consumers will be less likely to choose a health plan ill-fitted to their circumstances, which may discourage consumers from using and maintaining their coverage in the future.

Furthermore, we believe that the implementation of the proposed *de minimis* ranges can lead to higher enrollment in plans. Requiring that plans offer the levels of coverage described at section 1302(d) of the ACA promotes consumers' ability to more easily recognize, understand, and compare plan offerings. As commenters noted, there is a general consensus of a connection between the ease of consumer plan selection and their enrollment decisions. These narrower de minimis ranges will allow consumers to better differentiate between plan offerings and reduce consumer confusion, which we believe will motivate increased overall enrollment.

In response to comments that the new *de minimis* ranges may eliminate popular plan options at lower bound levels of coverage and could lead to limited plan design flexibility, we are of the view that the burdens to issuers of conforming their plan offerings to the new *de minimis* ranges will be offset by the positive impacts on the consumer plan selection process. We reiterate our note from the proposed rule that we have no evidence that the expanded variation in allowable levels of coverage under current rules actually improved the consumer experience, including a consumer's ability to choose the plan that best meets their needs. As we stated previously, we believe the revised *de minimis* ranges we are finalizing in this rule will improve comparability, ensuring that consumers can more meaningfully distinguish between plans in different metal levels of coverage.

Although initial compliance with the new *de minimis* ranges may require additional effort from stakeholders, we still believe that this change is necessary to respond to observed changes in consumer plan selection behavior. We note that any initial disruption to issuer plans in the –4 to –2 percentage point *de minimis* range will be limited to a one-time cost-sharing adjustment to conform with up to a 2-percentage point change in the AV (except for individual market silver QHPs, which would have up to a 4-percentage point change). Issuers will be permitted to make these changes to existing plans consistent with the uniform modification provisions under the guaranteed renewability statute and regulation. Furthermore, while we believe issuers can operationalize these changes in time for plan year 2023, we recognize that this one-time cost-sharing adjustment may create substantial burden for issuers. This is a burden we do not impose lightly; in addition to increasing PTC and APTC for eligible enrollees, these changes to the *de minimis* ranges are necessary to assure consumers that a plan's generosity conforms to the appropriate metal level and to prevent overlap in plan generosity across metal levels.

Comment: Some commenters stated that plans within States requiring the individual and small group insurance markets to be merged into a single risk pool under § 156.80 would be disrupted by the proposal to establish different *de minimis* ranges for individual market silver QHPs and for other individual and small group plans.

Response: Vermont, which previously had merged its individual and small group markets transitioned to separate individual and small group market risk pools beginning January 1, 2022.[302] While both Massachusetts and the District of Columbia have State-specific factors that combine certain aspects of their individual and small group plans, we do not consider their individual and small group markets to be merged into a single risk pool under § 156.80.[303] For example, Massachusetts permits issuers in its small group market to update their index rates once every quarter, allowing small group market rating to operate separately from individual market rating in a manner that does not reflect a merged single risk pool. Similarly, the District of Columbia permits issuers to use different premium rating factors for its individual and small group markets in a manner that does not reflect a merged single risk pool. As such, there are currently no States with individual and small group markets that meet the Federal definition of a merged market under § 156.80. Therefore, we do not agree with commenters that there will be disruption to existing plans in merged markets in 2023. However, we recognize that if a State chooses to merge risk pools in future plan years, plans in that State could not utilize separate *de minimis* ranges for individual and small group market silver QHPs, and would need to conform all individual market silver QHPs to a +2/0 *de minimis* range, and income-based silver CSR plan variations to a +1/0 *de minimis* range.

9. QHP Issuer Participation Standards (§ 156.200)

Section 156.200(e) states that a QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex. In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 671), we proposed to amend 45 CFR 156.200(e) such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. As explained in the Supplemental Information section earlier in this preamble, HHS will address this proposed policy, as well as the public comments submitted in response to this proposal, in future rulemaking.

10. Standardized Plan Options (§ 156.201)

In the 2023 Payment Notice proposed rule (87 FR 584, 671 through 680), HHS proposed a requirement that issuers offering QHPs through FFEs and SBE–FPs, for PY 2023 and beyond, 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), metal level, and throughout every service area that they offer non-standardized QHP options. We did not propose to limit the number of non-standardized plan options that issuers can offer but noted that we were considering whether it would be appropriate to do so in a future plan year. Furthermore, we did not propose to subject issuers in State Exchanges to this requirement to avoid duplicative standardized plan option requirements on State Exchange issuers and because we are of the view that State Exchanges are best positioned to design and implement standardized plan option requirements for their State. We also proposed that FFE and SBE–FP issuers 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,[304] be exempt from the standardized plan option requirements in the proposal.

HHS proposed the following standardized plan options: one bronze plan, one bronze plan that meets the

[302] Information on state specific rating variation is available at *Market Rating Reforms.* (2021, December 10). CMS. *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/state-rating.* Also see *Green Mountain Care Board Reduces Rate Requests for Individual and Family Plans for 2022.* (2021, August 5). Green Mountain Care Board. *https://gmcboard.vermont.gov/sites/gmcb/files/documents/GMCB%20Press%20Release%20-%202022%20BCBSVT%20and%20MVP%20Individual%20Decisions.pdf.*

[303] Massachusetts is considered to have a merged market for purposes of the HHS-operated risk adjustment program. See *https://regtap.cms.gov/uploads/library/RA_MergedMarketsFAQ_021522_5CR_021522.pdf.*

[304] See Or. Admin. R. 836–053–0009.

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. We did not propose standardized plan options for the Indian CSR plan variations as provided for at § 156.420(b) since the cost sharing parameters for these plans are already largely specified.

HHS proposed two sets of standardized plan options to accommodate different States' cost sharing laws. HHS proposed that the first set apply to all FFE and SBE–FP issuers excluding issuers in Delaware and Louisiana, and that the second set apply to issuers in Delaware and Louisiana.

HHS also noted that it was considering exercising the existing authority under § 155.205(b)(1) to differentially display standardized plan options on *HealthCare.gov.* Similarly, HHS noted that it was considering resuming enforcement of the existing 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—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively. HHS noted that if it did exercise these existing authorities, these entities would be required to differentially display standardized plan options beginning with the PY 2023 open enrollment period 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. We also noted that any requests from web-brokers and QHP issuers seeking approval for an alternate differentiation format would be reviewed based on whether the same or a similar level of differentiation and clarity is being provided under the requested deviation as is provided on *HealthCare.gov.*

We proposed this approach for several reasons. To begin, the 2019 Payment Notice final rule eliminated standardized plan options with the intention of maximizing innovation and variety at a time when the individual market was considered to be at risk of destabilization. In the proposed rule, we explained that we believe that current market conditions differ significantly from the market conditions that defined the individual market when standardized plan options were eliminated. For example, the number of issuers offering plans on the Exchanges has increased considerably, the number of counties with a single issuer offering plans through the Exchange has decreased significantly, and the number of plan options that consumers have access to on the Exchanges has increased substantially since standardized plan options were discontinued in the 2019 Payment Notice final rule.

We explained in the proposed rule that with increased enrollment, increased issuer participation, decreased single issuer counties, and increased plan options available to consumers, HHS is of the view that resuming standardized plan options at this time could play a constructive role in enhancing the consumer experience, increasing consumer understanding, simplifying the plan selection process, combatting discriminatory benefit designs that disproportionately impact disadvantaged populations, and advancing health equity. We also explained that we believe that given the large number of plan offerings on the Exchanges, a sufficiently diverse range of plan offerings exists for consumers to continue to select innovative plans that meet their unique health needs.

We did not propose to require issuers in State Exchanges to offer standardized plan options for several reasons, including that eight State Exchanges already require or will require issuers to offer standardized plan options by PY 2023. In addition, imposing duplicative standardized plan option requirements on issuers in State Exchanges that already have existing State standardized plan option requirements runs counter to our goals of enhancing the consumer experience, increasing consumer understanding, simplifying the plan selection process, combatting discriminatory benefit designs, and advancing health equity. We also explained that we believe that State Exchanges are uniquely positioned to best understand the nature of their respective markets as well as the consumers in these markets. As such, we explained in the proposed rule that we believe that State Exchanges are best positioned to design standardized plan options suitable for their respective markets.

We further explained in the proposed rule that we 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. We explained that we do not wish to impede these innovative policies so long as they comply with existing legal requirements. However, because we proposed to impose this requirement in the FFEs, and because the SBE–FPs use the same platform as the FFEs, we proposed to apply these requirements equally on FFEs and SBE–FPs. We explained that changing the platform to permit distinction on this proposal between FFEs and SBE–FPs would require a very substantial financial and operational burden that we believe outweighs the benefit of permitting such a distinction.

In the proposed rule, we explained that we proposed to exempt FFE and SBE–FP issuers that are subject to State standardized plan option requirements from these standardized plan option requirements since we do not wish to impose duplicative requirements that could conflict with these existing State standardized plan option requirements and the QHP plan designs applicable in such States. Regardless, we proposed to differentially display these existing State standardized plan options on the Federal platform in the same manner as the standardized plan options in this rule to ensure a consistent experience for all consumers utilizing the Federal platform.

In the proposed rule, we explained that we designed two sets of standardized plan options to accommodate applicable State cost sharing laws in different sets of FFE and SBE–FP States. We also explained that we designed these standardized plan options to be similar to the most popular QHPs in FFEs and SBE–FPs in PY 2021 in terms of cost sharing parameters, MOOPs, and deductibles in order to ensure these plans are similar to plans that most consumers are already currently enrolled in, thereby reducing the risk of disruption for consumers and issuers alike.

In the proposed rule, we explained that we believe that resuming the differential display of standardized plan options on *HealthCare.gov* per the existing authority at § 155.205(b)(1) would further streamline the plan selection and enrollment process for Exchange consumers, aid consumers in distinguishing standardized plan options from non-standardized plan options, and enhance consumer understanding of the benefits of standardized plan options, such as having more pre-deductible coverage. We also explained that we believe that resuming enforcement of the existing standardized plan options display requirements applicable to 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, is important considering that a steadily increasing number of consumers are enrolling in Exchange plans via these pathways, and that doing so will ensure a consistent consumer experience whether consumers are selecting plans on or off the Exchanges.

We refer readers to the proposed rule (87 FR 671 through 680) for a complete description of the proposals and rationale.

After considering comments received, for the reasons set forth in this rule and in the proposed rule, HHS finalizes the policies as proposed. Specifically, HHS finalizes 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. We note that we added the phrase ''at every'' to the metal level component of the above requirement for additional clarification and to minimize the risk of misunderstanding these requirements. We also clarify that these requirements are applicable to the FFE and SBE–FP issuers offering QHPs in the individual market but not the small group market.

Similar to its stance in the proposed rule, HHS will not limit the number of non-standardized QHP options that issuers of QHPs in FFEs and SBE–FPs can offer through the Exchange in PY 2023. We also finalize, as proposed, that issuers in State Exchanges be exempt from the requirement to offer standardized plan options. Similarly, we finalize, as proposed, that issuers of QHPs 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,[305] are exempt from these requirements.

HHS finalizes the following standardized plan options, as proposed: 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 propose standardized plan options for the Indian CSR plan variations as provided for at § 156.420(b), and therefore is not finalizing standardized plan options for these plan variations.

HHS also finalizes two sets of standardized plan options to accommodate different States' cost sharing laws, as proposed. Specifically, the first set of standardized plan options will apply to all FFE and SBE–FP issuers, except issuers in Delaware and Louisiana. We add as a point of clarification that this first set of standardized plan options will also not apply to issuers in Oregon, since Oregon enacted standardized plan options requirements before January 1, 2020 and issuers in Oregon are thus exempt from these requirements. The second set of standardized plan options will apply only to issuers in Delaware and Louisiana in order to accommodate these two States' specialty tier prescription drug cost sharing laws.

In the first set of standardized plan options finalized in this rule (see Table 12), applicable to all FFE and SBE–FP issuers, except issuers in Delaware, Louisiana, and Oregon, there is cost sharing parity between the primary care visit, the speech therapy, and the occupational and physical therapy benefit categories. There are also copays for all prescription drug tiers, including the non-preferred brand and specialty tiers, instead of coinsurance rates. Finally, the copay for the mental health/substance use disorder in-network outpatient office visit sub-classification is equal to the least restrictive level for copays for medical/surgical benefits in the in-network, outpatient office visit sub-classification (and copays apply to substantially all medical/surgical benefits in this sub-classification), to ensure issuers can 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.[306]

The second set of standardized plan options finalized in this final rule (see Table 13), applicable only to issuers in Delaware and Louisiana, has copays of $150 or less for the specialty drug tiers of standardized plan options at all metal levels. This copay limitation for specialty drug tiers is the key feature that distinguishes the second set of standardized plan options from the first.

The two sets of standardized plan options finalized in this rule were designed to reflect the benefit categories in the actuarial value calculator (AVC), along with the addition of the ''Urgent Care'' benefit category. The cost sharing values for ''Mental/Behavioral Health Inpatient Services'' and ''Substance Abuse Disorder Inpatient Services'' benefits were not included in the proposed rule. However, we clarify that the ''Mental/Behavioral Health Inpatient Services'' and ''Substance Abuse Disorder Inpatient Services'' cost sharing values are populated based on the ''Inpatient Hospital Services (for example, Hospital Stay)'' cost sharing values since this benefit correlates to admission in a hospital or mental health facility. We further clarify that for the ''Inpatient Hospital Services'' benefit category in Tables 12 and 13, the ''(Including Mental Health and Substance Use Disorder)'' portion of the benefit category name was mistakenly excluded in the proposed rule. We therefore amended the name of this benefit category to more closely align with the corresponding benefit category in the AVC.

We also clarify that the AVs for several of the plans in each set differ slightly from the AVs of the corresponding plans in the proposed rule, due to a miscalculation with the AVC. We clarify that when a prescription drug formulary tier has copay after deductible as the form of cost sharing, both the ''Subject to Deductible? '' and ''Copay only applies after deductible?'' boxes must be selected in the AVC for that particular tier, or an incorrect AV will be calculated.

In both sets of standardized plan options, expanded bronze, standard silver, the silver 73 CSR variant, and the silver 87 CSR variant were affected by this miscalculation. After resolving this miscalculation, in the first set of standardized plan options, the AV for expanded bronze changed from 64.06 percent to 64.18 percent; the AV for standard silver changed from 70.04 percent to 70.06 percent; the AV for the silver 73 CSR variant changed from 73.10 percent to 73.11 percent; and the AV for the silver 87 CSR variant changed from 87.04 percent to 87.05 percent. In the second set of standardized plan options, the AV for expanded bronze changed from 64.07 percent to 64.18 percent; the AV for standard silver changed from 70.05 percent to 70.06 percent; the AV for the silver 73 CSR variant changed from

[305] See Or. Admin. R. 836–053–0009.

[306] In general, MHPAEA and its implementing regulations apply to group health plans and health insurance issuers in the group and individual markets, and require 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.

73.01 percent to 73.03 percent; and the AV for the silver 87 variant changed from 87.05 percent to 87.06 percent. The AVs for other metal levels were not affected by this miscalculation since these plans did not have copay after deductible as the cost sharing type for any benefits.

We also note that one asterisk (*) was mistakenly excluded in the plan designs in the proposed rule. Specifically, in the second set of standardized plan options, the gold plan's specialty drug tier should be exempt from the deductible and should thus have an asterisk next to its cost sharing amount. All other cost sharing parameters in both of the below sets of standardized plan options remain unchanged from the original plans in the proposed rule.

HHS also finalizes, as proposed, that we will exercise our existing authority under § 155.205(b)(1) to resume the differential display of standardized plan option plans on *HealthCare.gov* beginning with the PY 2023 open enrollment period.[307] Similarly, also beginning with the PY 2023 open enrollment period, HHS finalizes, as proposed, that we will resume 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 that these entities are required to differentially display standardized plan options in a manner consistent with how standardized plan options are displayed on *HealthCare.gov,* unless HHS approves a deviation.

HHS also finalizes, as proposed, that any requests from web-brokers or QHP issuers that seek approval for an alternate differentiation format will be reviewed based on whether the same or similar level of differentiation and clarity would be provided under the requested deviation as is provided on *HealthCare.gov.* We also reaffirm that a QHP issuer using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—including both the Classic DE and EDE pathways—only needs to differentially display those standardized plan options it offers.[308] To minimize the burden of complying with these display requirements, HHS will provide access to information on standardized plan options to web-brokers and QHP issuers through the Health Insurance Exchange Public Use Files (PUFs) and QHP Landscape file.

[307] The PY 2023 OEP is scheduled from November 1, 2022 to January 15, 2023. See 45 CFR 155.410(e)(3).

[308] See 81 FR 94118.

TABLE 12: 2023 Final Standardized Plan Options Set One (For All FFE and SBE-FP Issuers, Excluding Issuers in Delaware, Louisiana, and Oregon)

	Bronze	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Actuarial Value	59.86%	64.18%	70.06%	73.11%	87.05%	94.02%	78.00%	88.00%
Deductible	$9,100	$7,500	$5,800	$5,700	$800	$0	$2,000	$0
Annual Limitation on Cost Sharing	$9,100	$9,000	$8,900	$7,200	$3,000	$1,700	$8,700	$3,000
Emergency Room Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$100*
Inpatient Hospital Services (Including Mental Health and Substance Use Disorder)	No charge after deductible	50%	40%	40%	30%	25%*	25%	$350*
Primary Care Visit	No charge after deductible	$50*	$40*	$30*	$20*	$0*	$30*	$10*
Urgent Care	No charge after deductible	$75*	$60*	$45*	$30*	$5*	$45*	$15*
Specialist Visit	No charge after deductible	$100*	$80*	$60*	$40*	$10*	$60*	$20*
Mental Health and Substance Use Disorder Outpatient Office Visit	No charge after deductible	$50*	$40*	$30*	$20*	$0*	$30*	$10*
Imaging (CT/PET Scans, MRIs)	No charge after deductible	50%	40%	40%	30%	25%*	25%	$100*
Speech Therapy	No charge after deductible	$50*	$40*	$30*	$20*	$0*	$30*	$10*
Occupational, Physical Therapy	No charge after deductible	$50*	$40*	$30*	$20*	$0*	$30*	$10*
Laboratory Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$30*
X-rays and Diagnostic Imaging	No charge after deductible	50%	40%	40%	30%	25%*	25%	$30*
Skilled Nursing Facility	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Facility Fee (Ambulatory Surgery Center)	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Surgery Physician and Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*
Generic Drugs	No charge after deductible	$25*	$20*	$20*	$10*	$0*	$15*	$5*
Preferred Brand Drugs	No charge after deductible	$50	$40*	$40*	$20*	$15*	$30*	$10*
Non-Preferred Brand Drugs	No charge after deductible	$100	$80	$80	$60	$50*	$60*	$50*
Specialty Drugs	No charge after deductible	$500	$350	$350	$250	$150*	$250*	$150*

*Benefit category not subject to the deductible

TABLE 13: 2023 Final Standardized Plan Options Set Two (For Issuers in Delaware and Louisiana)

	Bronze	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Actuarial Value	59.86%	64.18%	70.06%	73.03%	87.06%	94.02%	78.02%	88.01%
Deductible	$9,100	$7,500	$5,800	$4,100	$800	$0	$2,000	$0
Annual Limitation on Cost Sharing	$9,100	$9,000	$8,900	$7,200	$3,000	$1,800	$8,700	$3,000
Emergency Room Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$100*
Inpatient Hospital Services (Including Mental Health and Substance Use Disorder)	No charge after deductible	50%	40%	40%	30%	25%*	25%	$350*
Primary Care Visit	No charge after deductible	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Urgent Care	No charge after deductible	$75*	$60*	$60*	$30*	$5*	$45*	$15*
Specialist Visit	No charge after deductible	$100*	$80*	$80*	$40*	$10*	$60*	$20*
Mental Health and Substance Use Disorder Outpatient Office Visit	No charge after deductible	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Imaging (CT/PET Scans, MRIs)	No charge after deductible	50%	40%	40%	30%	25%*	25%	$100*
Speech Therapy	No charge after deductible	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Occupational, Physical Therapy	No charge after deductible	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Laboratory Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$30*
X-rays and Diagnostic Imaging	No charge after deductible	50%	40%	40%	30%	25%*	25%	$30*
Skilled Nursing Facility	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Facility Fee (Ambulatory Surgery Center)	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Surgery Physician and Services	No charge after deductible	50%	40%	40%	30%	25%*	25%	$150*
Generic Drugs	No charge after deductible	$25*	$20*	$20*	$10*	$0*	$15*	$5*
Preferred Brand Drugs	No charge after deductible	$50	$40*	$40*	$20*	$5*	$30*	$10*
Non-Preferred Brand Drugs	No charge after deductible	$100	$80	$80	$60	$10*	$60*	$50*
Specialty Drugs	No charge after deductible	$150	$125	$125	$100	$20*	$100*	$75*

*Benefit category not subject to the deductible

We summarize and respond to public comments received on the proposals related to the standardized plan options.[309] We also offer several points of clarification.

[309] In connection with HHS' proposal to require FFE and SBE–FP issuers to offer standardized plan options, HHS sought comment on: (1) Requiring FFE and SBE–FP issuers to offer standardized plan options at every product network type, metal level, and throughout every service area that they offer non-standardized plan options; (2) not limiting the number of non-standardized plan options that issuers can offer through the Exchanges; (3) the feasibility, advantages, and disadvantages of gradually limiting the number of plan options over the course of several PYs; (4) whether standardized plan options should be differentially displayed on *HealthCare.gov* as well as the best manner for doing so; (5) whether web-brokers and issuers using the Classic DE and EDE Pathways should remain subject to differential display requirements; (6) the continuation of an exceptions process that allows these entities to deviate from the display of standardized plan options on *HealthCare.Gov;* (7) exempting State Exchange issuers from these requirements; (8) whether these plan designs should apply to State Exchanges that do not use the Federal platform and that have not implemented their own standardized plan options; (9) exempting FFE and SBE–FP issuers that are subject to existing state standardized plan options requirements under state action taking place on or before January 1, 2020 from being required to offer the standardized plan options in this proposal; (10) the methodology used to design these standardized plan options; (11) if the proposed standardized plan options are compliant with state cost sharing laws in FFE and SBE–FP states; (12) the cost-sharing parameters and plan designs for these standardized plan options; (13) how these plans can be designed in a way that maximizes the likelihood that plans will be able to

Continued

Comment: Many commenters supported requiring issuers offering QHPs through FFEs and SBE–FPs to offer standardized plan options at every product network type, at every metal level, and throughout every service area that they offer non-standardized plan options, explaining that standardized plan options could play an important role in simplifying the plan selection process. These commenters explained this approach will enable consumers to more easily compare plans by standardizing cost sharing parameters, thereby allowing individuals to focus on other factors crucial to their health, such as premiums, networks, quality, and customer satisfaction.

Many commenters also explained that requiring issuers to offer standardized plan options could improve affordability by requiring pre-deductible coverage of key services. These commenters explained that lowering cost barriers to services and supplies that address health conditions that disproportionately affect historically underserved communities aligns with broader Federal efforts intended to reduce health disparities. These commenters also explained that consumers frequently choose plans based only on premiums—without a clear understanding of additional out-of-pocket costs they might experience. These commenters thus explained that requiring issuers to offer standardized plan options with enhanced pre-deductible coverage could reduce the risk of consumers experiencing unexpected financial costs for receiving care.

Several commenters explained that the effectiveness of plan standardization in improving access to care and enhancing affordability is evinced by the experience of the nine States that have already adopted standardized plan option requirements in their respective State Exchanges. These commenters explained that several of these State Exchanges have required issuers to offer standardized plan options since their inception in 2014. These commenters also explained that standardized plan option requirements have played an important role in achieving some of the lowest rates of premium growth in the country in these State Exchanges.

Response: We agree that consumers will benefit from tools that further streamline the decision-making process, especially given that there has been a proliferation of plan offerings on the Exchanges in the last several years. We also agree that standardized plan options can play an important role in that simplification by allowing consumers to compare offerings based on other meaningful features, such as premiums, networks, formularies, and quality ratings. We believe that employing standardized plan option requirements while simultaneously narrowing the AV *de minimis* ranges will allow consumers to more easily and more meaningfully differentiate between choices and select a plan that meets their unique needs.

We believe the approach to standardized plan options finalized in this rule strikes an appropriate balance between simplifying the plan selection process, making it easier for consumers to more meaningfully compare available plan options, combatting potentially discriminatory benefit designs, reducing health disparities, and advancing health equity, while simultaneously preserving a sufficient range of consumer choice, minimizing the degree of disruption arising from the implementation of these requirements, and continuing to foster competition in the Exchanges.

We also agree that implementing the standardized plan option requirements finalized in this rule will improve access to care, enhance affordability, and advance health equity. The standardized plan options finalized in this rule include several important plan design features that we believe will provide additional consumer protections and mitigate health disparities, aligning with several of HHS' top priorities. Several of these design features include enhanced pre-deductible coverage for many EHB services, greater consumer certainty from having copays instead of coinsurance as the form of cost sharing for as many benefits as possible, and having copays for all prescription drug tiers, including for the specialty drug tier.

Comment: Several commenters disagreed that HHS is legally obligated to resume standardized plan options, explaining that the *City of Columbus, et al.* v. *Cochran* ruling simply stated that the prior administration provided insufficient justification for discontinuing standardized plan options, but not that doing so was unlawful. These commenters noted that instead of resuming standardized plan options, HHS should issue a new rule with a more thorough explanation than what was provided in the 2019 Payment Notice final rule explaining why standardized plan options should remain discontinued.

Response: As we discussed in the proposed rule, we first introduced standardized plan options in the 2017 Payment Notice. We then discontinued standardized plan options 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.[310] The court specifically vacated the portion of the 2019 Payment Notice that ceased HHS' practice of designating some plans in the FFEs as ''standardized plan options,'' a policy that the 2019 Payment Notice (83 FR 16930, 16974 through 16975) described as seeking to maximize innovation by issuers in designing and offering a wide range of plans to consumers. As such, we announced our intent to engage in rulemaking under which we would propose to resume standardized plan options in time for PY 2023.[311] More recently, President Biden's Executive Order on Promoting Competition in the American Economy directed HHS to implement standardized plan options to facilitate the plan selection process for consumers on the Exchanges.[312]

Although we agree with commenters that the *City of Columbus* ruling did not require HHS to resume standardized plan options, it did cause HHS to reevaluate its prior decision to discontinue the designation of standardized plan options in the 2019 Payment Notice. As we explained in the proposed rule (87 FR 672), we believe that the conditions that currently define the individual market differ significantly from the conditions that defined the market when standardized plan options were discontinued in 2019, when the market was considered to be at risk of destabilization. We believe that the risk of market destabilization has subsided, as is demonstrated by the proliferation of plan offerings, increased issuer participation in the Exchanges, and record high enrollment. We believe that resuming standardized plan options at this time can play a constructive role in enhancing the consumer experience, increasing consumer understanding, and simplifying the decision-making process for consumers on the Exchanges

comply with MHPAEA; (14) the policy approach for PY 2023 and beyond; and (15) having two sets of standardized plan options (that is, a separate set for Delaware and Louisiana). See 87 FR 671 through 680.

[310] 523 F. Supp. 3d 731 (D. Md. 2021).

[311] In part 3 of the 2022 Payment Notice final rule, 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.

[312] Executive Order 14036 on Promoting Competition in the American Economy. (2021, July 9). 86 FR 36987.

despite the fact that the *City of Columbus* ruling does not legally obligate HHS to do so.

Comment: Several commenters who opposed these standardized plan option requirements noted that the current degree of standardization enabled by plan AV, different metal tiers of coverage, and mandatory coverage of EHB is sufficient to allow for easier plan comparison.

Response: We disagree that the current degree of standardization enabled by AV, different metal tiers of coverage, and mandatory coverage of EHB is adequate to enable sufficiently easy plan comparison, especially given the proliferation of plan offerings in recent years. As discussed later in the Choice Architecture and Preventing Plan Choice Overload Comment Solicitation, the proliferation of plan offerings available to consumers increases the risk of choice overload, coverage disruption, and suboptimal plan selection. We believe that given this proliferation of plan offerings, additional standardization is needed, and that consumers will benefit from additional tools that facilitate decision-making, including from the standardized plan option requirements finalized in this rule.

Comment: Some commenters stated that HHS should not require issuers to offer standardized plan options since consumer uptake of standardized plan options was low in previous years.

Response: We believe it is appropriate to require FFE and SBE–FP issuers to offer standardized plan options despite the comparatively low uptake of these plans in PY 2017 and PY 2018 for several reasons. As previously discussed, there has been a considerable proliferation of plan offerings available to consumers on the Exchanges over the last several years, and we believe that requiring issuers to offer these standardized plan options will play an important role in mitigating the risk of plan choice overload associated with the proliferation of plan offerings.

We also believe that these standardized plan options contain several plan design features, such as enhanced pre-deductible coverage, copays for as many benefit categories as possible, and copays for all tiers of prescription drug coverage, that provide important consumer protections. We believe these design attributes can play a significant role in decreasing barriers to access for several important health services, reducing the risk of unexpected costs and the associated financial harm, mitigating the risk of health disparities, combatting potentially discriminatory benefit designs, and advancing health equity. Altogether, we believe the advantages of standardized plan options outweigh the fact that consumer uptake of these options was comparatively low in previous plan years.

Comment: Many commenters opposed to requiring issuers to offer standardized plan options generally noted that these requirements would impede innovative plan designs that are tailored to meet the unique needs of enrollees. These commenters explained that when issuers develop plan offerings, they conduct extensive research to develop innovative plans that meet the needs of the populations and communities within their service areas. These commenters also expressed concerns that standardized plan options would not be able to keep pace with the innovation in the market.

Response: We disagree that requiring issuers to offer these standardized plan options will impede innovative plan designs tailored to meet the unique needs of enrollees. After considering comments received in response to the proposed rule, and based on our experience with reviewing plan cost-sharing structures during QHP certification, we are not of the view that non-standardized plans have sufficiently innovated with cost-sharing structures to justify not requiring issuers to offer standardized plans. We believe these standardized plan options requirements will increase enrollment and improve health outcomes without impeding issuers' ability to innovate in plan designs in their non-standardized offerings. We also note that we will continue to investigate whether there are lessons that we can draw from non-standardized plan options in terms of innovative plan designs that can apply to standardized plan options in future plan years.

Comment: Many commenters opposed to requiring standardized plan options stated that these requirements would unnecessarily constrain consumer choice. These commenters pointed out that some consumers choose less generous plans while others choose more generous plans, suggesting that there is not a one-size-fits-all plan design capable of satisfying all enrollees' unique health needs.

Response: We disagree that requiring issuers to offer standardized plan options would unnecessarily constrain consumer choice. First, the standardized plan options finalized in this rule reflect the most popular plan design attributes that consumers are already accustomed to. Second, as discussed elsewhere in this section, there has been a proliferation of plan choices available to consumers on the Exchanges. This proliferation significantly complicates the plan selection process, and increases the risk of choice overload, coverage disruption, and suboptimal plan selection. Contrary to the claim that these standardized plan option requirements will constrain consumer choice, we believe they will facilitate consumer choice by allowing consumers to more meaningfully compare between plans. Finally, if consumers believe that their unique health needs are not met with the standardized plan options finalized in this rule, they retain the ability to choose from non-standardized plan options.

Comment: Several commenters stated that requiring issuers to offer standardized plans at every product network type, at every metal level, and throughout every service area in which they offer non-standard plans could increase the total number of plan offerings on Exchanges that rely on the Federal platform, exacerbating consumer confusion and increasing the risk of choice overload.

To circumvent this problem, some of these commenters recommended that HHS simply not require issuers to offer standardized plans, while others recommended requiring issuers to offer standardized plan options while also simultaneously limiting the number of non-standardized plan options that issuers can offer. The commenters who supported limiting the number of non-standardized plan options issuers can offer cited the increased number of plans that HHS described in the proposed rule as evidence that the number of plan choices on the Exchanges has increased to a point where it is difficult for consumers to make informed decisions, which can result in decreased enrollment. Several of the commenters who supported limiting the number of non-standardized plan options issuers can offer also cited the success of State Exchanges that limit the number of plan offerings in order to facilitate consumer decision-making.

Response: We are aware that these standardized plan option requirements could potentially increase the total number of plan offerings on the Exchanges. We also agree that the number of plan offerings on the Exchanges has increased to a point that is detrimental to consumers. That said, we chose to require issuers to offer standardized plan options while not also simultaneously limiting the number of non-standardized plan options issuers can offer in order to strike the greatest balance between simplifying the plan selection process and not causing

an excessive amount of disruption in too condensed a timeframe. Considering that the QHP certification cycle for PY 2023 will have begun by the time this rule has been published, we do not believe it feasible to limit the number of non-standardized plan options that issuers can offer without causing significant disruption to issuers' portfolios of plan offerings, which would also increase the risk of enrollment disruption.

In addition, we believe it would be important to first conduct extensive stakeholder engagement in order to determine whether limiting the number of non-standardized plan options that issuers can offer would be appropriate before proposing adoption of such an approach. We anticipate initiating this stakeholder engagement in the coming months and applying the lessons learned from this stakeholder engagement to our approach to standardized plan options in the 2024 Payment Notice.

Furthermore, we encourage issuers to modify their existing non-standardized plan offerings—in accordance with uniform modification requirements at 45 CFR 147.106(e)—to conform with the cost-sharing parameters of the standardized plan options finalized in this rule, if possible and so desired. This would significantly reduce the number of total new plan offerings on the Exchanges, which would also reduce the risk of choice overload, while allowing issuers to easily crosswalk enrollees from their current non-standardized plan offering to the standardized plan option equivalent.

Comment: Some commenters explained that requiring issuers to offer standardized plan options would increase issuer burden by increasing the total number of plan offerings in their portfolios. Several of these commenters stated that this increased burden could discourage issuers from entering new markets, thus reducing competition.

Response: We believe that requiring issuers to offer the standardized plan options finalized in this rule will not significantly increase issuer burden. As previously discussed, we encourage issuers to modify their existing non-standardized offerings to conform with the cost sharing parameters for the standardized plan options finalized in this rule so they do not have to offer both their non-standardized plan offerings and standardized plan option equivalents side by side in order to minimize issuer burden, if so desired. We also believe that issuers will be able to utilize the same provider networks and formularies for these standardized plan options as they do for their current non-standardized offerings, which we believe will further minimize issuer burden. Given these considerations, we do not expect these requirements to impose an excessive amount of issuer burden that will discourage issuers from entering new markets, and we therefore do not expect these requirements to reduce competition in this regard.

Comment: Several commenters recommended that HHS narrow the scope of the proposed rule and require issuers to offer only one standardized plan option at the silver metal level if it requires issuers to offer them at all. These commenters generally noted that HHS should only expand standardized plan options gradually, if at all, to minimize disruptions.

Response: We disagree that we should narrow the scope of the rule and require issuers to offer only one standardized plan option at the silver metal level, and that we should only expand standardized plan options gradually to minimize disruption. We believe that our approach of requiring issuers to offer standardized plan options at every product network type, at every metal level, and throughout every service area (but not at product network types, metal levels, or service areas where issuers do not offer non-standardized plan options) while also not limiting the number of non-standardized plan options that issuers can offer strikes an appropriate balance between simplifying the plan selection process while also minimizing the risk of disruption.

Comment: Many commenters explained that resuming the meaningful difference standard (previously codified at 45 CFR 156.298) would be an effective and targeted method to prevent duplicative plan offerings while simultaneously ensuring that issuers continue to have the flexibility necessary to innovate. Several of these commenters supported resuming the meaningful difference standard in conjunction with requiring issuers to offer standardized plan options, while several of these commenters supported resuming the meaningful difference standard in place of the standardized plan option requirements finalized in this rule. Many of the commenters who supported resuming the meaningful difference standard recommended that HHS adopt a more stringent approach than that previously taken, explaining that the standard in its previous iteration failed to prevent duplicative plan offerings.

Several commenters cited States' role in regulating individual market health insurance plans, requesting that HHS coordinate with State regulators in the event of HHS implementing a meaningful difference standard.

Response: Although we do agree that resuming the meaningful difference standard in conjunction with the standardized plan option requirements finalized in this rule could be an effective and targeted method to prevent duplicative plan offerings, we do not believe it is appropriate to resume the meaningful difference standard for PY 2023. We believe that additional research is needed to build upon and refine the previous version of the meaningful difference standard. We also believe that resuming the meaningful difference standard for PY 2023 would not grant issuers and States sufficient time to modify their portfolio of plan offerings prior to the PY 2023 QHP certification cycle.

Comment: Several commenters requested that HHS clarify if issuers are required to offer these standardized plan options off-Exchange.

Response: We clarify that issuers are generally required to offer standardized plan options off-Exchange pursuant to guaranteed availability requirements at 45 CFR 147.104. That said, issuers are not required to actively market these plans off-Exchange.

Comment: Several commenters requested that HHS clarify if issuers are required to offer the standardized plan options finalized in this rule in the small group market.

Response: We clarify that FFE and SBE–FP issuers are only required to offer the standardized plan options finalized in this rule in the individual market, but not the small group market.

Comment: Several commenters requested that HHS clarify whether issuers are required to offer standardized plan options for family plans, and if so, if HHS has designed standardized plan options for family plans.

Response: HHS affirms that issuers are required to offer standardized plan options for family plans. HHS also clarifies that issuers are able to offer standardized plan options as family plans by applying a family (other than self-only) MOOP and a family (other than self-only) deductible that is double the self-only MOOP and the self-only deductible, respectively, provided for in the standardized plan options finalized in this rule. We note that this approach is consistent with the approach taken in the 2017 Payment Notice (81 FR 12204, 12292).

Comment: Several commenters supported exempting FFE and SBE–FP issuers that are already subject to State standardized plan option requirements

from the standardized plan option requirements finalized in this rule.

Response: We agree that it is appropriate to exempt FFE and SBE–FP issuers that are already required to offer standardized plan options under State action taking place on or before January 1, 2020 from the standardized plan option requirements finalized in this rule. We believe imposing duplicative Federal standards on these issuers would yield no benefit to consumers or issuers and that it would unnecessarily increase issuer burden. We further believe that FFE and SBE–FP States that have enacted standardized plan option requirements and implemented specific plan designs are positioned to best understand the unique needs and conditions in their respective markets.

Comment: Several commenters requested that HHS clarify whether the requirement for FFE and SBE–FP issuers to offer standardized plan options applies to issuers in States that are transitioning to a State Exchange model type in a future plan year.

Response: We clarify that all FFE and SBE–FP issuers are subject to these requirements, even if they anticipate that their State will transition from having an FFE or SBE–FP to a State Exchange in a future plan year (such as issuers in the State of Virginia). We reiterate that the only FFE and SBE–FP issuers exempt from the requirement to offer standardized plan options at every product network type, at every metal level, and throughout every service area they offer non-standardized plan options are those that are already subject to State requirements enacted prior to January 1, 2020, such as issuers in the State of Oregon.

Comment: Several commenters recommended applying these standardized plan options requirements to State Exchange issuers that are not already required to offer standardized plan options per existing State requirements, while many were opposed to this approach, citing that State Exchanges are most familiar with the nuances and demands of their respective markets and should therefore be allowed to determine if issuers should be required to offer standardized plan options in these markets.

Response: We do not believe it is appropriate to apply the standardized plan option requirements finalized in this rule to State Exchange issuers, including issuers that are not already required to offer standardized plan options per existing State requirements, because we believe State Exchanges are best positioned to understand both the nuances of their respective markets and consumer needs within those markets. We also believe that State Exchanges are best positioned to determine whether standardized plan options would be beneficial to consumers in their respective States. However, because the SBE–FPs use the same platform as the FFEs, we are finalizing the requirements equally on FFEs and SBE–FPs. Changing the platform to permit distinction on this proposal between FFEs and SBE–FPs would require a very substantial financial and operational burden that we believe outweighs the benefit of permitting such a distinction.

Comment: Several commenters requested that HHS clarify whether pediatric dental benefits can be included in standardized plan options.

Response: We affirm that pediatric dental benefits can be included in these standardized plan options if so desired, but note that the cost sharing parameters for these benefits are not standardized.

Comment: Several commenters requested that HHS clarify if telehealth services can be offered at a lower cost sharing amount than in-person services.

Response: Telehealth services cannot be offered at a lower cost sharing amount than in-person services, primarily due to limitations in the AVC. We intend to consider whether this flexibility should be afforded for future plan years.

Comment: Several commenters asked HHS to clarify how they should assign cost sharing to benefits not included in the AVC or the standardized plan options finalized in this rule.

Response: We note that when offering the standardized plan options finalized in this rule, issuers only have to match the cost sharing parameters for the benefits specified in the plan designs for the standardized plan options finalized in this rule. Issuers retain the ability to determine the cost sharing for benefits not included in the standardized plan options finalized in this rule, subject to State and Federal law.

Comment: Many commenters made recommendations regarding specific features of the plan designs. Several commenters disagreed with the methodology used in designing these standardized plan options, stating that designing standardized plan options to reflect popular plan design features (in the form of enrollee-weighted medians) would fail to meet the unique health needs of consumers. Commenters also stated that health care markets vary dramatically between States, as do the most popular plan design features in each of these markets, and therefore, that these plan designs would not resonate with consumers in every State.

Response: We designed the standardized plan options in this proposal by mirroring the most popular plan design features of QHPs offered through the FFEs and SBE–FPs in PY 2021 (in the form of enrollee-weighted medians), meaning that these plan designs are similar to those that millions of consumers are already currently enrolled in. Furthermore, though we do agree that there are some differences between the health care markets of different States, as well as between the most popular plan design features in these States, there are many similarities between different States and plan design features, as well.

For example, in the FFEs and SBE–FPs in PY 2021, 90 percent of non-CSR silver plan enrollees had plans with copays exempt from the deductible as the form of cost sharing for primary care visits. The 30th percentile copay amount for this benefit category was $30 per visit, while the 70th percentile was $40 per visit. Thus, the range between the 30th and 70th percentiles for copay amounts for primary care visits for non-CSR silver plan enrollees in all FFEs and SBE–FPs in PY 2021 was only $10, meaning the standardized plan options finalized in this rule have design features that are largely compatible with plan design features that millions of enrollees are already accustomed to. The fact that there is little variation in many of the most frequently utilized benefit categories across FFEs and SBE–FPs supports the decision to employ an enrollee-weighted median methodology in designing these plans.

To ensure these standardized plan options are able to meet the unique health needs of all consumers, we reiterate that we intend to conduct extensive stakeholder engagement (including with State regulators, issuers, provider groups, health advocacy groups, and consumer groups) over the next year. We anticipate incorporating the feedback we receive during this stakeholder engagement when designing standardized plan options for future plan years so that we can design plans that meet the unique health needs of all consumers. In the meantime, we believe the fact that consumers can still select from an unlimited number of non-standardized plan options in PY 2023 means that all consumers can select plans that meet their unique health needs.

Comment: Several commenters expressed concern with having one set of standardized plan options apply to all FFE and SBE–FP States. These commenters stated that a uniform national set of plan designs is unlikely to be attractive to consumers since health care markets vary dramatically between States, as do the most popular

plan design features in these States. These commenters also stated that having State-specific plan designs could help mitigate the degree of disruption to local markets and increase consumer uptake of standardized plan options. These commenters also requested clarification on how these standardized plan options would interact with State cost sharing laws.

Response: We designed two sets of standardized plan options to apply to different sets of States in order to more precisely tailor these plan designs to the unique market conditions in different States and to comply with the unique cost sharing laws in these different States. We also conducted extensive stakeholder engagement with more than 30 State departments of insurance to ensure that these plan designs comply with unique cost sharing laws. We also solicited comments on potentially relevant State cost sharing laws that could affect plan designs in the proposed rule. We also note that we intend to assess the feasibility and utility of designing State-specific standardized plan options to further mitigate the risk of disruption and to increase consumer uptake of these plans in future plan years.

Comment: Several commenters requested clarification regarding how these standardized plan options interact with State-mandated benefits.

Response: Nothing in the design of these standardized plan options supersedes the obligation to cover State-mandated benefits, as applicable. Similar to other benefits not included in these standardized plan options, issuers retain the ability to set the cost sharing parameters for these benefits, subject to State and Federal law.

Comment: Several commenters requested that HHS confirm that the standardized plan options finalized in this rule are compliant with MHPAEA and its implementing regulations.

Response: We affirm that the cost sharing parameters for these plan designs are designed so that issuers can design standardized plan options that are compliant with the MHPAEA and its implementing regulations. For example, copays for mental health or substance use disorder benefits in the outpatient, in-network office visit sub-classification in each plan design are equal to the least restrictive level for copays that apply to substantially all medical and surgical benefits in that sub-classification. Since standardized plan options do not include standardized treatment limitations on any of these benefits, issuers will be responsible for ensuring that the plan features they design outside of these standardized cost sharing parameters are compliant with MHPAEA and its implementing regulations.

Comment: Several commenters suggested that HHS incorporate VBID principles into future iterations of standardized plan options, explaining that doing so could further reduce barriers to necessary services and promote health equity among consumers. Similarly, many commenters supported including low deductibles and pre-deductible coverage for as many benefits as possible in plan designs, explaining that doing so would improve accessibility to important services. Some commenters requested that HHS modify the plan designs to include more pre-deductible coverage for particular benefits, including for preventive services beyond those mandated by Federal requirements, maternity care, laboratory and radiologic services, and some or all tiers of prescription drug coverage. Several commenters added that by improving the affordability of basic services that underserved populations typically lack access to, standardized plan options could also help address health disparities.

Response: We affirm that VBID principles were incorporated into these plan designs by exempting particular services from the deductible, decreasing barriers to access for particular services and prescriptions drug tiers, and having copays as the form of cost sharing instead of coinsurance rates for particular benefit categories. We also intend to explore the utility of incorporating additional VBID principles into future iterations of standardized plan options.

We attempted to exempt as many benefits as possible from the deductible while also maintaining the lowest deductible possible, designing a plan that has an AV within the permissible *de minimis* range of the metal level AVs, and ensuring the competitiveness of these plans' premiums by having AVs near the floor of these *de minimis* ranges. Given these constraints, we are not able to exempt other benefits, such as laboratory and radiologic services, from the deductible without also raising the deductible or increasing the AV and therefore the expected premiums of these plans. We are also unable to decrease the deductibles for these plans without offsetting the change to AV by subjecting additional benefits to the deductible or increasing these plans' AV or premiums.

Comment: Several commenters requested that HHS clarify the specific types of specialist visits that are exempt from the deductible in these standardized plan options and if there are any limits on the number of visits exempt from the deductible. One commenter requested that HHS clarify that deductible exemptions apply to the full range of pediatric preventive services, including those provided by a pediatric specialist.

Response: We clarify that we defer to issuers in how they classify which benefits belong to which benefit category, including how issuers classify ''specialist visits'' and therefore which specialist visits are exempt from the deductible per the cost sharing parameters in these plan designs. We also clarify that there are no visit limits for any of the benefit categories, including specialist visits, for any metal level in either of the two sets of standardized plan options finalized in this rule. We also reiterate that nothing in the design of these standardized plan options supersedes the obligation to cover certain benefits, such as the preventive services required under § 147.130, without cost sharing, even if such benefits would also fall into a category for which cost sharing is specified for the standardized plan option.

Comment: Several commenters recommended including separate medical and drug deductibles in the plan designs to allow those who rely on prescription drugs to manage a particular health condition to more quickly meet their drug deductible.

Response: We chose integrated medical and drug MOOPs and deductibles for these plan designs because this was the most popular plan design feature in the FFEs and SBE–FPs in PY 2021. Since the majority of enrollees have a plan with this design feature, and since we wish to minimize the risk of disruption, we included this feature in these standardized plan options. We also note that we intend to consider the utility of splitting medical and drug MOOPs and deductibles in future iterations of standardized plan options for future plan years.

Comment: Several commenters requested that HHS clarify how deductibles and cost sharing should be applied to the specific benefit categories included in the standardized plan options finalized in this rule.

Response: We clarify that in both sets of the standardized plan options above in Tables 12 and 13, if a cost sharing amount for a particular metal level is accompanied by a (*), this benefit category's cost sharing is exempt from the deductible.

Comment: Many commenters supported including copays instead of coinsurance for as many benefits as

possible. These commenters explained that coinsurance disproportionately burdens persons with chronic illness and disabilities and that by improving affordability for basic services that underserved populations typically lack access to, these plan designs would help address health disparities. Some commenters further explained that copays are more transparent than coinsurance and that copays make it easier to predict out-of-pocket costs.

Several commenters recommended applying copays to more benefit categories, including for the emergency room, hospital inpatient, imaging, and lab work benefit categories. Several other commenters recommended eliminating coinsurance from the plan designs altogether. Several other commenters expressed concern that copays were too high for certain services.

Response: We affirm that we applied copays instead of coinsurance rates for as many benefits as possible in order to enhance consumer certainty and decrease barriers that obstruct access to these services. We agree this design feature will play an important role in improving affordability and transparency for important services, and that this design feature will also address health disparities. That said, since we designed these standardized plan options to reflect the most popular design features of QHPs in the FFEs and SBE–FPs in PY 2021, and since the majority or plurality of consumers did not have copays for particular benefit categories (such as for hospital inpatient), we chose coinsurance rates for these particular benefit categories. For this reason, we are unable to eliminate coinsurance from the plan designs altogether. We also note that we are unable to decrease copays for certain services without concurrently offsetting these changes with increases to deductibles, MOOPs, or subjecting additional benefits to the deductible.

Comment: Many commenters supported including copays as opposed to coinsurance specifically for prescription drugs, including for the non-preferred and specialty tiers, explaining that doing so would alleviate the burden for persons with chronic illnesses and disabilities. Commenters who supported the use of copays rather than coinsurance for prescription drugs explained that high cost sharing on prescription drugs negatively affects medication adherence, leading to increased health care costs overall. Several commenters requested that HHS exempt all drugs from the deductible, lower copays for the different drug tiers, and cap all specialty drug copays at $150 (as was done in the second set of standardized plan options).

Conversely, some commenters were opposed to both incorporating copays instead of coinsurance for all tiers of prescription drugs as well as exempting non-preferred and specialty tier prescription drugs from the deductible. These commenters expressed concern that these plan design features would increase the risk of adverse selection and could therefore contribute to an increase in premiums that would undermine access to affordable health coverage. These commenters also explained that these plan designs are more generous than existing plan offerings, demonstrating that plan designs with these features are not sustainable within current market conditions. One commenter requested that HHS clarify whether the plan designs allow prescription drugs associated with preventive services to be covered with zero cost sharing.

Response: We agree that having copays for all prescription drug tiers (including the non-preferred brand and specialty tiers) will enhance predictability, increase medication adherence, and decrease overall health care costs. We note that we were unable to exempt all drugs from the deductible and lower the cost sharing for all tiers due to constraints with AV. Exempting additional tiers from the deductible and lowering the cost sharing amounts for these tiers would require subjecting other medical benefits to the deductible, increasing the cost sharing for other medical benefit categories, or increasing the AV, and therefore increasing the premiums of these plans. We also note that we decided not to apply the $150 copay cap to both sets of standardized plan options because only Delaware and Louisiana had State cost sharing laws that necessitated this design feature.

We understand that these design features may increase the risk of adverse selection, but we believe this risk is sufficiently mitigated by the fact that all FFE and SBE–FP issuers are required to offer these plans at every product network type, at every metal level, and throughout every service area they offer non-standardized plan options. Therefore, we believe this risk to be distributed evenly among issuers. Furthermore, we reiterate that we designed these plans to have AVs near the floor of the *de minimis* range for each AV metal level to ensure these plans' premiums are competitive.

HHS reiterates once more that nothing in the design of these standardized plan options supersedes the obligation to cover certain benefits, such as the preventive services required under § 147.130, without cost sharing, even if such benefits would also fall into a category for which cost sharing is specified for the standardized plan option. We clarify that these plan designs allow prescription drugs associated with preventive services to be covered with zero cost sharing.

Comment: Several commenters expressed concern with the plan design including only four tiers of prescription drug cost sharing, stating that this plan design feature would be difficult for issuers to implement and disruptive for consumers. These commenters explained that having six tiers of formulary cost sharing is becoming increasingly common among commercial issuers and that this design feature is permitted under Medicare Part D. These commenters therefore recommended that HHS include six tiers of prescription drug cost sharing in the plan designs to allow issuers the flexibility to develop formularies in a way that is most effective in promoting affordability. Conversely, several commenters supported including only four tiers of prescription drug cost sharing in the plan designs, explaining that doing so would offer more affordable, predictable, understandable prescription drug coverage.

Response: We agree that including only four tiers of prescription drug cost sharing in these plan designs offers more affordable, predictable, and understandable drug coverage, and that this design feature will play an important role in facilitating the consumer decision-making process by allowing consumers to more easily compare formularies between plans. That said, we intend to explore the feasibility and utility of including more than four tiers of prescription drug cost sharing in future iterations of standardized plan options in future plan years.

Comment: Several commenters requested that HHS clarify if standardized plan options are permitted to have more than one tier of provider networks.

Response: We clarify that we designed the standardized plan options finalized in this rule to have only one cost sharing tier such that no standardized plan option may have a tiered provider network. This approach aligns with the goals of simplifying the consumer decision-making process and making health insurance more understandable for consumers on the Exchanges. Furthermore, considering that the vast majority of plans offered through the Exchanges (nearly 90 percent) do not have tiered provider networks, we believe this plan design feature reflects

current market realities and minimizes the risk of disruption for both issuers and enrollees.

Comment: Several commenters requested that HHS include health savings account (HSA)-eligible HDHPs in these sets of standardized plan options.

Response: We have not included HSA-eligible HDHPs in these sets of standardized plan options because enrollees still have the opportunity to enroll in non-standardized HSA-eligible HDHPs, if they so desire.

Comment: Many commenters supported differentially displaying standardized plan options on *HealthCare.gov*. Most of these commenters also supported extending standardized plan options differential display requirements to web-brokers and issuers' direct enrollment websites. Citing the overwhelming number of plan offerings available for consumers, these commenters urged HHS to improve and simplify the shopping experience by allowing consumers to easily identify standardized plan options. Many of these commenters noted that differentially displaying standardized plan options assumes even greater importance if issuers are permitted to offer an unlimited number of non-standardized plan options. These commenters also noted that extending these display requirements to web-brokers' and issuers' direct enrollment websites would promote consistent messaging across platforms. Several commenters also explained that several State Exchanges have had success in differentially displaying standardized plan options and that HHS should draw from this experience.

In contrast, many commenters opposed differentially displaying standardized plan options, explaining that doing so could direct consumers to more expensive plans that may not be best suited for their needs. Several of these commenters urged HHS to give web-brokers and issuers that utilize alternative enrollment pathways—including Classic DE and EDE—flexibility in how to display standardized plan offerings to consumers utilizing their platforms due to concerns over technical and platform limitations.

Response: We agree that differentially displaying standardized plan options on *HealthCare.gov* and direct enrollment websites will improve and simplify the shopping experience by allowing consumers to more easily identify the standardized plan options. We also disagree that differentially displaying standardized plan options could direct consumers to more expensive plans that may not be best suited for their needs. We first note that we designed these standardized plan options to have AVs near the floor of the AV *de minimis* range for each metal level to ensure the competitiveness of these plans' premiums. We also note that we designed these plans to reflect the most popular plan design features throughout the FFEs and SBE–FPs in PY 2021 and we therefore do not believe these plans' premiums will differ significantly from the premiums of non-standardized plan options.

Further, since we are differentially and not preferentially displaying these standardized plan options, we believe that we can structure choice architecture in a way that allows consumers to meaningfully evaluate other non-standardized plan options and select these plans, if they so desire. A comment summary regarding specific recommendations for the differential display of standardized plan options is discussed in the Comment Solicitation on Choice Architecture and Preventing Choice Overload section later in this rule.

We also note that we will continue to provide web-brokers and issuers that utilize alternative enrollment pathways—including Classic DE and EDE—the ability to request to deviate from how standardized plan options are differentially displayed on *HealthCare.gov* due to concerns over technical and platform limitations. We will provide additional technical guidance on how to submit this request to deviate in the future.

Comment: Several commenters expressed concern about the timing of the implementation of these requirements. These commenters explained that complying with these requirements would impose a significant burden on issuers as they try to meet filing deadlines for PY 2023, with several commenters requesting that HHS delay the implementation of these requirements until the plan year 2024, if they are implemented at all.

Response: We are finalizing our proposal to require issuers to offer standardized plan options for PY 2023 and beyond, as proposed. We first announced in part 2 of the 2022 Payment Notice final rule (86 FR 24140, 24265) our intent to resume standardized plan options and to propose specific plan designs in the 2023 Payment Notice. We also sought comment on the best method to resume standardized plan options in part 3 of the 2022 Payment Notice proposed rule (86 FR 35156, 35162 through 25163). We then affirmed our intent to resume standardized plan options in PY 2023 and explained our rationale for doing so in part 3 of the 2022 Payment Notice final rule (86 FR 53412, 53419 through 23420). We believe these announcements provided ample notice of our intent to propose standardized plan option requirements in the 2023 Payment Notice proposed rule such that States, issuers, and other affected stakeholders should have sufficient time to prepare for compliance with the requirements we finalize in this rule.

Additionally, since the cost sharing parameters for the EHBs covered under these plans are already specified, issuers will be able to utilize existing networks and formularies they already utilize in connection with other plans in their portfolios, and since issuers are not required to offer standardized plan options at product network types, metal levels, or services areas in which they do not already offer non-standardized plan options, we do not anticipate that issuers will be unable to meet the filing deadlines.

11. Network Adequacy (§ 156.230)

We proposed to adopt FFE QHP certification standards that would ensure that QHP enrollees would have sufficient access to providers. HHS is of the view that strong network adequacy standards are necessary to achieve greater equity in health care and enhance consumer access to quality, affordable care through the Exchanges. We engaged and received feedback from numerous stakeholders representing diverse perspectives in developing the proposed policies. We are finalizing the following provisions as proposed, with two exceptions: (1) We are not finalizing the proposal on network tiering; (2) for appointment wait time standards, we are finalizing and delaying implementation until PY 2024. We are also finalizing the following updates to § 156.230: Substituting the phrase ''substance use disorder'' in place of ''substance abuse''; and retaining paragraph (f), which was deleted in error.

a. Background of Network Adequacy Standards

Section 1311(c)(1)(B) 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) and provide information to current and prospective enrollees on the availability of in-network and out-of-network providers. Federal network adequacy standards were first detailed in the Patient Protection and Affordable

Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers final rule (77 FR 18309) and codified at § 156.230. HHS seeks to ensure that quantitative, prospective network adequacy reviews occur for QHPs offered through the FFEs so that enrollees have reasonable, timely access to health care providers.

The FFEs conducted network adequacy reviews of time and distance standards for QHPs for PYs 2015–2017. The 2017 Market Stabilization final rule (82 FR 18346) deferred reviews of network adequacy for QHPs to States that HHS determined to have a sufficient network adequacy review process, an approach that was extended by the 2019 Payment Notice (83 FR 16930.) Specifically, CMS deferred to States that possessed sufficient authority to enforce standards that were at least equal to the reasonable access standard defined in § 156.230 and that had the means to assess the adequacy of plans' provider networks. For PYs 2018–2022, HHS determined that all States had sufficient legal authority and means to assess the adequacy of plans' provider networks. On March 4, 2021, as noted previously, the United States District Court for the District of Maryland decided *City of Columbus, et al.* v. *Cochran.*[313] One of the policies the court vacated was the 2019 Payment Notice's elimination of the Federal Government's reviews of the network adequacy of QHPs and plans seeking QHP certification to be offered through the FFEs.

As such, we announced in Parts 2 and 3 of the 2022 Payment Notice final rules (86 FR 24140; 86 FR 53412) our intent to undertake rulemaking to establish network adequacy standards, beginning in this rulemaking for PY 2023.

b. FFE Network Adequacy Reviews

In the 2023 Payment Notice proposed rule (87 FR 584), HHS proposed to evaluate the adequacy of provider networks of QHPs offered through the FFEs, or of plans seeking certification as FFE QHPs, except for FFEs in certain States beginning with the QHP certification cycle for PY 2023. HHS proposed not to evaluate QHP network adequacy in FFE States performing plan management functions that elect to perform their reviews of plans seeking QHP certification in their State, so long as the State applies and enforces quantitative network adequacy standards that are at least as stringent as the Federal network adequacy standards established for QHPs under § 156.230, and that network adequacy reviews are conducted before QHP certification. States performing plan management functions are States served by an FFE where the State has agreed to assume primary responsibility for reviewing issuer-submitted QHP certification material and making certification recommendations to HHS.

We are finalizing this policy as proposed.

We summarize and respond to public comments received on this proposal below.

Comment: Many commenters expressed strong support for HHS' proposal to conduct network adequacy reviews of the provider networks of QHPs offered through the FFEs. Key reasons for this support included ensuring consistency of network adequacy standards and reviews across States; providing a minimum set of network adequacy standards that States can meet or exceed; and addressing various issues related to consumer access.

Response: We concur that conducting robust network adequacy reviews of QHPs on the FFEs will have numerous benefits, including strengthening QHP enrollees' access to a variety of health care providers.

Comment: Some commenters stated that HHS should defer to States' reviews as they believe States are the most appropriate regulators of network adequacy. These commenters expressed that States understand and can tailor network adequacy reviews based on unique market conditions and that HHS network adequacy reviews could be duplicative and burdensome.

Response: We understand that some States, issuers, and other stakeholders believe that States are best positioned to regulate network adequacy. Given that States have unique knowledge and experience that are beneficial to assessing QHPs' provider networks, HHS will continue to partner with and learn from States as we conduct network adequacy reviews and pursue future network adequacy rulemaking. In recognition of this viewpoint, and as proposed, HHS will allow States performing plan management functions to choose to conduct their reviews, as long as they adhere to standards as stringent as HHS' standards and conduct prospective reviews. For all other FFEs, HHS will conduct network adequacy reviews to assure that QHP enrollees across States have reasonable access to a variety of health care providers to meet their needs.

Comment: Some commenters urged HHS to allow States performing plan management functions to conduct their network adequacy reviews if they have an approach that is ''comparable to'' Federal network adequacy standards, rather than ''as stringent as'' Federal standards.

Response: HHS believes it is important for States performing plan management functions to conduct network adequacy reviews that are at least as stringent as Federal reviews for two main reasons. First, HHS seeks to ensure QHP enrollees in all FFEs have a minimum standard of consumer protections regarding reasonable access to providers. We believe the Federal standards set a strong floor from which States performing plan management functions can implement even more robust standards if desired. If HHS were to allow States performing plan management to conduct network adequacy reviews that are comparable to Federal reviews, rather than as stringent, this could lead to reviews of a smaller provider specialty list or reviews that have less stringent parameters, for example. Second, whether a network adequacy review is ''comparable'' is a less concrete determination than whether it is ''as stringent.''

HHS is defining ''as stringent as'' to mean that the reviews include assessing compliance with time and distance standards and appointment wait time standards using the same specialty list and parameters. Time and distance reviews must be based on quantitative data collected from the issuer (not attestation) and supported by a justification requirement if an issuer does not meet one or more of the standards. We believe assessing quantitative data for time and distance reviews, rather than using qualitative measures, gives a fuller and more accurate picture of how a QHP assures reasonable access to providers. Assessing time and distance using quantitative data also allows us to make comparisons year-over-year and across issuers. We are codifying in § 156.230 that time and distance reviews must be based on quantitative issuer-submitted data.

Appointment wait time reviews, which will begin in PY 2024, must be based on methods as stringent as HHS' methods (as a minimum standard) and supported by a justification requirement if an issuer does not meet one or more of the standards. HHS will propose the method for assessing compliance with appointment wait time standards in future rulemaking. States can implement network adequacy standards and reviews that are more stringent than HHS' standards, described here. For example, we consider shorter time and distance or appointment wait time

[313] 523 F. Supp. 3d 731 (D. Md. 2021).

standards to be more stringent than longer ones.

We also acknowledge that State-specific challenges (for example, provider supply shortages, topographic barriers, etc.) may necessitate justification allowances, such as mitigating measures (for example, in-network cost sharing for out-of-network providers) that ensure access to a provider specialty type that would otherwise be unavailable to enrollees, while the States partner with issuers and providers to reach a more permanent solution. We believe the justification process for network adequacy will sufficiently accommodate such challenges and allowances.

Comment: Several commenters requested that HHS closely assess the network adequacy reviews of States performing plan management that elect to perform their reviews to ensure they review and enforce standards at least as stringent as HHS' standards.

Response: We will closely partner with these States to ensure they understand HHS' standards, that the States have adequate State authority to conduct such reviews, and that their reviews will appropriately assess network adequacy for QHPs in their State before plan confirmation to support timely QHP certification.

Comment: Some commenters expressed concern that the additional contracting required to achieve the new network adequacy standards could increase costs to consumers, while other commenters believe that the standards are unlikely to raise consumer costs.

Response: We acknowledge that commenters shared mixed feedback about whether the new network adequacy standards would raise consumer costs. We do not anticipate that the updated network adequacy requirements will substantially raise costs to consumers. We acknowledge that there may be some additional burden for QHP issuers and States to comply with the new network adequacy requirements. We will work to minimize the burden to the extent feasible by increasing transparency of the network adequacy review process, offering technical assistance resources and consultations, and collaborating with issuers and States to address questions and issues that arise during the PY 2023 network adequacy review process. We believe the benefits to consumer protection resulting from strengthened network adequacy standards strike a reasonable balance with the potential for increased issuer burden and cost, given the strategies described above that HHS will undertake to mitigate the burden.

Comment: Some commenters expressed concern regarding the implementation timeline for network adequacy reviews and requested that reviews be delayed until PY 2024 due to the time needed by issuers and States to prepare for the reviews and given the continued impacts of the COVID–19 pandemic on the health care system.

Response: We understand the desire expressed by some commenters to delay the implementation of network adequacy reviews given the time needed to collect information from providers on appointment wait times in the COVID–19 context. We acknowledge these concerns and, as discussed in the Appointment Wait Times section of this preamble, we will finalize the appointment wait time standards, but delay their implementation until PY 2024. We believe it is reasonable to implement the other finalized elements of the network adequacy proposal in PY 2023 for reasons described in the Time and Distance and Telehealth sections of this preamble.

Comment: Some commenters requested that HHS further align Federal network adequacy standards with the National Committee for Quality Assurance (NCQA) accreditation standards.

Response: We have reviewed the NCQA standards regarding network adequacy. We believe it is appropriate to align with NCQA in its use of business days to measure appointment wait time standards, which will be finalized in the final PY 2023 Letter to Issuers. We will also finalize that the appointment wait time standard for the behavioral health category will align with NCQA's standards; NCQA does not have quantitative parameters for the other categories we are finalizing for appointment wait times. NCQA does not currently have quantitative standards for time and distance so we cannot consider alignment.

Comment: One commenter requested HHS retain the provision in the network adequacy regulation text that clarifies that QHPs do not have to use provider networks.

Response: HHS will retain this provision that clarifies that QHPs do not have to use provider networks. In the proposed rule, the deletion was an error, and we appreciate the commenter bringing it to our attention.

c. FFE Network Adequacy Standards Beginning With PY 2023

i. Network Adequacy Standards Applicable to Plans That Use a Provider Network

Section 1311(c)(1)(B) of the ACA directs HHS to establish criteria for the certification of the health plan as QHPs, which includes the requirement that QHPs must ''ensure a sufficient choice of providers.'' HHS codified QHP network adequacy requirements under § 156.230(a)(2). In the 2012 Exchange final rule (77 FR 18309), we established the minimum network adequacy criteria that health and dental plans must meet to be certified as QHPs at § 156.230. This regulation provided that an issuer of a QHP that uses a provider network must maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorder services, to assure that all services will be accessible to enrollees without unreasonable delay. In the 2016 Payment Notice final rule (80 FR 10749), we modified § 156.230(a) in part to specify that network adequacy requirements only apply to QHPs that use a provider network and that a provider network includes only providers that are contracted as in-network.

In section c, parts ii, ii, and iv of this preamble, we proposed to refine the FFE's QHP certification standards regarding the adequacy of plans' provider networks by imposing time and distance standards, appointment wait time standards, and standards related to tiered networks.

ii. Time and Distance Standards

For the certification cycle for PYs beginning in 2023, HHS proposed to adopt for QHPs offered through the FFEs time and distance standards that HHS would use to assess whether FFE QHPs (or QHP candidates) fulfill network adequacy standards applicable to plans that use provider networks.

The proposed provider specialty lists for time and distance standards for PY 2023 were informed by prior HHS network adequacy requirements, consultation with stakeholders, and other Federal and State health care programs, such as Medicare Advantage and Medicaid. The provider specialty lists cover more provider types than previously evaluated under FFE standards so that QHP networks will be more robust, comprehensive, and responsive to QHP enrollees' needs. The proposed provider specialty lists are generally consistent with standards used to evaluate Medicare Advantage plans. For brevity purposes, when discussing provider types for network adequacy, we will use the term ''behavioral health'' to encompass mental health and substance use disorders.

HHS proposed reviewing additional specialties for time and distance,

beyond those included by Medicare Advantage, that are necessary to meet the health care needs of QHP enrollees since Medicare Advantage and the FFEs serve different populations. The additional specialties proposed are emergency medicine, outpatient clinical behavioral health, pediatric primary care, and urgent care.

HHS proposed that time and distance standards be calculated at the county level and vary by county designation. We would use a county type designation method that is based upon the population size and density parameters of individual counties, in alignment with Medicare Advantage. The time and distance standards would apply to the provider specialty lists contained in Tables 14 and 15. To count towards meeting the time and distance standards, individual and facility providers listed in Tables 14 and 15 must be appropriately licensed, accredited, or certified to provide services in their State, as applicable, and must have in-person services available.

TABLE 14: Individual Provider Specialty List for Time and Distance Standards

Individual Provider Specialty Types
Allergy and Immunology
Cardiology
Cardiothoracic Surgery
Chiropractor
Dental
Dermatology
Emergency Medicine
Endocrinology
ENT/Otolaryngology
Gastroenterology
General Surgery
Gynecology, OB/GYN
Infectious Diseases
Nephrology
Neurology
Neurosurgery
Occupational Therapy
Oncology – Medical, Surgical
Oncology – Radiation
Ophthalmology
Orthopedic Surgery
Outpatient Clinical Behavioral Health (Licensed, accredited, or certified professionals)
Physical Medicine and Rehabilitation
Physical Therapy
Plastic Surgery
Podiatry
Primary Care – Adult
Primary Care – Pediatric
Psychiatry
Pulmonology
Rheumatology
Speech Therapy
Urology
Vascular Surgery

TABLE 15: Facility Specialty List for Time and Distance Standards

Facility Specialty Types
Acute Inpatient Hospitals (Must have Emergency services available 24/7)
Cardiac Catheterization Services
Cardiac Surgery Program
Critical Care Services - Intensive Care Units (ICU)
Diagnostic Radiology (Free-standing; hospital outpatient; ambulatory health facilities with Diagnostic Radiology)
Inpatient or Residential Behavioral Health Facility Services
Mammography
Outpatient Infusion/Chemotherapy
Skilled Nursing Facilities
Surgical Services (Outpatient or ASC)
Urgent Care

The county-specific time and distance parameters that plans would be required to meet would be detailed in future guidance. These parameters would be informed by industry standards.

Issuers that are unable to meet the specified standards would be able to submit a justification to account for variances. HHS proposed to review such justifications to determine whether the variance(s) is/are reasonable based on circumstances, such as the local availability of providers and variables reflected in local patterns of care, and whether offering the plan through the FFE would be in the interest of qualified individuals and employers. We proposed to codify the network adequacy justification process in regulation at § 156.230(a)(2)(ii).

HHS sought comment on this proposal, including on the specific parameters for time and distance standards, and flexibilities that may be needed in rural areas when there are provider or plan shortages. In particular, HHS sought comment on the parameters that should apply with respect to behavioral health providers to ensure adequate access to these services. HHS also sought comment on the specialty list to which time and distance standards would apply and whether HHS should establish time and distance standards for additional specialties in future PYs.

We are finalizing this policy as proposed.

We summarize and respond to public comments received on this policy below.

Comment: Many commenters, across a range of stakeholder types, supported the proposed quantitative time and distance standards. Key reasons for this support included appreciation for instituting a quantitative assessment of consumer access; concurrence with the inclusion of a variety of individual and facility provider types, including QHP-specific additions to the Medicare Advantage provider specialty list; and varying time and distance standards by county type since provider availability can be influenced by local population density.

Response: HHS agrees that stringent quantitative time and distance standards for the expanded provider specialty lists that vary by county designation will help strengthen QHP enrollees' access to a variety of providers to meet their health care needs.

Comment: There was mixed feedback on the inclusion of emergency medicine physicians: Some commenters stated that the addition would be duplicative of required facility types and No Surprises Act protections, while others agreed with HHS' contention that including emergency medicine physicians would provide proactive consumer protections and increase enrollee access to in-network providers.

Response: HHS understands that some stakeholders have differing opinions about the inclusion of emergency medicine physicians on the provider specialty list for time and distance reviews. We believe that the anticipated benefits to consumer access and protections outweigh the concerns about duplication, and we will include emergency medicine physicians as proposed.

Comment: Numerous commenters requested that HHS consider additional provider specialties (for example, anesthesiologists, audiologists, and providers offering gender-affirming care, among others) for inclusion in future time and distance standards.

Many commenters specifically requested additions to or refinement of the Outpatient Clinical Behavioral Health category, such as separate categories for mental health and substance use disorder services, and delineating between pediatric and adult behavioral health providers. Some commenters requested refining certain provider specialty types, including allowing OB/GYNs to count as primary care providers; aligning OB/GYN parameters with the parameters for specialists rather than for primary care; considering how safety-net family planning and sexual health services are delivered by a range of non-OB/GYN providers; dividing requirements for oncology providers into separate categories for medical and surgical oncology; allowing mid-level practitioners to count as specialty care providers for time and distance standards; and allowing family medicine physicians to count towards pediatric primary care.

Response: HHS is finalizing the individual and facility provider specialty lists for time and distance as proposed. We believe the current specialty list builds on and strengthens the specialty list that HHS used for assessing time and distance when we previously did so in PYs 2015–2017, which will help increase access to a variety of provider types and strengthen consumer protections. HHS appreciates the feedback suggesting additions to and refinement of the provider specialty list for time and distance standards. Prior to considering the adoption of these suggestions in future rulemaking, HHS will need to conduct further assessment and research as they may also have unintended consequences.

We appreciate the suggestion from commenters that OB/GYNs count towards time and distance standards for primary care providers. We believe there could be potential unintended consequences if we were to allow OB/GYNs to count as primary care providers for time and distance standards. For example, since OB/GYNs most commonly care for female patients, including OB/GYNs as primary care providers for time and distance standards could hamper access to

primary care for male patients. We will further assess this suggestion and its potential implications and will consider this for future rulemaking.

For PY 2023, while we will not have separate adult and pediatric standards for Outpatient Clinical Behavioral Health, we have unique specialty codes in the Essential Community Provider/Network Adequacy (ECP/NA) template that distinguish the two age categories (adult and pediatric) for some behavioral health specialty types, allowing for data collection and analysis, and consideration of further refinement in the future.

Though we do not have a time and distance standard specifically for gender-affirming care and surgery providers, the provider specialty list does include many providers who offer services that may be useful for individuals seeking gender-affirming care, like endocrinologists, urologists, and behavioral health clinicians.

Comment: Some commenters expressed concerns that Federal time and distance standards cannot adequately account for geographic variations, like provider supply and population density. One commenter expressed concerns that many issuers in their state might fail the new standards, that the network adequacy standards could disincentivize new issuers from entering the market, and that counties would be left without available Exchange health insurance options. Several commenters shared suggestions for less stringent time and distance reviews, like broader qualitative standards, or separate time and distance standards for rural areas, geographies with provider shortages, and narrower networks.

Response: We understand that some stakeholders have concerns about HHS assessing QHPs for compliance with quantitative time and distance standards. We believe that quantitative time and distance standards, when varied by county type, provide a useful assessment of whether QHPs provide reasonable access to care, and when combined with appointment wait time standards, will offer a more comprehensive evaluation of the adequacy of QHPs' networks. HHS believes that less stringent time and distance standards (like qualitative standards or separate standards for rural areas, geographies with provider shortages, and narrower networks) would not sufficiently assure reasonable access to providers.

Where QHPs cannot comply with these standards due to provider shortages and other factors that affect issuers of given service areas similarly (like topographic challenges, such as a lake in the middle of a county), issuers can include such explanations in their justifications. HHS will take such considerations into account in determining whether the justification is sufficient to satisfy this QHP certification standard.

HHS is aware of the potential risks related to implementing time and distance standards, such as standards being too stringent, not accounting for geographic variations, and leading to fewer QHPs. We believe these risks can be managed with increased transparency, updates to network adequacy QHP application documents, and coordination and partnership with States and issuers. We have made several changes to increase transparency, which we anticipate will make it easier for issuers to understand and comply with network adequacy standards. The ECP/NA template will include the Taxonomy Codes tab that shows which taxonomy codes crosswalk into which individual provider and facility specialty types. The Instructions and FAQs will provide more detail on the network adequacy review process and what issuers need to submit to HHS to demonstrate satisfaction of network adequacy standards. The Network Adequacy Justification Form is a streamlined tool that will enable issuers to show HHS how they are making progress toward compliance with network adequacy standards. Coordination with States will allow for a two-way exchange of information so HHS can better understand local patterns of care and how they may relate to Federal network adequacy standards. This information helps us give issuers as much credit for their networks as possible.

Comment: Other commenters expressed that due to the differences between QHPs and Medicare Advantage plans—in terms of consumers, provider reimbursements, and contracting dynamics—network adequacy standards applying to Medicare Advantage plans may not be appropriate to apply to QHPs.

Response: HHS acknowledges that QHPs and Medicare Advantage plans serve different enrollee populations. HHS has tailored the provider specialty list accordingly to better align with the provider access needs of QHP enrollees. HHS has added the following provider specialties for time and distance: Emergency medicine, outpatient clinical behavioral health, pediatric primary care, and urgent care. Details on why each of these specialties was added are included in the proposed rule (87 FR 584, 681). When HHS conducted Federal network adequacy reviews during PYs 2015–2017, our time and distance standards for network adequacy were also foundationally based on Medicare Advantage standards. Based on that prior experience, our research on network adequacy standards, and the public comments received on this rule supporting this approach, we believe it is reasonable to resume using time and distance network adequacy standards that are based on Medicare Advantage standards.

Comment: Some commenters expressed that time and distance metrics are not appropriate for SADPs and that a network breadth measure might be more appropriate. However, while some commenters noted that time and distance standards are not appropriate for SADPs, most commenters supported the inclusion of dental providers.

Response: Based on prior rates of SADPs' compliance with time and distance standards and our assessment of the availability of dental providers against the time and distance parameters finalized in the 2023 Letter to Issuers, HHS anticipates most SADPs and medical QHPs with embedded dental benefits will be able to meet the standards for dental providers. If a plan is still working to come into compliance with network adequacy standards, they will be able to use the justification process as needed. Consequently, as proposed, HHS will include dental as a specialty for which compliance with time and distance standards is assessed.

Comment: Several commenters stated that facility-based providers, such as physical, occupational, speech, and behavioral health therapists, should not be included in the individual provider specialty list for time and distance since some issuers may contract at the facility level for those services.

Response: For rehabilitation and behavioral health therapists, we understand that some issuers contract at the facility level rather than with individual providers. We have decided to include these providers on the individual provider list because many of these providers offer services in varied locations and may not be contracted with a single facility.

Comment: Several commenters made requests related to the justification process for issuers that do not meet network adequacy standards, including requests for greater clarity on the process; requested that HHS adopt a justification process that mirrors Medicare Advantage's approach to justifications; and requested that HHS ensure that justifications are not used in

lieu of issuers contracting with additional providers.

Response: Issuers with network adequacy deficiencies will receive a partially pre-populated Network Adequacy Justification Form via the Plan Management (PM) Community and will need to submit the completed form to the PM Community by the required deadline. The justification process will require issuers that do not yet meet network adequacy standards detail: The reasons that one or more standards were not met; the mitigating measures the issuer is taking to ensure enrollee access to respective provider specialty types; information regarding enrollee complaints regarding network adequacy; and the issuer's efforts to recruit additional providers. HHS will use any updated provider data submitted on its ECP/NA template and the completed Network Adequacy Justification Form submitted as part of the certification process to assess whether the issuer meets the regulatory requirement, prior to making the certification decision.

HHS reviewed the Medicare Advantage exception process and made the QHP network adequacy justification process align where it made sense to do so. HHS has made some distinctions, like using a partially pre-populated Excel form with information on all needed corrections, rather than issuers having to complete a separate justification request for each county/specialty/network combination for which deficiencies are required. The justification process for QHP network adequacy is designed to help an issuer demonstrate its progress toward greater compliance with the standards. HHS will partner with issuers and States to ensure that the justification process is not used in place of contracting with additional providers.

Comment: Some commenters also requested that HHS clarify what provider and facility types count towards certain provider specialty categories, including dental providers and urgent care. Several commenters requested greater transparency regarding how compliance with time and distance standards would be calculated.

Response: In response to requests for additional clarity, further details on which provider specialty types count towards each time and distance category; and how compliance with time and distance standards are calculated, such information will be made available through materials such as the QHP Application Instructions, the ECP/NA template, Frequently Asked Questions and the final PY 2023 Letter to Issuers.

Comment: Several commenters expressed concern about county type designations. They requested that HHS develop parameters for updating county type designations; requested that HHS ensure that county type designations can accurately reflect counties with both rural and metropolitan areas; and encouraged HHS to monitor the functionality of county type designations across various types of States, to ensure meaningful provider availability.

Some commenters shared other suggestions regarding potential additions to time and distance standards, including requiring issuers to contract with all ECPs in the service area when provider shortages prevent the issuer from meeting time and distance standards. A commenter also suggested HHS consider possible interventions like provider incentives or transportation programs to assist areas experiencing provider shortages. One commenter requested that HHS systematically test network adequacy data submission and require issuers to provide additional information, like out-of-network claims data, to enhance HHS' understanding of how consumers are experiencing QHP networks in practice.

Response: HHS thanks commenters for their feedback regarding county type designations and possible additions to the time and distance requirements. HHS will need to further research these suggestions and their implications before considering them for future rulemaking.

Comment: A commenter encouraged HHS to require issuers to make telehealth psychiatry services available when Advanced Practice Registered Nurses (APRNs) are counted towards the Outpatient Clinical Behavioral Health category regardless of whether they are psychiatric APRNs.

Response: In the ECP/NA template, HHS will detail which taxonomy codes will crosswalk into each individual provider and facility specialty type. For Outpatient Clinical Behavioral Health, only psychiatric APRNs would count towards this provider type; other APRNs are not included.

iii. Appointment Wait Times

For the certification cycle for PYs beginning in 2023, HHS proposed to adopt appointment wait time standards to assess whether QHPs offered through the FFEs fulfill network adequacy standards applicable to plans that use a provider network. We proposed a short list of critical service categories for which appointment wait time standards would be assessed. The proposed provider specialty list for appointment wait time standards for PY 2023 is included below and is informed by prior Federal network adequacy requirements and consultation with stakeholders, including issuers and other Federal and State health care programs, such as Medicare Advantage and Medicaid.

HHS proposed that the appointment wait time standards would apply to medical QHPs. For stand-alone dental plans (SADPs), only the dental provider specialty within the Specialty Care (Non-Urgent) category of appointment wait time standards would apply. To count towards meeting appointment wait time standards, providers listed in Table 16 must be appropriately licensed, accredited, or certified to practice in their State, as applicable, and must have in-person services available.

TABLE 16: Final Provider Specialty List for Appointment Wait Time Standards

Provider/Facility Type
Behavioral Health
Primary Care (Routine)
Specialty Care (Non-Urgent)

The specific appointment wait time parameters that plans would be required to meet, including specifications for individual provider and facility types, would be detailed in future guidance. These parameters would be informed by industry standards. Issuers applying for FFE QHP certification would need to attest that they meet these standards as part of the certification process. HHS proposed to conduct post-certification reviews to monitor compliance with these standards. These compliance reviews would occur in response to access to care complaints or through random sampling.

Similar to the proposed justification process for time and distance standards, issuers that are unable to meet the appointment wait time standards would be able to submit a justification to account for variances. HHS would review such justifications to determine whether the variance(s) is/are reasonable based on circumstances, such as the local availability of providers and variables reflected in local patterns of care, and whether offering the plan through the FFE would be in the interest of qualified individuals and employers. We proposed to codify the network adequacy justification process in regulation at § 156.230.

HHS sought comment on this proposal, including on the specialty list to which appointment wait time standards would apply, specific parameters for appointment wait time standards, and other ideas to strengthen network adequacy policy in future years, such as provider-enrollee ratios, provider demographics, and accessibility of services and facilities. We also sought comment on possible methods to collect and analyze claims data to inform future network adequacy standards and other aspects of QHP certification that impact health equity.

We are finalizing this policy as proposed and delaying the implementation of network adequacy reviews for appointment wait time standards until PY 2024.

We summarize and respond to public comments received on this policy below.

Comment: Many commenters from a variety of stakeholders supported the proposal to institute appointment wait time standards to assess the adequacy of provider networks. Other commenters suggested additions to and refinement of the list of categories for appointment wait time standards. Some commenters requested that the Primary Care (Routine) category apply to routine dental services, such as cleanings. Several commenters requested that HHS create separate appointment wait time standards for different levels of urgency, such as routine, urgent, and emergent, as well as discharge follow-up. One commenter requested that HHS apply appointment wait time standards to all individual providers and facility types. Other commenters suggested separate appointment wait time categories for substance use disorder treatment services, oncology specialties, urgent care, family planning providers, and sexual health care providers. One commenter encouraged HHS to partner with patient groups to further refine appointment wait time standards.

Response: HHS agrees that implementing quantitative appointment wait time standards for network adequacy has multiple benefits, including helping ensure that QHP enrollees have timely access to care. We appreciate the feedback suggesting additions to and refinement of the list of categories for appointment wait time standards. HHS may pursue additional strategies to evaluate the appropriateness of appointment wait time standards for a variety of provider types. HHS also may engage with consumer groups on this topic as suggested in public comment for future policymaking. HHS will further assess these suggestions and consider them for future rulemaking.

Comment: Many commenters encouraged HHS to conduct additional oversight of provider networks throughout the year (outside of QHP certification), using strategies such as direct testing and monitoring of appointment wait times, to ensure enrollees have reasonable access to providers. One commenter requested that HHS consider providing funding for one entity in each State to conduct ongoing monitoring of appointment wait times.

Response: HHS is investigating approaches to monitor network adequacy outside of the QHP certification process. We appreciate commenters' suggestions on possible methods for additional oversight and will assess further prior to future rulemaking.

Comment: Some commenters suggested that appointment wait time standards be calculated using business days instead of calendar days to align with NCQA standards, some State network adequacy standards, and common business practices.

Response: Draft parameters for appointment wait time standards were detailed in the draft PY 2023 Letter to Issuers.[314] HHS agrees that aligning appointment standards with NCQA and some State network adequacy standards by using business days instead of calendar days will help minimize the burden and is reasonable given that many providers operate using business days. This change will be finalized in the final PY 2023 Letter to Issuers.

Comment: Some commenters opposed the implementation of the proposed appointment wait time standards, stating that the standards may be too dynamic, non-standardized, and beyond the control of issuers (and sometimes providers, particularly given the context of the COVID–19 pandemic). Some commenters expressed concern that the data collection required for the appointment wait time standards would be burdensome for issuers and providers, and they suggested possibly delaying the implementation of such standards to PY 2024 or beyond.

Response: HHS acknowledges that some stakeholders have concerns about the appointment wait time standards and the timeline for their implementation, including that appointment wait time requirements are not standardized, can be challenging for issuers to improve, and that data collection would be too burdensome. In recognition of those concerns, we have made several accommodations to the implementation of this new provision to ease the transition to this new standard. As noted above, HHS is finalizing appointment wait time standards, but delaying their implementation until PY 2024. HHS will also align the appointment wait time standards with appointment wait time standards used by NCQA and some States by using business days instead of calendar days.

Regarding concerns that appointment wait time requirements are not standardized, specific draft parameters for appointment wait times are described in the draft PY 2023 Letter to Issuers [315] and will be finalized in the final PY 2023 Letter to Issuers. The ECP/NA template [316] shows which provider types crosswalk into which appointment wait time categories. We believe that the appointment wait time parameters are reasonable based on

[314] *2023 Letter to Issuers in the Federally-facilitated Exchanges.* CMS. (2022, January 7). *https://www.cms.gov/files/document/2023-draft-letter-issuers-508.pdf.*

[315] *2023 Letter to Issuers in the Federally-facilitated Exchanges.* CMS. (2022, January 7). *https://www.cms.gov/files/document/2023-draft-letter-issuers-508.pdf.*

[316] Draft ECP/NA template: *Essential Community Providers and Network Adequacy.* CMS. *https://www.qhpcertification.cms.gov/s/ECP%20and%20Network%20Adequacy.*

existing industry standards, such as those from NCQA and some States.

Issuers that do not yet meet the appointment wait time standards, once implemented in PY 2024, can use the justification process to update HHS on the progress of their contracting efforts for the respective plan year. HHS will review such justifications to determine whether the variance(s) described is/are reasonable based on circumstances, such as the local availability of providers and variables reflected in local patterns of care, and whether offering the plan through the FFE would be in the interest of qualified individuals and employers. HHS understands that some issuers may not already collect appointment wait time data, which is one of the reasons we are delaying the implementation of this requirement until PY 2024. Issuers that are unable to meet the specified standards would be able to submit a justification to account for variances.

Comment: Some commenters requested that SADPs either be exempt from compliance with appointment wait time standards or held to a lower compliance threshold than the threshold to which medical QHPs are held.

Response: We appreciate the feedback suggesting that SADPs be exempt from appointment wait time standards or held to a lower compliance threshold. We do not agree that SADPs should be exempt from compliance with appointment wait time standards or have a lower threshold applied than for medical QHPs. HHS believes it is important that timely access to care is ensured, regardless of plan type. Additionally, medical QHPs that have embedded dental benefits will be held to the same appointment wait standards for dental providers as SADPs. The compliance threshold is detailed in the draft PY 2023 Letter to Issuers [317] and will be finalized in the final PY 2023 Letter to Issuers.

Comment: One commenter requested that HHS consider removing the requirement that providers have in-person services available to count towards these standards since some behavioral health providers only offer services via telehealth.

Response: We are aware that some providers only offer services via telehealth. We acknowledge the growing importance of telehealth, and we want to ensure that telehealth services do not displace the availability of in-person care. Consequently, we are finalizing that, to count towards the standards, providers must have in-person services available. Providers that do not have in-person services available will not be counted when assessing appointment wait times.

Comment: A commenter requested that appointment wait time standards should be overridden by provider assessment of when it would be appropriate for the enrollee to access care.

Response: We appreciate the suggestion that appointment wait time standards should be overridden by provider assessment of when it would be appropriate for the enrollee to access care. We will further assess this idea prior to considering it for future rulemaking.

Comment: A commenter requested that HHS allow issuers the opportunity to conduct outreach to providers and reassess appointment wait time measurement when they are not meeting the appointment wait time standards before any enforcement action would occur.

Response: We acknowledge the commenter's concern that issuers might be subject to enforcement action for not meeting appointment wait time standards without having the opportunity to come into compliance. HHS will work in partnership with issuers who are not yet meeting network adequacy standards and support their efforts to come into compliance as part of issuer compliance monitoring and workplans.

Comment: Some commenters requested more clarity, such as what provider types are included in the behavioral health category for appointment wait time standards, and how appointment wait time standards apply to dental providers. Commenters also inquired as to whether the standards apply to appointments for existing patients, new patients, or both. Some commenters requested additional insight regarding methodological ambiguities related to the appointment wait time standards, including what period of time the standards will be based on, how the parameters of appointment wait time are defined, how to account for seasonality, and how to best validate this data.

Response: The provider types that filter into the Behavioral Health category for appointment wait time standards will be detailed in the Taxonomy Codes tab of the ECP/NA template.[318] For clarification on how appointment wait time standards apply to dental providers, all dental providers—general dentists and specialists—would be included in the Specialty Care category. Appointment wait time standards apply to both new and existing patients. In response to all other requests for additional clarity on the appointment wait time standards, including information on methodology, we will provide further information in the QHP Application Instructions, the ECP/NA template, Frequently Asked Questions, and the final PY 2023 Letter to Issuers.

In the proposed rule, HHS solicited comments on other ideas to strengthen network adequacy policy in future years and other aspects of QHP certification that impact health equity.

Comment: Several commenters suggested other ideas to strengthen and expand network adequacy policy in future years. Many commenters shared requests related to access to providers with certain competencies, skills, or specializations. Several commenters requested HHS consider standards that ensure a network provides an adequate supply of culturally and linguistically competent providers, and they requested that HHS have QHPs collect and display languages spoken by providers and their staff. Some commenters requested that HHS require that QHPs ensure access to providers who serve enrollees with rare, complex, or chronic health conditions, and providers who are culturally competent to serve LGBTQ+ individuals.

We received several comments requesting that we consider a requirement for QHPs to track the number of providers accepting new patients throughout the year, and one request to have QHPs collect information on provider hours of operation. Some commenters requested that HHS collect and share data on provider demographics and report provider accessibility by public transit.

Some commenters suggested provider-enrollee ratios as an additional network adequacy standard to consider for future rulemaking. Several commenters were in favor of HHS developing unique standards for pediatric specialty providers and implementing enrollee ratios by specialty, geographic accessibility, and population density. Some commenters also requested that HHS define minimum appropriate provider standards to meet the needs of children with special health care needs as well as of diverse cultural, ethnic, and

[317] *2023 Letter to Issuers in the Federally-facilitated Exchanges.* CMS. (2022, January 7). *https://www.cms.gov/files/document/2023-draft-letter-issuers-508.pdf.*

[318] Draft ECP/NA template: *Essential Community Providers and Network Adequacy.* CMS. *https://www.qhpcertification.cms.gov/s/ECP%20and%20Network%20Adequacy.*

linguistic backgrounds. One commenter suggested HHS consider requiring issuers to report on the number of psychiatric providers and outpatient clinical behavioral health providers who have billed for services within a certain timeframe. Other commenters requested HHS measure the availability of integrated behavioral health in primary care.

Commenters encouraged the consideration of requiring issuers to report data by race and ethnicity on the population living in geographic areas that do not have access to providers within travel time and distance standards. Another commenter requested that HHS include auxiliary aids and services for people with disabilities, as well as data on the accessibility of all providers and facilities, in future network adequacy standards. One commenter requested that quality rating system measures be tied to network adequacy standards. Another commenter requested that provider non-discrimination policies be included in future rulemaking.

Response: HHS appreciates the suggestions on potential ways to enhance and grow network adequacy standards in the future. We will further assess these ideas prior to considering them for future rulemaking.

Comment: HHS also received numerous comments regarding suggestions for future rulemaking related to consumer protections. Many commenters requested further clarity on how QHPs can ensure enrollees can access care when not available in-network for their specific needs, which would include covering out-of-network providers at in-network cost sharing rates if a qualified provider is not available within the network or at the lowest cost-sharing tier. Some commenters also requested a clear complaint process for enrollees to report network adequacy issues. HHS received a comment requesting that QHP issuers be required to pay for interpretation services and auxiliary aids for contracted providers. Another commenter requested that HHS detail the actions that are taken when QHPs fail to meet network adequacy standards. Some comments received requested HHS consider the implications of MHPAEA on network adequacy standards.

Response: HHS appreciates the suggestions on potential ways to strengthen consumer protection through enhanced network adequacy standards in the future. We will further assess these ideas prior to considering them for future rulemaking.

Comment: HHS received some suggestions related to provider availability, such as requirements for issuers to provide reasonable notice of terminations of a provider's in-network status and allowing the ability for enrollees to change plans when provider availability in a network changes significantly.

Response: We acknowledge the suggestions related to provider availability, such as requirements for the issuer to provide reasonable notice of provider terminations. These recommendations also implicate provisions enacted in sections 113 and 116 of the No Surprises Act.[319] These provisions of No Surprises Act establish continuity of care protections [320] in instances when terminations of certain contractual relationships result in changes in provider or facility network status and establish standards intended to protect participants, beneficiaries, and enrollees, such as a protocol for responding to requests about a provider's network participation status. HHS, along with the Departments of Labor and the Treasury, intends to issue future rulemaking or guidance to further implement those provisions, and will take these comments into account in developing such materials.

Comment: Some commenters shared feedback regarding the network breadth pilot, including both concern and support. HHS received some comments expressing that the network breadth pilot should not be continued in its current State. One commenter shared that the network breadth pilot is made more useful to consumers by using the actual percent participation value, prohibiting issuers from marketing plans based on the breadth categories, and allowing issuers to submit network adequacy data on machine-readable files. Some comments suggested that the network breadth methodology and labels be clarified as they can be confusing to consumers. HHS received one comment asking that the methodology be modified so that providers are not excluded based on taxonomies in the National Plan & Provider Enumeration System (NPPES) and that special types of PCPs are more appropriately documented. Some comments expressed support for the continuation of the network breadth pilot with its current labels.

Response: Although these comments were not within the scope of HHS' proposals on network adequacy presented in the proposed rule, HHS appreciates the comments received regarding the network breadth pilot. We will consider the above suggestions for future rulemaking after further assessment.

iv. Tiered Networks

HHS proposed that, for plans that use tiered networks, to count toward the issuer's satisfaction of the network adequacy standards, providers must be contracted within the network tier that results in the lowest cost -sharing obligation. For example, a QHP issuer cannot use providers contracted with their PPO network when certifying a plan using their HMO network, if the use of PPO network providers would result in higher cost-sharing obligations for the HMO plan enrollees. 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 would be counted towards network adequacy standards. We proposed to codify the network tiering requirement for network adequacy in regulation at § 156.230.

Network adequacy standards are tailored to ensure QHP enrollees have reasonable access to a sufficient number and type of providers to meet their health care needs. HHS is aware of instances in which issuers have attempted to satisfy QHP certification requirements related to networks, such as ECP standards, using providers that would require enrollees to pay higher cost sharing. We sought to ensure that QHP enrollees have access to networks with sufficient numbers and types of providers without the imposition of a higher cost-sharing requirement.

After considering commenter concerns that the policy could unduly restrict plan network designs and innovation, we have decided not to finalize this policy. While we continue to believe this proposal has potential consumer protection benefits and would promote greater cost-sharing affordability, further research is warranted to evaluate the potential

[319] The Consolidated Appropriations Act, 2021 (CAA) was enacted on December 27, 2020 and includes Title I (No Surprises Act) in Division BB.

[320] Section 9818 of the Code, section 718 of ERISA, and sections 2799A–3 and 2799B–8 of the PHS Act, as added by section 113 of division BB of the Consolidated Appropriations Act, 2021 (CAA) establish continuity of care protections in instances when terminations of certain contractual relationships result in changes in provider or facility network status. The Departments of HHS, Labor and Treasury have announced that until rulemaking is completed to fully implement these provisions, plans, issuers, providers, and facilities are expected to implement the requirements using a good faith, reasonable interpretation of the statute. See FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49, *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf.*

benefits and drawbacks of requiring providers to be contracted within the network tier that results in the lowest cost-sharing obligation in order for those providers to be counted towards satisfaction of the network adequacy standards.

We summarize and respond to public comments received on this policy below.

Comment: HHS received numerous comments in support of the proposal that for plans that use tiered networks, to count towards network adequacy standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. However, several commenters broadly opposed or cautioned against the lowest cost-sharing tier requirement, citing concerns that it would restrict the success of network innovation strategies, such as value-based steering and contracting arrangements, or encourage issuers to remove the lowest cost-sharing tier entirely.

Response: We agree with commenters who supported the proposal as we concur that the proposal could help ensure that network adequacy standards provide reasonable access to care and help enhance health equity by enabling enrollees to access care at the lowest cost-sharing rate. Notwithstanding, we understand commenters' concerns that finalization of this policy could inadvertently restrict innovation and the issuers' ability to design and implement plan networks across all Exchange plans, which may result in decreased cost sharing for enrollees and decreases in overall health care costs. While we believe this proposal has potential benefits to consumer protection and affordability for cost sharing, we believe further research on the potential benefits and drawbacks is warranted prior to finalizing such a proposal.

Comment: One commenter suggested that a lower-cost virtual primary care option should not be considered a ''lowest tier.''

Response: While we are not finalizing this proposal regarding network tiering, we will consider this suggestion for future rulemaking.

Comment: Another commenter expressed that the network tiering requirement would not be appropriate for SADPs as tiered networks are uncommon for this plan type.

Response: We acknowledge that network tiers may be less common among SADPs. While we are not finalizing this proposal, we do not agree that any future network tiering requirements should not apply to SADPs—they simply would not be relevant for the particular QHPs (medical or SADPs) that do not use network tiers.

v. Telehealth Services

HHS proposed to require all issuers seeking certification of plans to be offered as QHPs through the FFEs to submit information about whether network providers offer telehealth services. HHS proposed that this requirement would be applicable beginning with the QHP certification cycle for PY 2023. We believe this information could be relevant to HHS' analysis of whether a QHP meets network adequacy standards. For PY 2023, this data would be for informational purposes; it would be intended to help inform the future development of telehealth standards and would not be displayed to consumers. Issuers should not construe this proposal to mean that telehealth services could be counted in place of in-person service access for the purpose of network adequacy standards.

HHS sought comment on this proposal, including comments on how HHS might incorporate telehealth availability into network adequacy standards in future PYs. We specifically sought comment on whether HHS should consider aligning the FFE network adequacy standards with Medicare Advantage's telehealth approach in which issuers are offered a credit for meeting time and distance standards.

We are finalizing this policy as proposed.

We summarize and respond to public comments received on this policy below.

Comment: Commenters expressed widespread support regarding the proposal to require issuers to identify which of their in-network providers offer telehealth services. Commenters also suggested additional telehealth information to consider collecting, like the availability of tele-mental health services and audio-only services, as well as tracking prescription digital therapeutics.

Response: HHS appreciates the comments received in support of the requirement for QHPs to report whether their in-network providers offer telehealth services. We agree that this data collection will be relevant to HHS' analysis of whether a QHP meets network adequacy standards and will help inform the future development of telehealth standards. We appreciate the suggestions regarding additional telehealth-related information that HHS could collect and will consider this for future rulemaking.

Comment: Some commenters requested that HHS either not require issuers to report telehealth service availability or delay the implementation of this requirement. These commenters expressed concern that collecting and reporting telehealth capability would be overly burdensome for issuers and premature given the evolving nature of telehealth. One commenter suggested that telehealth data collection be delayed until a Federal database of provider telehealth availability is created. Several commenters requested that HHS minimize the burden related to telehealth data collection as much as possible, including one who suggested that State-level efforts might be able to be repurposed to gather this information. Some commenters stated that telehealth data collection and reporting is not appropriate for SADPs since telehealth is a newer modality for dental providers and the data collection and reporting may not lead to helpful insights at this time. One commenter suggested that HHS should incentivize QHPs to increase telehealth availability among their contracted providers as a benefit design rather than through network adequacy requirements.

Response: We understand some commenters are concerned about the implementation of telehealth data collection, including the timeline, due to the increased burden for issuers and that telehealth services are still evolving. HHS acknowledges that some commenters believe telehealth data collection is not appropriate for SADPs at this time due to the newness of tele-dentistry. We recognize that some QHPs may not have data available on whether their contracted providers offer telehealth and that for those QHPs, this data collection may result in an increased burden. Simultaneously, we understand that some QHPs may already have this information available through sources like provider surveys or claims data. While telehealth services continue to evolve for many specialties, including dental providers, we believe that collecting telehealth availability data at this point in time will provide key insights that can influence future policy development, and that these benefits outweigh the associated potential burden for some QHPs. We will work to minimize the burden where possible, like by providing technical assistance to issuers and allowing issuers flexibility with what methods they use to collect telehealth data.

Comment: Many commenters expressed that more research is needed to understand whether and how to count telehealth providers towards network adequacy standards. Numerous

commenters identified additional considerations for incorporating telehealth into network adequacy standards, such as inequities for rural and low-income providers, health plan location, broadband access, and variation in types and requirements of telehealth between providers and States. These commenters also emphasized that the appropriateness of telehealth should be a decision made between the patient and provider and that telehealth should not expand at the expense of available in-person care.

Several commenters shared suggestions with HHS regarding possible additional requirements related to telehealth services. Some commenters requested that we consider offering a telehealth credit for network adequacy standards, similar to Medicare Advantage. Some commenters stated telehealth standards and policies should ensure access to culturally, linguistically competent providers who can serve consumers with disabilities and should also increase access in low-income and geographically remote regions. One commenter encouraged HHS to adopt a separate national network adequacy standard for telehealth providers. Some commenters requested that HHS ensure telehealth information is reported promptly and that telehealth information is included in provider directories. One commenter suggested that HHS consider requiring QHPs to contract with telehealth services in areas where there are shortages of in-person providers.

Response: We concur with the recommendations from commenters that more research is needed before HHS could consider incorporating the availability of telehealth services into network adequacy policy for QHPs, such as a telehealth credit like Medicare Advantage. We also agree that telehealth services should be made available in addition to, rather than instead of, in-person care. HHS appreciates the suggestions received regarding additional requirements for telehealth services and other telehealth-related information that HHS could collect from QHPs. We will consider this information for future rulemaking. We thank commenters for their ideas about other ways to collect telehealth data, like a partnership with States, through a Federal database on telehealth or encouraging telehealth services through other means. We will consider these ideas for future rulemaking.

vi. Solicitation of Comments—Unintended Impacts of Stronger Network Adequacy Standards

HHS is of the view that the network adequacy standards we included in the proposed rule are reasonable, necessary, and appropriate to ensure that QHPs enrollees have the access to the in-network providers the ACA requires. We acknowledge, however, that there is some risk that stronger network adequacy standards could be leveraged to create an uneven playing field in network agreement negotiations that could result in higher health care costs for consumers. We are also interested in exploring rules and policies that would promote competition, taking into consideration the interests of issuers, providers, and consumers by limiting the potential that network adequacy standards may be used by parties to network agreements as leverage to obtain more favorable contract terms, leading to higher health care costs for consumers.

We sought comment on ways that HHS could help stem the use of all-or-nothing contracts that may drive up health care costs for consumers; how issuers can use provider networks to drive costs down; and what impact all-or-nothing contracting has on enrollees, plans, providers, and the market.

We summarize and respond to the comments received below.

Comment: Numerous commenters expressed diverse viewpoints regarding potential unintended impacts of stronger network adequacy standards. Several commenters expressed their belief that stronger network adequacy standards would not impact contracting negotiations between issuers and providers. Two commenters shared concerns that the proposed network adequacy standards could disproportionately harm smaller QHP issuers and reduce market competition. A commenter expressed apprehension that appointment wait time standards could be codified in provider contracting agreements and particularly harm providers that are in highest demand. Another commenter stated that the stronger network adequacy standards could help mitigate declining provider reimbursement rates. One commenter encouraged consideration of a requirement for issuers to offer at least one QHP Statewide for each metal level at which they offer coverage to mitigate the risk of network adequacy standards disincentivizing QHP issuers from offering plans in rural counties. HHS received another comment asking us to consider potential cost implications of including specialized cancer providers in network adequacy requirements.

Some commenters requested that HHS not enact prohibitions against all-or-nothing contract clauses or steerage prohibitions, sharing concerns that such policies could limit enrollee access to providers. Another commenter encouraged HHS to consider regulation to eliminate all-or-nothing contract clauses, while a separate commenter expressed that they did not anticipate prohibition of all-or-nothing contract clauses would sufficiently protect plans from unintended consequences of network adequacy standards. One commenter suggested that any future regulation regarding restrictions on contracting terms should only be applied to provider types that would benefit from the network adequacy standards. One commenter shared that they had experienced regional struggles with all-or-nothing contract clauses in the context of QHPs and offered a further discussion on what they learned.

Response: HHS understands that stakeholders have a variety of opinions regarding the impact of stronger network adequacy standards, as well as all-or-nothing contracting clauses. We appreciate the feedback received and will consider it in future rulemaking.

vii. Solicitation of Comments—Network Adequacy in State Exchanges

HHS is interested in learning more about network adequacy in States with State Exchanges. HHS understands that State Exchanges have a mix of network adequacy policies in place, and that about 75 percent of those States have at least one quantitative standard for time and distance, appointment wait times, or both. While the new proposed network adequacy standards for QHP issuers in FFEs differ from those in State Exchanges, HHS was not inclined to propose additional regulations that specifically target network adequacy reviews for QHP issuers in State Exchanges, and we are not inclined to propose regulating network adequacy for State Exchanges at this time. However, we considered whether there is a need for greater alignment in FFE and State Exchange network adequacy standards.

HHS sought comment on whether a more coordinated, national approach to network adequacy rules across all Exchanges that is suited to address contemporary conditions in the health care markets is needed. For example, we sought comment on whether in future PYs, HHS should consider imposing network adequacy rules in FFEs and State Exchanges that would be intended to increase the standardization of

network adequacy across the Exchanges. Moreover, we sought comment on specific measures to support such standardization to ensure that all Exchange enrollees can access the benefits and services under their plans as required by the ACA. We further sought comments that identify specific gaps in provider accessibility that exist under disparate State Exchange network adequacy standards that might be addressed through greater Federal regulation of network adequacy standards across all Exchanges.

We summarize and respond to the comments received below.

Comment: Commenters had mixed feedback on whether HHS should regulate network adequacy for all Exchanges, including setting standards and conducting reviews for QHPs in State Exchanges. Many commenters requested that regulators of State Exchanges be allowed to continue using their network adequacy standards and conducting their reviews. Some commenters suggested that HHS direct State network adequacy reviews, rather than conducting separate Federal reviews, to avoid duplication since some States have mandates to review network adequacy. Some commenters emphasized the importance of having only one applicable set of network adequacy standards per State. One commenter suggested that Federal network adequacy standards are not needed, as they stated was evidenced by high consumer satisfaction and consumer selection of narrow network plans. Many commenters requested that HHS extend Federal network adequacy standards to State Exchanges in future rulemaking. Several commenters suggested that State alignment with Federal standards would be ideal, and that Federal standards should offer a strong floor that all States must meet.

Response: We appreciate the comments received and understand that there are diverse opinions regarding the appropriate regulator for network adequacy standards in State Exchanges. HHS will monitor existing network adequacy standards in State Exchanges relative to the Federal standards finalized in this rule and will consider whether application to State Exchanges in future PYs is warranted.

12. Essential Community Providers (§ 156.235)

Essential community providers (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 ECP categories include family planning providers, Indian health care providers, Federally Qualified Health Centers, hospitals, Ryan White providers, and other ECP providers. QHP issuers must include a sufficient number and geographic distribution of ECPs in their networks, where available. Section 156.235 establishes the requirements for the inclusion of ECPs in QHP provider networks and provides an alternate standard for issuers that provide a majority of their covered professional services through physicians employed directly by the issuer or a single contracted medical group.

In assessing the appropriate PY 2023 ECP standard for medical QHP and SADP QHP certification, HHS has considered multiple options for strengthening our ECP policy. After careful consideration, HHS proposed the approaches described below. States performing plan management functions in the FFEs would be permitted to use a similar approach.

Section 156.235(a)(2)(i) provides that a plan has a sufficient number and geographic distribution of ECPs if it demonstrates, among other criteria, that the network includes as participating practitioners at least a minimum percentage, as specified by HHS, of available ECPs in the plan's service area. HHS proposed that for PY 2023 and beyond, the required ECP provider participation standard be raised from 20 percent to 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 would consider a plan to have satisfied the regulatory standard if the issuer contracts with at least 35 percent of available ECPs in each plan's service area to participate in the plan's provider network, in addition to satisfying the contract offering requirements described in § 156.235(a)(2)(ii) that require a plan to offer a contract 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 to all available Indian health care providers in the plan's service area. The calculation methodology outlined in the 2018 Letter to Issuers in the Federally-facilitated Marketplaces and 2018 Payment Notice would remain unchanged for issuers offering plans with a provider network.

In developing this proposal, HHS considered that when the ECP threshold was 30 percent in PYs 2015–2017, all QHP issuers satisfied the 30 percent threshold with minimal reliance on ECP write-ins and justifications. HHS anticipates that any QHP issuers falling short of the 35 percent threshold for PY 2023 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 describing how the issuer's provider networks, as presently constituted, provides an adequate level of service for low-income and medically underserved individuals and how the issuer plans to increase ECP participation in the issuer's provider network(s) in future years. At a minimum, such justification must include the number of contracts offered to ECPs for PY 2023, the number of additional contracts an issuer expects to offer and the timeframe of those planned negotiations, the names of the specific ECPs to which the issuer has offered contracts that are still pending, and contingency plans for how the issuer's provider network, as currently designed, will provide adequate care to enrollees who might otherwise be cared for by relevant ECP types that are missing from the issuer's provider network.

HHS also proposed that, for plans that use tiered networks, to count toward the issuer's satisfaction of the ECP standard, ECPs must be contracted within the network tier that results in the lowest cost sharing obligation. For example, a QHP issuer cannot use the number of ECPs contracted with their PPO network when certifying a plan using their HMO network if the use of PPO network providers would result in higher cost sharing obligations for HMO plan enrollees. 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 the preferred network would be counted towards ECP standards. We proposed to codify the network tiering requirement for satisfying the ECP standard in regulation at § 156.235.

Additionally, for PY 2023 and beyond, HHS proposed that issuers could comply with the requirement at § 156.235(a)(2)(ii)(B) to offer contracts to at least one ECP in the category of ''other ECP providers'' by offering a contract to a Substance Use Disorder Treatment Center. These facilities are critical to HHS' efforts to ensure that low-income, medically underserved individuals have sufficient access to this EHB. We also considered making non-substantive revisions to § 156.235, which requires QHPs to offer contracts to at least one ECP in each of the ECP categories, to improve readability and

clarity, and to more closely reflect how Exchanges may operationalize this requirement. For example, the regulation text presently does not include language that specifically identifies which providers may fit the category of 'Other ECP Providers.' We solicited comments on whether clarifying revisions are necessary and on how best to clarify this requirement in the regulation text.

In addition to these proposed changes, HHS sought comment on whether and how QHP issuers should increase the use of telehealth services as part of their contingency planning to ensure access to adequate care for enrollees who might otherwise be cared for by relevant ECP types that may be missing from the issuer's provider network. We also sought comment on if we should consider adding newly Medicare-certified Rural Emergency Hospitals to our Hospitals ECP category.

These proposed changes are consistent with the directive from E.O. 13985. HHS anticipates positive health equity impact as we believe these changes will increase access to quality, relevant health care for low-income and medically underserved individuals. HHS sought comment on these proposals, including from ECPs and issuers serving low-income and medically underserved populations. HHS also sought comment on ideas for further strengthening ECP policy.

After reviewing the public comments, we are finalizing all provisions as proposed. Additionally, in response to comments we solicited on whether and how to clarify the ''Other ECP Providers'' requirement, we have amended the regulatory text at § 156.235(a)(2)(ii)(B) to clearly define the ''Other ECP Providers'' category, as follows:

At least one ECP in each of the six (6) 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, and Other ECP Providers. The Other ECP Providers category includes the following types of providers: 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.

We summarize and respond to public comments received on essential community providers (§ 156.235) below.

Comment: The majority of commenters supported increasing the required ECP participation standard from 20 percent to 35 percent of available ECPs in the plan's service area that are included within the applicable plan year HHS ECP list, citing expanded access to health care for vulnerable populations and improved health equity. Several of these commenters indicated that HHS should require QHPs to demonstrate that they can meet the 35 percent participation threshold in all ECP categories, or in specific categories such as Substance Use Disorder Treatment Centers, Ryan White providers, hospitals, and each subcategory of ''Other ECP Providers''; while other commenters suggested that HHS implement an ''any willing provider'' standard.

Response: We are finalizing the required ECP participation standard at 35 percent as proposed. Many commenters, including providers, provider associations, and consumer advocacy groups, supported the proposal to raise the ECP participation standard from 20 percent to 35 percent. In response to suggestions that HHS require QHPs to contract with 35 percent of the ECPs as applied to each of the specific categories of ECPs, HHS continues to require QHPs to contract with at least one ECP within each of the six ECP categories in each county in the issuer's service area and believes the current approach better ensures geographic distribution of such ECPs in each of the six ECP categories across the issuer's service area than applying the 35 percent threshold to each of the six ECP categories would achieve. Regarding commenters' recommendations that HHS apply a 35 percent threshold standard to each of the six ECP categories and/or implement an ''any willing provider'' standard, HHS recognizes that issuer network participation negotiations are a tool that issuers use to manage costs, which are generally reflected in lower premium rates. Reducing issuers' ability to limit the scope of their networks could eliminate that cost management tool and potentially cause premiums to increase substantially; therefore, we do not support these recommendations at this time.

Comment: While agreeing with the proposed increase to 35 percent, numerous commenters cautioned against a one-size-fits-all approach to ensure there are enough ECPs in all networks. Some commenters stated that a fixed percentage for all QHPs may not be sufficient to achieve the desired goal due to geographic areas varying in demographic composition, including the difficulty of meeting the 35 percent participation standard in rural areas. Some commenters stated that this standard could deter issuers from entering service areas with few ECPs.

Response: In response to concerns raised about potential difficulties meeting the increased standard in rural areas and other geographic areas that vary in demographic composition that can lead to the presence of few ECPs, section 1311(c)(1)(C) of the Affordable Care Act requires that a QHP's network include ECPs, *where available,* that serve predominantly low income and medically-underserved populations. We reflect this in our regulations by permitting issuers that cannot meet the contracting standards to satisfy the QHP certification standard by submitting a justification. Therefore, the standard does not penalize issuers that cannot meet the ECP standard because of a lack of certain types of ECPs within a service area.

Comment: Several commenters opposed the increase of the required ECP provider participation standard from 20 percent to 35 percent of available ECPs in the plan's service area included within the applicable plan year HHS ECP list. These commenters expressed concern about the increased administrative burden and cost that the raised threshold would place on issuers and providers. A few commenters pointed out unintended negative consequences that could arise from the increased standard, including price increases for consumers. Some commenters recommended delaying any threshold increase until the 2024 plan year or implementing a more moderate increase for the 2023 plan year, from 20 to 25 percent, to account for this increased burden.

Response: Regarding commenters' concerns about the increase of the ECP threshold to 35 percent, we do not anticipate the majority of issuers having difficulty meeting the increased standard. For the plan year 2021, the percentage of medical and dental FFE issuers that could have satisfied a 35 percent ECP threshold was 80 percent and 74 percent, respectively; while the mean and median ECP contracting percentage across all FFE issuers was 55 percent and 54 percent, respectively. Given that during the 2015–2017 plan years, all issuers satisfied the 30 percent standard when permitted to supplement their QHP applications with ECP write-ins and justifications, CMS anticipates that any issuers falling shy of the 35 percent threshold for the 2023 plan year could satisfy the standard by relying on these same methods of compliance. Given issuers' success with meeting the

30 percent standard in previous plan years, HHS believes that the 35 percent standard will provide both issuers and providers with sufficient flexibility to negotiate contract terms that do not lead to increased prices for consumers. Accordingly, as we do not anticipate that compliance with this increased threshold will be too large a burden for issuers to meet for plan year 2023, we decline to delay implementation.

Comment: The majority of commenters supported the proposal to require QHPs with tiered networks to meet the ECP threshold in the lowest cost-sharing tier. One commenter noted that plans' preferred tiers often have providers that agree to accept more favorable rates and provide additional services such as coordinating care. The commenter stated that such plans should not be placed at a disadvantage for placing ECPs on a second general tier with providers that do not offer additional services.

Response: We are finalizing this provision as proposed. We intend to monitor consumer complaints regarding any potential disadvantages that could result from this requirement; however, we anticipate the benefit of the lowest cost-sharing tier requirement for low-income, medically underserved consumers, such as ensuring that these consumers can access an ECP provider offering essential health benefits through more affordable cost-sharing, to outweigh any disadvantages incurred by plans due to their choice of tiering structure.

Comment: In response to HHS' solicitation for comments on clarifying which providers may fit the category of ''Other ECP Providers'' in the regulatory text, two commenters recommended that HHS define the ECP category of ''Other ECP Providers'' in the regulatory text. Numerous commenters supported the addition of ''Substance Use Disorder Treatment Centers'' to the ''Other ECP Providers'' ECP category, including provider associations and advocacy groups. One commenter opposed the addition of Substance Use Disorder Treatment Centers to the ''Other ECP Providers'' ECP category, citing variability in the quality, oversight and services provided at such centers; another commenter noted HHS should explore how it will define ''substance use treatment centers'' and allow stakeholders additional time to comment prior to adding to the ''Other ECP Providers'' ECP category.

Response: In response to these comments recommending that we clarify the meaning of the ECP category of ''Other ECP Providers,'' we are amending § 156.235(a)(2)(ii)(B), as referenced in the preamble. The provider types that we have included in the ECP category of ''Other ECP Providers'' reflect, for the most part, those that have been listed within this ECP category in the Letter to Issuers in previous years and with whom many issuers have already been including in their provider networks. The only new provider type that we are adding to this ECP category of ''Other ECP Providers'' is Substance Use Disorder Treatment Centers. We are adding Substance Use Disorder Treatment Centers to the ECP category of ''Other ECP Providers'' as proposed. HHS will rely on the Substance Use Treatment Locator (*https://findtreatment.gov/*) made available by the Substance Abuse and Mental Health Services Administration (SAMHSA) to identify such treatment centers providing quality care to the consumers that they serve. This addition of Substance Use Disorder Treatment Centers effectively gives issuers an additional provider type by which they can satisfy the contract offering requirement for the ECP category of ''Other ECP Providers'' in each county in their service area. In some counties or service areas, depending on which types of ECPs are available, HHS acknowledges that this addition could decrease the chance that an issuer would choose to contract with another provider type grouped under the ''Other ECP Providers'' ECP category, but it is our opinion that adding this new category outweighs that potential effect because it is critically important to ensure access to SUD treatment to all consumers who require such treatment. Additionally, we note that issuers may increase access to a variety of providers by contracting with more than one available ECP per ECP category, including ''Other ECP Providers,'' in each county in their service area if they choose to do so.

Comment: Several commenters suggested that we disaggregate hemophilia treatment centers and behavioral health providers from the ''Other ECP Providers'' category and create new ECP categories for freestanding birth centers and for providers that are essential to specialized cancers such as brain tumors.

Response: In previous years, we have considered such recommendations to disaggregate provider types included in the ''Other ECP Providers'' ECP category and creating a separate ECP category for each, in addition to creating a separate ECP category for freestanding birth centers; however, because our analysis of the available ECPs in each of these ECP subcategories continues to indicate that there are too few ECPs within each of these provider types appearing on our ECP list to afford issuers sufficient flexibility in their contracting, we will not be disaggregating these subcategories of providers or creating new ECP categories at this time. While we may revisit this consideration in the future, we encourage QHP issuers to include in their networks these additional providers to best meet the needs of the populations they serve.

Comment: Two commenters recommended that HHS should improve the overall accuracy of the HHS ECP List.

Response: HHS has recently launched a monthly provider outreach initiative that automatically notifies providers on the HHS ECP List that they should revisit the online ECP petition to verify the accuracy of their data if they have not refreshed their provider data in over 12 months. Additionally, HHS has recently programmed additional validation checks within its online ECP petition to better ensure that only qualified providers can petition for inclusion on the HHS ECP List. Furthermore, HHS, through its operating divisions HRSA, SAMHSA, and along with other entities, continues to verify the operating status and qualifications of providers for inclusion on the HHS ECP List to help ensure that the number and types of providers to which issuers are held to contracting to satisfy the ECP standard reflect an accurate universe of qualified ECPs that are available within the issuer's respective service area.

Comment: One commenter suggested that HHS should require QHPs to comply with ECP standards throughout the coverage year and report any material change in their ECP contracts to ensure that at no time their network falls below the ECP participation standard. Several commenters suggested HRSA's HIV/AIDS Bureau monitor and enforce contracting requirements for Ryan White HIV/AIDS Program Providers.

Response: We appreciate commenters' suggestions on how to better monitor issuers' compliance with the ECP standard throughout the plan year and will consider different methods of enforcing compliance with the ECP standard in future plan years.

Comment: One commenter suggested that HHS include regulatory language specifying that good faith contract terms must include all of the services the plan covers and that the provider offers and include reimbursement at generally applicable payment rates; another suggested that HHS require QHPs to contract with ECPs at a reimbursement level no lower than the established rate

at which they are compensated under Medicaid or Medicare to ensure that ECPs have a financial incentive to participate. Another commenter requested that HHS include in guidance that health systems contract with ECPs separately.

Response: Comments on good faith contract terms and reimbursement rates are out of the scope of this rule. However, we expect issuers to comply with existing regulatory provisions [321] and sub-regulatory guidance [322] that may apply to these topics.

Comment: One commenter recommended that HHS eliminate QHP issuers' option to submit a narrative justification that describes why they could not meet the standard but still have a network that is sufficient to meet the needs of low-income and underserved enrollees.

Response: We appreciate the commenter's recommendation to eliminate the option for issuers to submit a narrative justification to satisfy the ECP standard. More information on changes to the ECP justification process for the plan year 2023, including the format of the justification and how and where it will be submitted, will be made available through forthcoming materials, including the QHP Application Instructions, the ECP/NA template, the ECP Tools, Frequently Asked Questions, and the Final Plan Year 2023 Letter to Issuers.

Comment: Several commenters recommended that HHS should include information on which ECPs have telemedicine services available on the HHS ECP List. One State expressed support for ECPs offering telehealth services because consumers seeking care in their first language could benefit from telehealth services provided by ECPs. Several commenters urged that HHS monitor the use of telehealth services to ensure that they do not undermine access to care protections. Commenters cautioned that allowing issuers to meet the ECP participation standard with telehealth services in lieu of in-person care could improve health care access in some areas while jeopardizing care quality and exacerbating health inequities in other areas.

Response: We appreciate commenters' recommendations for integrating telehealth services into the ECP list. We acknowledge concerns that telehealth should not be used as a substitute for in-person care. We will consider these recommendations for adding telehealth services information to the ECP list in future rulemaking.

13. Standards for Downstream and Delegated Entities (§ 156.340)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 686), we proposed to amend and add language to § 156.340 to extend the existing downstream and delegated standards to QHP issuers on all Exchange models, including State Exchanges and State Exchange SHOPs, and Exchange models that use the Federal platform, including, FFEs, SBE–FPs, FF–SHOPs. We proposed to add a requirement that all agreements between QHP issuers and their downstream and delegated entities include language stating that the relevant Exchange authority, including State Exchanges, may demand and receive the downstream or delegated entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period. We refer readers to the proposed rule for a more detailed discussion of the proposal and its supporting rationale (87 FR 686 through 687).

After reviewing the public comments, and based on the rationale provided in the proposed rule and in this rule, we are finalizing the amendments to § 156.340, as proposed, to clarify and strengthen requirements holding QHP issuers in all models of Exchange responsible for their downstream and delegated entities' adherence to applicable Federal standards related to Exchanges, and to make their oversight obligations, and the obligations of their downstream and delegated entities, explicit in regulation and in the QHP issuers' agreements with their downstream and delegated entities. We are also finalizing the proposal to amend the title of subpart D of 45 CFR part 156 from ''Standards for Qualified Health Plan Issuers on Federally-facilitated Exchanges and State-based Exchanges on the Federal platform'' to ''Standards for Qualified Health Plan Issuers on Specific Types of Exchanges.''

We summarize and respond to public comments received on standards for QHP issuer downstream and delegated entities (§ 156.340).

Comment: The commenters expressed support for the proposed amendments to § 156.340 and lauded its clarification and its strengthening of oversight standards for QHP issuers toward their downstream and delegated entities with regard to relevant Exchange regulations. One commenter stated that they supported the changes proposed because they clarify that QHP issuers and their downstream and delegated entities remain responsible for complying with all Federal requirements, including QHP certification standards, Exchange processes and procedures, the maintenance of records, and enrollment rules for agents, brokers, and web-brokers. Another commenter stated the increased requirements for QHP issuers to hold their downstream and delegated entities accountable, including the increased record-keeping requirements, are essential to hold QHP issuers accountable for meeting applicable federally-defined performance standards and without that accountability, issuers could evade those standards by delegating duties to other entities which could avoid accountability by ''neither maintaining records, nor reporting data showing compliance''.

Response: We appreciate the support for the proposed amendments to § 156.340 and the accompanying clarification of the standards applicable to QHP issuers and their downstream and delegated entities in all Exchange models. These comments articulate the reasons behind the decision to make the amendments and clarifications to the 156.340. Moreover, these supportive commenters describe the scenario the changes are intended to prevent or mitigate: Evasion by issuers of applicable Exchange requirements by the delegation of duties to entities otherwise capable of avoiding accountability. By codifying a regulatory requirement that holds QHP issuers in all Exchange models responsible for compliance with Exchange requirements by their downstream and delegated entities, the appropriate Exchange authority can ensure compliance with applicable requirements and hold issuers accountable for their actions and the actions of their downstream and delegated entities in situations of non-compliance.

Comment: Several commenters were not supportive of the proposal and objected to the language as it pertains to the record retention requirement in the new paragraph (b)(5) as overly broad. These commenters expressed concern that the proposed new record retention requirement in § 156.340(b)(5) appeared to give HHS access to ''virtually all data and information,'' including consumer data maintained by the downstream and delegated entities, and that it would

[321] 45 CFR 156.235(d) and (e).

[322] 2018 Letter to Issuers in the Federally-facilitated Marketplaces (2017, February 17). CMS. *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2018-Letter-to-Issuers-in-the-Federally-facilitated-marketplaces-and-February-17-Addendum.pdf.*

enable HHS to go on a ''fishing expedition'' for information unrelated to Exchange activity. One commenter suggested the proposed requirement in new paragraph (b)(5) would place ''undue burden'' on downstream and delegated entities and also echoed the perception that it provides HHS with ''unyielding authority'' to request information from them, but did not otherwise quantify or further define these concerns. Some commenters also requested additional guidance about the types of information downstream and delegated entities would have to provide, and generally requested modification of the regulatory language in new paragraph (b)(5) to be more specific and limited in scope. Several commenters made general requests that the documents and systems to which the relevant authority may request access pursuant to the downstream and delegated entity's Exchange activities be limited without providing examples. One commenter requested an exception to permit downstream and delegated entities to challenge requests that would be ''commercially impracticable.'' The commenter also requested the language in paragraph (b)(5) be limited to requests and information that are of such vital importance to Exchange operations that the Exchange could not operate without the disclosure. The commenter did not include data or information to support these assertions, describe what constituted ''commercially impracticable'' requests, or provide examples of what would constitute an instance that might be of such vital importance to Exchange operations.

Response: We respectfully disagree with the comments suggesting the language required in Exchange agreements between QHP issuers and downstream and delegated entities by new paragraph (b)(5) expands HHS' authority to demand information, making it unlimited in scope and imposing new risk and undue burden on both QHP issuers and their downstream and delegated entities. The amendments to § 156.340(b)(5) make clear and explicit in regulation downstream and delegated entity obligations to maintain Exchange-related records and comply with the relevant Exchange authority's demand to receive the entity's books, contracts, computers or other electronic systems relating to the QHP issuer's obligations in accordance with applicable Federal Exchange standards. Because the provision applies to all types of Exchange, including State Exchanges, HHS is not inclined to be overly prescriptive with regard to provision of more specific guidance. More descriptive details will be provided by the relevant Exchange authority. With regard to information that could be requested by HHS, as administrator of the FFE, more specificity is provided in § 156.715, which describes the records and information requested of FFE and SBE–FP issuers during compliance reviews. By way of a further illustrative example, documents that are typically requested as part of compliance reviews under § 156.715 include, but are not limited to; issuers' contracts with all downstream and delegated entities for Exchange-specific language, records of agent and broker registration and training, and records of the handling of complaints concerning affiliated agents, brokers, and web-brokers. While we generally anticipate requesting similar information from downstream and delegated entities under § 156.340(b)(5), we emphasize that the exact information, data, records, books, contracts, computers, and electronic systems that could be requested as part of a review under § 156.340(b)(5) will vary depending on the facts and circumstances at hand. We also affirm that, like the existing authority in § 156.340(b)(4), the authority captured in § 156.340(b)(5) is specific to Exchange operations.

We also disagree that the record retention requirement in new paragraph (b)(5) is overly broad or that it would allow HHS to request or access information unrelated to Exchange activity. This regulatory provision is narrowly drafted and codifies the relevant Exchange authority's—that is, the State Exchange, the FFE, or the SBE–FP—right to access records that are related to the QHP issuer's participation in the relevant Exchange to confirm compliance with applicable Federal Exchange standards. As such, under § 156.340(b)(5), the relevant Exchange authority can demand and receive information on consumers enrolled in the Exchange from a downstream or delegated entity of a QHP issuer participating on its Exchange to ensure or otherwise confirm compliance with applicable Federal Exchange standards. Additionally, HHS has authority to access the records of downstream and delegated entities of QHP issuers participating in FFEs and Exchanges using the Federal platform under the existing requirements in § 156.340(b)(4).[323] Affirming HHS' authority to access this information, as the relevant Exchange authority for FFEs, while codifying similar rights for State Exchanges when they are the relevant Exchange authority, in new paragraph (b)(5) does not represent an expansion of HHS authority or access to records. To that end, by affirming the relevant Exchange authority's right to access information for purposes of ensuring all entities participating in or supporting another entity's participation in the Exchange are compliant with applicable Federal Exchange standards, HHS declines to incorporate language in the regulation that would limit this authority to situations concerning issues of vital importance to the Exchange. We did not propose such a limitation and further note that the establishment of such a restriction would require further notice with comment rulemaking to define the phrase and identify parameters for what could constitute issuers of ''vital importance'' to the Exchange. The suggested limitation could also create unnecessary barriers to the relevant Exchange authority accessing information relevant to Exchange operations and compliance of regulated entities with applicable Federal Exchange standards. Finally, we note the adoption of a 10-year standard in § 156.340(b)(5) aligns with other Exchange record retention requirements. Therefore, it too, does not represent an expansion of record retention obligations for QHP issuers participating in Exchanges or their downstream and delegated entities pertaining to Exchange related records, data, information, or systems. We also did not propose and decline to adopt in this rule an exception or carve-out. The adoption of these amendments is intended to make clear the obligations and responsibilities of all QHP issuers participating in all Exchanges models, and all of their downstream and delegated entities with no exceptions. However, as the relevant Exchange authority for the FFEs, we welcome an open dialogue with QHP issuers and their downstream and delegated entities about the burdens and time associated with complying with any particular request for records under § 156.340(b)(5). We encourage State Exchanges to similarly be open to such conversations.

Comment: Additionally, several commenters expressed concern about the impact the changes could have on agreements and contract negotiations

[323] As noted above, the existing text at § 156.340(b)(4) requires downstream and delegated entities of QHP issuers participating in FFEs or SBE–FPs to provide HHS access to the entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations with applicable Exchange standards.

between issuers and potential and existing downstream or delegated entities. One commenter suggested the language required by new paragraph (b)(5) could bring contract negotiations to a ''stalemate'' or considerably slow them down, because it requires both downstream and delegated entities and QHP issuers submit to the Exchange's authority to ''request any information they desire under the pretext of Federal standards.'' The commenter did not provide further information or evidence to support the claim that the Federal standards have been used as a pretext to demand information unrelated to Exchange activity.[324] Another commenter suggested the language in new paragraph (b)(5) would increase downstream and delegated entities' responsibility and risk, potentially causing them to raise their rates, but did not specify what additional responsibility or risk the downstream and delegated entities would assume. That commenter also recommended that responses to inquiries pursuant to paragraph (b)(4) and new paragraph (b)(5) from the relevant Exchange authority come directly from the downstream or delegated entity, when applicable, and not flow through the QHP issuer. The commenter did not provide the rationale for this recommendation.

Two commenters also expressed concern with respect to the proposed applicability date and the timing for implementation of any necessary change(s) to contract language. They indicated contracts will have to be modified, and 60 days from rule publication is not sufficient to come into compliance with the requirement. Additionally, a commenter requested a burden estimate for modification of contracts, pursuant to the comment, summarized above, that the inclusion of the contract language constitutes a significant change that would impose an ''undue burden'' on QHP issuers and downstream and delegated entities. The commenters did not provide an explanation for why the contract modifications required more time, or describe the nature of the ''undue burden'' beyond the suggestion of HHS overreach due to language that it asserted was not sufficiently narrow or specific. No data or information beyond these general assertions was presented to substantiate the request for a new implementation date.

One commenter indicated that while it agreed QHP issuers should retain full oversight over downstream and delegated entities, it objected to what it characterized as the imposition of required contract terms by new paragraph (b)(5), on the grounds that each organization should be free to contract in a manner governed by their own risk tolerance. The commenter offered several alternative options, including ''required written delegation agreements with performance report expectations for content and frequency'' and ''documented and recorded annual audits of each delegated entity's performance, which the issuer properly distributes for review and approval by the issuer's governing body.'' However, the commenter did not provide an explanation as to why these recommendations were preferable to inclusion of the issuer's oversight obligations in its agreements with downstream and delegated entities. A different commenter expressed support for clarifying that the general obligations and requirements regarding downstream and delegated entities of QHP issuers are applicable across all Exchanges types, but requested an explanation as to the reason for the clarification. The commenter noted that if the reason for requiring explicit contract language in agreements between QHP issuers and their downstream and delegated entities is to align with MA requirements, such alignment would be inappropriate, given the ''significant differences'' between the two programs. The commenter further explained that the Federal government has financial obligations to MA programs and assumes some of the enrollees' risk with regard to claims, whereas the QHP issuers on the Exchanges assume all risk with regard to enrollees' claims.

Response: As explained above and in the proposed rule, the proposed amendments to § 156.340 were drafted so QHP issuers on all Exchange types are subject to the same minimum downstream and delegated entity standards. HHS is finalizing these amendments as proposed to hold QHP issuers in all models of Exchange responsible for their downstream and delegated entities' adherence to applicable Federal standards related to Exchanges, and to make their oversight obligations, and the obligations of their downstream and delegated entities, explicit in regulation and in the QHP issuers' agreements with their downstream and delegated entities. HHS appreciates the comments about the burdens associated with implementation of the amendments; however, we are finalizing the implementation date and burden estimates as proposed and without changes, as we disagree that there is a significant or ''undue'' burden associated with these amendments. No evidence has been provided substantiating any added burden is placed on the downstream and delegated entities or on the QHP issuers, and while HHS appreciates the entities' desire to contract with respect to their own risk tolerance, the requirement that issuers maintain oversight and accountability for their downstream and delegated entities' actions is not a new requirement. The alternative methods proposed by the commenter, such as required written delegation agreements with performance report expectations for content and frequency, would likely be more onerous and inflexible for both the issuer and its downstream or delegated entity than modification of existing contracts to include language describing risk the issuer has already assumed by engaging the downstream or delegated entity's assistance with Exchange related activities, because the suggested alternatives would also require drafting entirely new documents, follow-up, and evaluation of performance metrics. In addition, the commenters did not provide any evidence or information to support their general assertions about the ''undue burden'' and additional time needed to modify contracts. As explained in the proposed rule, we anticipate the amendments to § 156.340 will impose minimal burden on QHP issuers and Exchange authorities. We recognize that some QHP issuers may need to make changes to existing record retention policies and their agreements with delegated and downstream entities. But since issuers participating in FFEs and SBE–FPs were already subject to the existing downstream and delegated entity standards in § 156.340, and to HHS' existing authority to request records under § 156.715, and commenters did not provide analysis or other information to substantiate the request for a new implementation date, that record requests should flow through the downstream or delegated entity and not the issuer, or support the claims of ''undue burden,'' HHS will finalize the amendments to § 156.340 as proposed.

We recognize there are differences between the Medicare Advantage program and the Exchanges. For example, the populations served are different. Also, as noted in the comment

[324] As noted above, we disagree with this assertion. Affirming HHS' authority to access this information, as the relevant Exchange authority for FFEs, in new paragraph (b)(5) while codifying similar rights for State Exchanges when they are the relevant Exchange authority does not represent an expansion of HHS authority or access to records or otherwise allow HHS to request or access information unrelated to Exchange activity.

submitted, HHS subsidizes premiums for qualified individuals enrolled in Exchange coverage, but it is not responsible for or at risk for claims incurred by Exchange enrollee the way it does for Medicare Advantage coverage. Notwithstanding these differences, there are also similarities and the use of downstream and delegated entities by the regulated entity is one example of a similarity. As such, our intention is to learn from and leverage the experience from the Medicare Advantage program, where appropriate. As explained when we first established the QHP issuer downstream and delegated entity standards in § 156.340, we believe the most legally effective way to ensure that a QHP issuer retains the necessary control and oversight over its downstream or delegated entities is to require that all agreements governing the relationships among a QHP issuer and its delegated and downstream entities contain provisions specifically describing each of the downstream and delegated entity's obligations.[325] We looked to the existing standards for entities that contract with Medicare Advantage organizations at 42 CFR 422.504(i)(3)–(4) as a guide because it was a framework familiar to HHS, regulated entities, other stakeholders, as well as the general public. It also met the goals of protecting consumers from harm and holding QHP issuers and their downstream and delegated entities accountable for compliance with applicable Federal Exchange requirements.

In this final rule, we clarify and extend the requirements in § 156.340 to hold QHP issuers in all models of Exchange responsible for their downstream and delegated entities' adherence to applicable Federal standards related to Exchanges, and to make their oversight obligations, and the obligations of their downstream and delegated entities, explicit in regulation and in the QHP issuers' agreements with their downstream and delegated entities.

14. Payment for Cost-Sharing Reductions—Clarification of CSR Payment and Data Collection Processes (§ 156.430)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 687 through 688), we proposed to amend § 156.430 to clarify when CSR data submission is mandatory or voluntary. Section 156.430 establishes parameters for the advance payment for CSRs, the associated data submission standards, and how final CSR payment and charges are reconciled. On October 11, 2017, the Attorney General issued a legal opinion that HHS did not have a valid Congressional appropriation with which to make CSR payments to issuers.[326] As a result, CSR payments ceased as of October 12, 2017. Because issuers were not receiving CSR payments from HHS, beginning with the 2018 benefit year CSR Reconciliation Data Submission process, HHS made the CSR data submission process voluntary. To clarify the data submission requirements, we proposed to amend § 156.430 to state that this data submission is mandatory for those issuers that receive CSR payments from HHS for any part of the benefit year and voluntary for other issuers.

To do this, we proposed several modifications to § 156.430. First, we proposed to amend § 156.430(b)(1) to clarify that when there is an HHS appropriation to make CSR payments to issuers, an issuer will receive periodic advance payments to the extent permitted by the appropriation and based on the advance payment amounts established in guidance. We believe that this change clarifies that the data submission requirements are mandatory for those issuers that receive CSR payments from HHS for any part of the benefit year. Further, and in line with the current practice, HHS will continue to provide those issuers that do not receive CSR payments from HHS the option to submit CSR data.

Second, we proposed to amend § 156.430(d) to reflect a change of focus from reconciliation of CSR amounts to the timing and nature of CSR data submissions, specifically when CSR payments are made. We proposed to amend § 156.430(d) to state that HHS will periodically provide a submission window for issuers to submit CSR data documenting CSR amounts issuers paid, as specified in § 156.430(d)(1) and (2), in a form and manner specified by HHS in guidance and calculated in accordance with § 156.430(c). When an appropriation is available for HHS to make CSR payments to QHP issuers, HHS will notify QHP issuers that the submission of the CSR data is mandatory for those issuers that received CSR payments from HHS for any part of the benefit year, and will use the data to reconcile advance CSR payments to issuers against the actual amounts of CSRs issuers provided, as determined by HHS based on amounts specified in § 156.430(d)(1) and (2), and calculated in accordance with § 156.430(c).

When CSR payments are not made, HHS will notify those QHP issuers that did not receive CSR payments from HHS for any part of the benefit year that the submission of the CSR data is voluntary. The CSR data that must be submitted in either a voluntary or mandatory submission includes the data elements listed in § 156.430(d)(1) and (2). The purpose of this change is to clarify when HHS will use CSR data to reconcile CSR payments. Specifically, we proposed that to the extent that CSR payments from HHS are made to issuers, the CSR data submission process would be mandatory for those issuers having received CSR payments for any part of the benefit year from HHS, and it would be voluntary for issuers that did not receive CSR payments from HHS for any part of the benefit year. This approach is consistent with how HHS has conducted these data submission processes since the 2018 benefit year CSR data submission process.

Third, we proposed to amend the title of § 156.430(e) from ''Payment of discrepancies'' to ''Cost-sharing Reductions Payments and Charges'' to reflect that this section governs both payments to issuers for CSR and charges levied against issuers for CSR.

Lastly, we proposed to amend § 156.430(e)(1) to clarify that HHS will collect data regarding the CSRs actually provided by issuers to their enrollees as opposed to collecting data on the dollar value of CSRs HHS provided to the issuer, and to further clarify that HHS only pays reconciled CSR amounts when there is an appropriation to make CSR payments and to the extent permitted by such appropriation.

We noted that, regardless of whether HHS makes CSR payments, issuers are required to provide CSRs to enrollees as specified at § 155.1030. We sought comment on these proposals.

After reviewing the public comments, we are finalizing, as proposed, that CSR data submission is mandatory for those issuers that receive CSR payments from HHS for any part of the benefit year and voluntary for other issuers.

We summarize and respond to public comments received on payment for cost-sharing reductions—clarification of CSR payment and data collection processes (§ 156.430) below.

Comment: One commenter supported the proposals.

Response: We appreciate the support and are finalizing, as proposed, that CSR data submission is mandatory for those issuers that receive CSR payments from

[325] See 78 FR 37056. Also see 78 FR 54120.

[326] *Payments to Issuers for Cost-Sharing Reductions (CSRs).* (2017, October 12). HHS. *https://www.hhs.gov/sites/default/files/csr-payment-memo.pdf.*

HHS for any part of the benefit year and voluntary for other issuers.

Comment: Another commenter requested additional clarification on how the proposals would impact the existing CSR reconciliation data submission process and schedule before HHS implements any changes.

Response: These amendments are not intended to change the existing CSR data submission process or schedule. In October 2017, the Attorney General declared that the government could not make CSR payments in the absence of an appropriation, and that because there was no appropriation, CSR payments must stop.[327] HHS then announced that CSR payments would be discontinued until an appropriation exists.[328] HHS has not made advance CSR payments for any period since October 2017 due to a lack of an appropriation. Also, in the absence of an appropriation, HHS cannot make CSR reconciliation payments for any past period. Because of this, since the 2018 benefit year, HHS has made the CSR data submission process optional. To this effect, HHS has periodically provided issuers an annual optional window to submit CSR data and restatements in light of ongoing litigation. Under the amendments finalized in this rule, the CSR data submission process would continue in the same manner as it has been operated since the 2018 benefit year CSR data submission, and these amendments are merely aligning our regulations with existing operations. If HHS makes CSR payments to QHP issuers in the future, HHS will notify QHP issuers that a CSR data submission will be mandatory for any issuers receiving CSR payments for any part of the benefit year.

Additionally, these amendments do not impact the CSR data submission schedule. Consistent with past benefit years, the timing of the CSR data submission process will continue to be announced annually in guidance.

15. Quality Standards: Quality Improvement Strategy (§ 156.1130)

In accordance with section 1311(c)(1)(E) of the ACA, quality improvement strategies described in section 1311(g)(1) of the ACA must be implemented across Exchanges as a QHP certification requirement. Section 1311(g)(1) of the ACA defines a QIS as a payment structure that provides increased reimbursement or other incentives for implementing activities related to five health care topic areas identified in statute: Improving health outcomes of plan enrollees, preventing hospital readmissions, improving patient safety and reducing medical errors, promoting wellness and health, and reducing health and health care disparities. Under § 156.1130(a), a QHP issuer participating in an Exchange for 2 or more consecutive years must implement and report on a QIS, including a payment structure that provides increased reimbursement or other market-based incentives in accordance with the health care topic areas in section 1311(g)(1) of the ACA, for each QHP offered in an Exchange, consistent with the guidelines developed by HHS under section 1311(g) of the ACA. In the 2016 Payment Notice (80 FR 10750), HHS established a phase-in approach for QIS implementation standards and reporting requirements to provide QHP issuers time to understand the populations enrolling in a QHP offered through the Exchange and to build quality performance data on their respective QHP enrollees.[329] HHS noted that implementation of a QIS should be a continuous improvement process for which QHP issuers define the health outcome needs of their enrollees, set goals for improvement, and provide increased reimbursement to their providers or other market-based incentives to reward achievement of those goals.[330]

In line with this approach and under the same authorities, in the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 688), HHS proposed to update the QIS standards and enter the next phase of implementation by adopting a new guideline that would apply to QHP issuers beginning in 2023. Specifically, we proposed a new guideline under which QHP issuers would be required to address health and health care disparities as a specific topic area within their QIS, in addition to at least one other topic area described in section 1311(g)(1) of the ACA, beginning in 2023. We proposed this expansion of the QIS standards, which aligns with health equity efforts across Federal government policies and programs; however, we did not propose amendments to the regulatory text outlined in § 156.1130.

Persistent inequities in health care outcomes exist in the United States, including among populations enrolling in QHPs across Exchanges. Belonging to a racial or ethnic minority group, living with a disability, being a member of the LGBTQI+ community, having limited English proficiency, living in a rural area, or being near or below the poverty level, is often associated with worse health outcomes.[331] [332] [333] [334] [335] [336] [337] Such disparities in health outcomes are the result of a number of factors and exist irrespective of health insurance coverage type. Although not the sole determinant, poor health care access and provision of lower quality health care contribute to health disparities. In fact, research has shown that the expansion of health insurance coverage, for example through Medicaid expansion under the ACA, and the resulting increased access to health care, is linked to reductions in disparities in health insurance coverage as well as reductions in disparities in health outcomes.[338]

We are specifically committed to achieving equity in health care outcomes for QHP enrollees by supporting QHP issuer quality improvement activities to reduce health and health care disparities, and promoting issuer accountability for improving equity in the health and health care of their enrollee populations. For the purposes of this final rule, we are using the definition of ''equity'' established in Executive Order 13985, issued on January 20, 2021, as

[327] Ibid.

[328] Ibid.

[329] 80 FR 10750, 10844 (2015, February 27).

[330] Ibid.

[331] Lindenauer, P.K., Lagu, T., Rothberg, M.B., Avrunin, J., Pekow, P.S., Wang, Y., Krumholz, H., & Hines, H. (2013). Income Inequality and 30-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal.

[332] Trivedi, A.N., Nsa, W., Hausmann, L.R.M., Lee, J., Ma, A., Bratzler, D., Mor, M., Baus, K., Larbi, F., & Fine, M. (2014). Quality and Equity of Care in U.S. Hospitals. *New England Journal of Medicine.* 371(24):2298–2308.

[333] Polyakova, M., Udalova, V., Kocks, G., Genadek, K., Finlay, K., & Finkelstein, A.N. (2021). Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. *Health affairs (Project Hope), 40*(2), 307–316. *https://doi.org/10.1377/hlthaff.2020.02142.*

[334] *Rural Communities: Age, Income, and Health Status. Rural Health Research Recap.* (2018). Rural Health Research Gateway. *https://www.ruralhealthresearch.org/recaps/5.*

[335] *2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities.* (2020). HHS Office of Minority Health. *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[336] *Sexual Orientation Disparities in Risk Factors for Adverse COVID–19–Related Outcomes, by Race/Ethnicity.* (2021, February 5). CDC. *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[337] Poteat, T.C., Reisner, S.L., Miller, M., & Wirtz, A.L. (2020). COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. *medRxiv: The preprint server for health sciences,* 2020.07.21.20159327. *https://doi.org/10.1101/2020.07.21.20159327.*

[338] Guth, M., Garfield, R., & Rudowitz, R. (2020). The Effects of Medicaid Expansion Under the ACA: Studies from January 2014 to January 2020. *Kaiser Family Foundation. https://www.kff.org/medicaid/report/the-effects-of-medicaid-expansion-under-the-aca-updated-findings-from-a-literature-review/.*

''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities who have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; LGBTQI+ persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [339] In light of the COVID–19 PHE, which is having a disproportionate and severe impact on underserved populations, and in line with the goals of Executive Order 13985, we are strengthening efforts across all programs to address disparities and advance health equity. In addition, this is a topic area that QHP issuers across the Exchanges have increasingly been focusing on in their QIS submissions.

A CMS evaluation of QHP issuer QIS submissions in the FFEs in PY 2020 found that an estimated 60 percent of QIS submissions addressed health care disparities. Building on the phase-in approach established in the 2016 Payment Notice and our experiences evaluating QIS submissions over the years and during the COVID–19 PHE, we proposed to update the QIS standards. We proposed to require QHP issuers to address health and health care disparities as one topic area of their QIS in addition to at least one other topic area described in section 1311(g)(1) of the ACA beginning in 2023. However, we did not propose amendments to the regulatory text outlined in § 156.1130. We sought comment on this proposal.

We summarize and respond to public comments received on the quality improvement strategy (§ 156.1130) proposal. After reviewing commenter responses, we are finalizing as proposed.

Comment: Many commenters supported the proposal to expand QIS standards to require issuers to address health and health care disparities in addition to one other topic area identified in section 1311(g)(1) of the ACA as part of their QIS beginning in 2023. Specifically, commenters expressed strong support for the increased focus on health and health care disparities within the QIS standards and achieving equity in health outcomes for QHP enrollees, as well as driving accountability for advancing health equity.

Response: We appreciate commenters' support to expand QIS standards to require QHP issuers address health and health care disparities which aligns with health equity efforts across Federal government policies and programs. QHP issuers in all Exchange model types will be required to address health and health care disparities in addition to one other topic area identified in section 1311(g)(1) of the ACA as part of their QIS beginning in 2023. This new guideline will apply for the first time to the QIS submissions QHP issuers provide to Exchanges in the 2023 calendar year, which would describe the issuer's strategy for addressing health and health care disparities for the 2024 Plan Year, beginning on January 1, 2024.

Comment: Several commenters stated that although the proposed QIS policy ties effective performance on reducing health and health care inequities to financial reward, the current proposal does not go far enough to advance health equity. Some commenters urged CMS to require more public transparency and accountability about the process of selecting, implementing, evaluating, and reporting the outcomes of QIS interventions to ensure QHPs prioritize health equity work. These commenters noted that currently there are no public reporting requirements for QIS activities (for example no list of QIS topics selected, no public report on progress or successful outcomes).

Response: We appreciate the comments on the proposals to expand QIS standards to address health and health care disparities and clarify that the QIS statutory provisions do not tie performance within a QIS to a financial reward for issuers. Instead, section 1311(g)(1) of the ACA defines a QIS as a payment structure developed by issuers that provides increased reimbursement or other market-based incentives for improving health outcomes of plan enrollees (for example, through provider incentives such as increased reimbursement or bonus payments, or through enrollee financial incentives such as a monetary reduction of enrollee premiums and other out-of-pocket costs). Thus, consistent with the requirement in section 1311(c)(1)(E) of the ACA, QHP issuers must implement a QIS and they are required to incorporate market-based incentives within their respective QIS programs. We also acknowledge commenters' requests for greater public transparency and interest in greater accountability regarding the process QHP issuers undertake to select, implement, evaluate, and report the outcomes of disparity-related QIS programs. Unlike other Exchange quality programs, section 1311(c)(1)(E) and (g) of the ACA do not provide for the public reporting of data on QHP issuer QIS programs.[340] Instead, the QIS requirements focus on collection of information by Exchanges from issuers within QIS forms to demonstrate compliance with the QHP certification requirements in section 1311(c)(1)(E) of the ACA. The collection of this information also facilitates the Exchange's understanding of its QHP issuers' payment structure frameworks that provide increased reimbursement or other market-based incentives for the implementation of activities related to the topics specified in section 1311(g) of the ACA. We recognize issuers use proprietary information in their QIS submissions they may not want published, and that their strategies may contain confidential information about their enrollee populations. Additionally, QIS requirements provide issuers flexibility in meeting this certification requirement by allowing diverse, qualitative, non-standardized information that would not be easily and clearly shared publicly.

We further note that the policy adopted in this final rule seeks to align the QIS with other Federal quality standards related to data collection efforts and disclosure of information focused on quality improvement and advancing health equity, which includes balancing the desire to encourage transparency with the need to safeguard confidential and proprietary information. Some types of confidential and proprietary information include the tools, resources, and data sets issuers use in describing their quality improvement strategies within their QIS forms. For example, an issuer may have concerns disseminating a patient data collection tool they consider propriety that is described within their QIS to a wider audience. Furthermore, some issuers choose to report on their internal quality improvement progress using measures that are included within other performance programs, and that may not be fully validated at the time they submit their QIS during the applicable benefit year's QHP Application Period. Finally, some issuers use internally developed measures they consider proprietary that are not intended for public reporting. At the same time, however, we understand the interest in the public reporting of QIS information, and HHS will continue to consider if there are ways or subsets of QIS information could be publicly released.

[339] 86 FR 7009 (2021, January 25).

[340] Compare, for example, the statutory provisions that established the Quality Rating System and Enrollee Satisfaction Survey, which require Exchanges to publish information on their respective websites. See sections 1311(c)(3) and (c)(4) of the ACA. Also see 45 CFR 155.1400 and 155.1405.

Comment: Several commenters noted that QHPs should have to seek input from underserved enrollees or stakeholders who represent underserved communities to guide their QIS activity selection.

Response: We appreciate the feedback related to QHP issuers seeking input from underserved enrollees or stakeholders who represent underserved communities to guide their QIS activity selection and to shape which activities they prioritize when addressing health or health care equity. HHS agrees that such feedback would help guide issuer development of QIS programs that target the needs of their specific populations, including those in underserved communities. HHS will consider including language further encouraging these outreach activities in the 2024 Plan Year Technical Guidance, which will inform submissions in the 2023 calendar year. However, we did not propose and decline to adopt a requirement mandating such outreach in this final rule.

Comment: A few commenters noted that QHP issuers may face barriers when collecting race, ethnicity, language and other data on certain sub-populations, including consumers in underserved communities. Commenters expressed that these barriers may be due to a lack of standardization across State and Federal data collection requirements. Commenters also recommended HHS consider approaches to standardize data collection that includes collection of information that may be used to develop tailored quality improvement strategies. Two commenters urged HHS to address data collection barriers and delay finalizing the QIS proposal until issuers have more robust data to identify disparities. The commenters noted that when race and ethnicity or social determinant of health (SDOH) data is collected, relatively few individuals voluntarily provide this information to their health plans due to concerns about how the data will be used, and that the data available to issuers to identify health care disparities is limited and may vary by issuer due to State laws limiting the data issuers can collect. One commenter recommended that, for QIS standards, HHS should define disparities more broadly, beyond race, ethnicity, and language, which may not apply to every health plan, and reiterated that HHS should use a broad definition that encompasses other factors such as LGBTQI+ status, location (rural/urban), and physical and mental disabilities.

Response: We recognize QHP issuers may experience barriers or other challenges when collecting certain data and that State and Federal data collection requirements for race, ethnicity, language, and other data on certain populations are currently not standardized. There are many reasons why the data collection requirements may not be standardized, including different statutory authorities and mandated data elements. The proposals being finalized in this rule are limited and specific to the QIS requirements under section 1311(c)(1)(E) of the ACA applicable to QHP issuers participating in Exchanges. The QIS statutory provisions do not provide HHS authority to standardize State and Federal data collection requirements or remove barriers that may exist with respect to collection of race, ethnicity, language and other data on certain sub-populations, including consumers in underserved communities. However, the QIS statute and the HHS implementing regulations provide a mechanism to encourage QHP issuers participating in Exchanges to focus more efforts on addressing health and health disparities. Section 1311(g)(1) of the ACA explicitly identifies the implementation of activities to reduce health and health care disparities, including through the use of language services, community outreach, and cultural competency trainings, as one of the topic areas for QHP issuer QIS programs. Issuers operating in States that have laws that limit the collection of certain data may have to rely on other data sources or indirect estimation (for example, geographic assignment, Bayesian indirect surname and geocoding) to incorporate activities to reduce health and health care disparities in their QIS programs. Similarly, issuers who do not have access to this type of data through existing data sources (for example, if enrollees decline to provide this information) will also have to identify other resources that can be used for this purpose. We are also aware of and intend to continue to monitor the development of industry standards, as well as State law activity, applicable to the collection and use of race and ethnicity data elements. As industry standards and state laws applicable to the collection and use of race and ethnicity data elements evolve, HHS will consider whether any changes to the QIS program requirements would be appropriate.

Flexibility is one of the key foundational principles of the QIS, and we intend to continue to offer flexibility to encourage issuer innovation and to promote a culture of continuous quality improvement. This will include taking into consideration steps issuers take to expand their data collection efforts to support QIS activities that address health and health care disparities (along with the other QIS topics identified in section 1311(g)(1) of the ACA). With respect to the new QIS guideline finalized in this rule, as noted above, we anticipate that indirect estimation (for example, geographic assignment, Bayesian indirect surname and geocoding) may be used by issuers until such time in which issuers are able to directly collect data, such as race, ethnicity, and language, to analyze and address potential health and health care disparities. For example, NCQA introduced race and ethnicity stratifications for select Healthcare Effectiveness Data and Information Set (HEDIS®) measures,[341] which allows an organization to report the stratification using their own directly collected member data as well as report directly collected data supplemented with indirect race and ethnicity data. QHP issuers would be permitted to take a similar approach for the development of their QIS programs and the incorporation of activities to reduce health and health care disparities. For this reason, we do not believe it is necessary to delay finalization of the QIS proposal until HHS has addressed data collection barriers or until issuers have more robust data to identify disparities.

Additionally, we emphasize that the requirement adopted in this final rule that requires QHP issuers to address health and health care disparities as a specific topic area within their QIS beginning in 2023 is not limited to implementing strategies that solely focus on race and ethnicity health and health care disparities. Nor does it mandate the collection and submission of individual enrollee's race and ethnicity data to HHS. QHP issuers will have flexibility in how they elect to address and define health and health care disparities in their QIS. For example, QHP issuers could focus on enrollee populations that belong to a racial or ethnic minority group, live with a disability, identify as a member of the LGBTQI+ community, have limited English proficiency, live in a rural area, or earn near or below the poverty level, which they have identified may be associated with worse health outcomes. Additionally, we affirm that QIS initiatives to address health and health care disparities may

[341] More information about NCQA's approach and timeline for stratification of select HEDIS measures can be found here: *Data, Measurement and Equity.* National Committee for Quality Assurance. *https://www.ncqa.org/about-ncqa/health-equity/data-and-measurement/.*

include a broad range of activities such as language services, community outreach, cultural competency trainings, social needs-sensitive self-management recommendations, and increased collection and use of demographic and disparities-related data that will be used to develop QIS program activities designed to identify and reduce disparities.

Comment: One commenter requested that CMS delay the implementation of the proposed expansion of the QIS standards until January 1, 2024, at the earliest, as this would align with the NCQA changes and the introduction of race and ethnicity stratification reporting requirements for certain select HEDIS® measures, which are lagging. The commenter stated that many health plans base their QIS on their HEDIS® measurements, and noted that aligning applicability of the QIS update with the NQCA change would ease administrative burden and ensure continuity for health plans. Another commenter noted that given the diversity of QIS requirements across Federal and State-based Exchanges, HHS should create a standardized approach to advancing equity and incorporating reducing health and health care disparities into existing QIS requirements by adding stratification by race/ethnicity for any associated quality measures.

Response: We clarify that we are finalizing the proposal to require QHP issuers to address health and health care disparities in addition to one other topic identified in section 1311(g)(1) of the ACA in the QIS submissions they provide to Exchanges beginning in the 2023 calendar year, which would apply to the 2024 Plan Year. As such, issuers will be required to describe their strategy for addressing health and health care disparities beginning on January 1, 2024. This aligns with the NCQA introduction and implementation of race and ethnicity stratification for select HEDIS® measures for the 2022 Measurement Year, that will be collected in the 2023 calendar year. We appreciate and share the commenter's commitment to advancing health equity by requiring QHP issuers to address potential disparities in their quality improvement strategies, but we also recognize the limitations issuers may face when collecting certain data in support of conducting their QIS activities. We further clarify and affirm that QHP issuers across all Exchange types must adhere to the same minimum QIS Federal standards established by HHS, but State Exchanges (both State Exchanges and SBE–FPs) have the flexibility to change certain details, such as the timeframe and format for submission of QIS information by their respective issuers, and they can establish standards that go beyond Federal QIS requirements.[342] However, they cannot reduce a QHP issuer's QIS obligations below the minimum QIS Federal standards established by HHS.

We understand the request from some commenters to create a standardized approach to advance health equity which includes stratification of race and ethnicity data in relation to QIS requirements. We generally support and strive for standardized and coordinated approaches across HHS to advance health equity. We also support flexibility to ensure that QHP issuers can develop various strategies across their populations and across their provider contracts. Although we have established Federal minimum standards for QHP issuers to follow and address in their quality improvement strategies, the QIS program is intended to provide QHP issuers with flexibility in the design and implementation of their respective QIS initiatives and activities. For example, QHP issuers have flexibility in how they elect to address health and health care disparities in their QIS, such that their data collection efforts do not need to be limited to race and ethnicity information. In addition, and based on public comment, HHS believes that imposing specific performance measures on QHP issuers would limit their ability to target their strategies to their specific populations and possibly limit innovation. We further recognize that State laws may impact the ability to collect certain data, which could limit the ability to develop standardized collection standards. Finally, as we noted previously, the QIS statutory provisions do not provide HHS authority to standardize State and Federal data collection requirements or remove barriers that may exist with respect to collection of race, ethnicity, language and other data on certain sub-populations, including consumers in underserved communities.

Comment: One commenter encouraged HHS to revise its proposal and allow issuers to embed a health equity strategy into their selected QIS topics instead of requiring QHP issuers to establish a separate QIS focused on addressing disparities. The commenter also urged HHS to provide detailed criteria to help issuers develop meaningful projects that fulfill the intent of addressing the health care needs of underserved populations, while also allowing issuers flexibilities to establish goals and metrics for success that accommodate the more limited data and longer timeframes to successfully address disparities, and in particular, the limitations for collecting data related to race and ethnicity. The commenter also requested HHS evaluate potential requirements to address disparities for populations other than the underserved communities and work to create QIS requirements that align with a more global population health approach to addressing disparities.

Response: We agree QHP issuers should advance equity as a foundational aspect of quality rather than consider equity as a siloed aspect of performance, and we encourage QHP issuers to incorporate health equity into each of their quality improvement strategies. We further clarify that under the QIS guideline, as proposed and as finalized, QHP issuers have flexibility in the design and implementation of their respective QIS initiatives and activities. This includes the flexibility to establish two separate QIS initiatives—one that focuses only on addressing health and health care disparities and a second one that focuses only on wellness and health promotion (or another topic identified in section 1311(g)(1) of the ACA)—or the flexibility to establish one QIS initiative that focuses on addressing health and health care disparities in addition to wellness and health promotion (or another topic identified in section 1311(g)(1) of the ACA). Both approaches would be complaint with the new QIS guideline finalized in this rule. In other words, QHP issuers will not need to develop de novo strategies or create and submit multiple QIS programs, but can address health and health care disparities within an existing QIS. If an issuer elects this approach, they should select ''reduce health and health care disparities'' as a topic area in addition to at least one other topic area when submitting its plan year 2024 QIS submission in the 2023 calendar year. We intend to address this, and other operational details related to this new guideline, as part of the Plan Year 2024 QIS Technical Guidance. We did not propose and generally decline to adopt detailed criteria to direct QHP issuer QIS programs that address health and health care disparities.

As detailed above, QHP issuers have flexibility in how they elect to address health and health care disparities in their QIS, such that their data collection efforts do not need to be limited to race

[342] See 45 CFR 156.1130 and 80 FR 10844 through 10848. Also see, for example, Section 4.2, *QIS Technical Guidance and User Guide for the 2022 Plan Year* (2021) CMS. *https://www.cms.gov/files/document/qis-technical-guidance-and-user-guide-2022-plan-year.pdf.*

and ethnicity information. For example, QHP issuers could focus on enrollee populations that belong to a racial or ethnic minority group, or those that live with a disability, identify as a member of the LGBTQI+ community, have limited English proficiency, live in a rural area, or earn near or below the poverty level, which may be associated with worse health outcomes. QHP issuers also have broad flexibility in terms of the goals they have identified, the activities they've employed to advance their QIS, and the measures they use. Within their QIS, issuers must report their initial baseline assessment results, and then must subsequently report their progress in relation to the baseline results they've provided. Since the QIS program promotes continuous quality improvement, issuers are asked to analyze their progress using their baseline data, but at this time they are not penalized for not meeting their progress targets or milestones. Additionally, QIS initiatives to address health and health care disparities may include a broad range of activities such as language services, community outreach, cultural competency trainings, social needs-sensitive self-management recommendations, and increased demographic and disparities-related data collection.

16. Disbursement of Recouped High-Cost Risk Pool Funds—Administrative Appeals of Issuers of Risk Adjustment Covered Plans (§ 156.1220)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 689), we proposed that any funds recouped as a result of a successful high-cost risk pool administrative appeal under § 156.1220(a)(1)(ii) would be used to reduce high cost-risk pool charges for that national high-cost risk pool for the current benefit year, if high-cost risk pool payments have not already been calculated for that benefit year. If high-cost risk pool payments have already been calculated for that benefit year, we proposed to use any funds recouped as a result of a successful high-cost risk pool administrative appeal to reduce high-cost risk pool charges for that national high-cost risk pool for the next benefit year. As discussed earlier in this rule, we also proposed similar treatment of high-cost risk pool funds HHS recoups as a result of audits of risk adjustment covered plans under § 153.620(c)(5)(ii) and as a result of actionable discrepancies under § 153.710(d).

In the proposed rule, we also clarified that when HHS recoups high-cost risk pool funds as a result of a successful administrative appeal, the issuer that filed the appeal would then be responsible for reporting that adjustment to its high-cost risk pool payments or charges in the next MLR reporting cycle consistent with the applicable instructions in 45 CFR 153.710(h). Additionally, for any benefit year in which high-cost risk pool charges are reduced as a result of high-cost risk pool funds recouped as a result of an administrative appeal, issuers whose charge amounts are reduced would report the high-cost risk pool charges paid for that benefit year net of recouped funds as a result of an administrative appeal in the next MLR reporting cycle consistent with 45 CFR 153.710(h). This same framework would also apply to high-cost risk pool funds recouped as a result of audits under § 153.620(c)(5)(ii) and actionable discrepancies under § 153.710(d).

We sought comment on this proposal.

After consideration of relevant comments, we are finalizing these policies, as proposed. We respond to the comments received on these policies.

Comment: Several commenters expressed general support for these proposals.

Response: After consideration of relevant comments, we are finalizing, as proposed, the policies related to disbursement of high-cost risk pool funds recouped as a result of audits of risk adjustment covered plans under § 153.620(c), actionable high-cost risk pool-related discrepancies filed pursuant to § 153.710(d), and successful high-cost risk pool administrative appeals filed pursuant to § 156.1220.

17. Direct Enrollment With the QHP Issuer in a Manner Considered To Be Through the Exchange (§ 156.1230)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 689), we proposed to amend § 156.1230 such that its nondiscrimination protections would explicitly prohibit discrimination based on sexual orientation and gender identity. As we explain in the Supplemental Information section earlier in the preamble, HHS will address this policy, as well as public comments submitted in response to the proposal, in a future rulemaking.

18. Solicitation of Comments—Choice Architecture and Preventing Plan Choice Overload

One of the primary goals of the ACA is to provide consumers access to quality, comprehensive health coverage options, as well as the information and assistance they need to make coverage choices that are right for them. For this reason, both Federal and State Exchanges invest significant time and resources to build Exchanges that support consumer access to competitive health plan options that offer sufficiently diverse benefit options that give consumers a meaningful choice between Exchange coverage options. Exchanges also work to ensure that QHP information is presented to consumers in a manner that is clear and easy to understand and that allows consumers to accurately recognize the material differences between plan options.

Although HHS continues to prioritize competition and choice on the Exchanges, we are concerned about plan choice overload which can result when consumers have too many choices in plan options on an Exchange. A 2016 report by the RAND Corporation reviewing over 100 studies 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.[343]

Earlier in this section E of the preamble, we finalized the provision to require FFE and SBE–FP issuers to offer the standardized plan options finalized in this rule. Standardized plan options offer one solution to the problem of choice overload through standardizing cost-sharing structures and increasing plan comparability by allowing consumers to focus on plan premiums, provider networks, formularies, and quality ratings.[344] In light of the proliferation of seemingly similar plans offered through the Exchanges over the last several years, HHS solicited comment regarding whether it should limit the total number of plans issuers may offer through the FFEs and SBE–FPs in future PYs in order to further streamline and optimize the plan selection process for consumers on the Exchanges.

HHS' desire to limit the number of plans that issuers can offer through the Exchanges arises following the sharp increase in plan offerings in recent years. For example, in the FFEs and SBE–FPs in PY 2019, there was an enrollee-weighted average of 1.2 catastrophic plans, 7.9 bronze plans,

[343] Taylor EA, Carman KG, Lopez A, Muchow AN, Roshan P, & Eibner C. (2016) Consumer *Decision-making* in the Health Care Marketplace. RAND Corporation. *https://www.rand.org/pubs/research_reports/RR1567.html.*

[344] Facilitating Consumer Choice: Standardized Plans in Health Insurance Marketplaces. (2021, December 28). Office of the Assistant Secretary for Planning and Evaluation. *https://aspe.hhs.gov/sites/default/files/documents/222751d8ae7f56738f2f4128d819846b/Standardized-Plans-in-Health-Insurance-Marketplaces.pdf.*

12.3 silver plans, 4.6 gold plans, and 1.1 platinum plans available per enrollee, amounting to a total of 27.1 plans available per enrollee. In the FFEs and SBE–FPs during the open enrollment period for PY 2022, there was an enrollee-weighted average of 2.7 catastrophic plans, 40.4 bronze plans, 45.3 silver plans, 19.2 gold plans, and 1.6 platinum plans available per enrollee, amounting to a total of 109.2 plans available per enrollee. In PY 2022, several rating areas have more than 50 silver plans, excluding CSR variations, available to consumers—a number we believe makes it difficult for consumers to make reasonably informed decisions.

This proliferation of plans is only partially attributable to new market entrants, since in PY 2019, consumers could select QHPs from an enrollee-weighted average of 2.8 issuers per enrollee, while during the open enrollment period for PY 2022, consumers were able to select QHPs from an enrollee-weighted average of 6.3 issuers per enrollee. The fact that the enrollee-weighted average number of plan offerings increased by a factor of four while the enrollee-weighted average number of issuers only increased by a factor of just over two between plan years 2019 and 2022 suggests consideration of the need to limit the proliferation of seemingly similar plans in order to further streamline and optimize the plan selection process for consumers on the Exchanges.

HHS remains concerned that having an excessive number of health plan options may make consumers less likely to complete any plan selection and more likely to select a plan that does not match their health needs. In studies of consumer behavior in Medicare Part D, Medicare Advantage, and Medigap, 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.[345] These conclusions are supported by the comments received during both this rulemaking and prior rulemaking, in which a significant number of commenters raised concerns that removing tools that facilitate the plan selection process causes consumers to face choice paralysis and leads to a reduction in overall enrollment in QHPs, undermining the purpose of Exchanges—to allow people to compare and purchase QHPs.

HHS' experience during its annual open enrollment period also suggests that ''many consumers, particularly those with a high number of health plan options, find the large variety of cost sharing structures available on the Exchanges difficult to navigate.'' [346] Thus, in order to streamline and optimize the plan selection process for consumers on the Exchanges, HHS expressed interest in exploring possible methods of improving choice architecture and solicited comments on doing so. Several provisions finalized within this rule complement this goal, including the standardized plan options provision at § 156.201 and the provisions that modify the applicable AV *de minimis* ranges at §§ 156.140, 156.200, and 156.400.

Specifically, the standardized plan options provision at § 156.201 requires FFE and SBE–FP issuers to offer plans with standardized cost sharing parameters at every product network type, at every metal level, and throughout every service area that they offer non-standardized plan options. Though this provision does not limit the number of non-standardized plan options for PY 2023, HHS stated that it intends to consider and propose future rulemaking, as appropriate, to determine whether to limit the number of non-standardized plan options that FFE and SBE–FP issuers may offer through the Exchanges in PYs beginning on or after January 1, 2024.

Additionally, the provisions at §§ 156.140, 156.200, and 156.400 finalized modifications to the applicable AV *de minimis* ranges. HHS modified the *de minimis* ranges at § 156.140(c) beginning in PY 2023 to +2/−2 percentage points for all individual and small group market plans subject to the AV requirements under the EHB package, other than for expanded bronze plans, for which HHS finalized a *de minimis* range of +5/−2. Under § 156.200, HHS finalized, as a condition of certification as a QHP, to limit the *de minimis* range to +2/0 percentage points for individual market silver QHPs. HHS also finalized under § 156.400 to specify *de minimis* ranges of +1/0 percentage points for income-based silver CSR plan variations. HHS explained that it anticipates that these provisions would have the effect of decreasing the number of plan offerings due to more restricted AV *de minimis* ranges.

HHS also solicited comment on resuming the meaningful difference standard (previously codified at 45 CFR 156.298) and the best approach for doing so. The meaningful difference standard was first finalized 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 consumer understanding of the differences between plans and enable optimal consumer choice. It was then considered to be no longer necessary given the decreased number of issuers and plans offered through the FFEs and SBE–FPs in PY 2019. Given that the number of plans offered through the Exchanges has increased sharply over the last several years, HHS explained that it continues to believe that resuming the meaningful difference standard could play a constructive role in limiting the proliferation of seemingly similar plans on the Exchanges, thus further streamlining and optimizing the plan selection process for consumers on the Exchanges.

HHS also acknowledged that a number of State Exchanges have successfully employed an active purchaser model in which these Exchanges selectively negotiate contracts with issuers, limit the total number of issuers that can offer QHPs through the Exchange, require issuers to offer standardized plan options exclusively, and exclude plans that have not demonstrated the administrative capability, prices, networks or product designs that improve consumer value. HHS explained that it intends to consider whether such a model would be appropriate in future PYs to achieve the aforementioned goals of streamlining the plan selection process for consumers on the Exchanges and solicited comments accordingly.

Altogether, we sought comment on the utility of limiting the number of plans that FFE and SBE–FP issuers can offer through the Exchanges in future PYs in order to avoid plan choice overload and to further streamline and optimize the plan selection process for consumers on the Exchanges. We also sought comment on the impact of limiting the number of plans that issuers can offer through the Exchanges and on effective methods to achieve this goal, the advantages, and disadvantages of these methods, and if there are alternative methods we have not considered.

We also sought comments on other evidence-based approaches to improve choice architecture within the Exchanges.

We summarize public comments on these topics below, but note that comments related to standardized plan

[345] Zhou, C. & Zhang, Y. (2012). ''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: 2259–2265.

[346] 80 FR 75488, 75542 (2015, December 2).

options, changes to the AV *de minimis* ranges, and the meaningful difference standard are summarized and addressed in more detail earlier in their respective sections in the preamble: §§ 156.201, 156.140, 156.200, and 156.400. We also acknowledge and appreciate comments on improving choice architecture within the Exchanges and on the benefits and potential drawbacks of adopting an active purchaser model and will take these comments into account as part of future research and decision-making processes.

Comment: In response to a comment solicitation regarding how HHS might address choice overload in the Exchanges, many commenters supported improving choice architecture on *HealthCare.gov* to enhance the consumer shopping experience, in addition to requiring issuers to offer standardized plan options. Many commenters suggested that HHS provide educational resources and accessibility support for consumers, such as interactive graphics and videos explaining relevant health care and insurance terminology. These commenters noted that modifying choice architecture on *HealthCare.gov* to make it more intuitive and educational could greatly benefit consumers with low health literacy.

Similarly, some commenters stated that Exchanges should prioritize decision support tools that direct consumers to consider total out-of-pocket costs instead of premiums. These commenters suggested using more plain language, utilizing hover text to define key terms and distinguishing features, improving accessibility for consumers with vision impairments, and developing tutorials. One commenter urged HHS to engage with issuers and stakeholders to identify tools and features that would be most meaningful for consumers. This commenter also suggested seeking consumer feedback to better identify, test, and launch changes to the *HealthCare.gov* shopping and plan selection user interface.

Response: HHS shares commenters' position that it is extremely important to make plan information accessible and actionable for all consumers, including those with visual, auditory or speech disabilities, those for whom English is a second language, or those who otherwise may have challenges with incorporating important but complex health insurance plan benefit design information into their decision-making process. HHS appreciates these comments and recommendations on additional educational resources to maximize consumers' ability to select the best plan for themselves and their families, and we note that we will take these recommendations into consideration as we continue to work towards this goal.

Comment: Many commenters also advocated for improving choice architecture and decision-support tools as an alternative to requiring standardized plan options or limiting plan offerings. These choice architecture suggestions included mandating decision-support tools, having shoppers ''opt-out'' rather than ''opt-in'' to provide their expected health care service utilization, actively redirecting consumers to plans with higher AVs and lower total costs, displaying estimated out-of-pocket costs, and highlighting patient-friendly cost sharing parameters such as fixed-dollar copayments and pre-deductible services on plan cards.

One commenter urged HHS to include pop-up alerts and to require consumers to click to confirm that they would like to enroll in plans with higher costs and lower actuarial values. These commenters also suggested improving the functionality of features such as filters and sort options by providers, facilities, formularies, quality ratings, and networks. One commenter encouraged HHS to collect consumer preferences and anticipated health care service utilization prior to displaying plans in order to ensure that plans are initially filtered and sorted for consumers. This commenter further recommended that HHS display the highest metal level plans first if the net premiums are $0 for multiple metal levels within a product.

Some commenters suggested that HHS employ choice architecture improvements to direct eligible shoppers to CSR plan variations so they can utilize the savings available to them. Specifically, these commenters suggested that an out-of-pocket cost sort option could help customers understand the concept of total costs and show CSR-eligible consumers that the most generous CSR plan variations are guaranteed to have lower total out-of-pocket costs than those of plans at higher metal levels. Similarly, some commenters recommended preferentially displaying silver cost-sharing reduction variants while continuing to display plans from low to high total cost.

Finally, one commenter stated that HHS should reform the choice architecture on the Exchanges. This commenter explained that both Federal and State Exchanges should be required to implement decision-support tools that direct consumers to contemplate total costs instead of just premiums. This commenter added that Exchanges should be required to actively redirect consumers to plans that provide the lowest cost for the highest actuarial value, such as a bronze to a silver plan with cost sharing reductions. This commenter cited several examples of State Exchanges that have implemented similar changes.

Response: HHS appreciates the variety and detail of comments on methods of enhancing choice architecture to further streamline consumers' decision-making process and empower individuals to select the best plan for themselves and their families. We note that we will take these comments into consideration as we continue to explore advancements in choice architecture on *HealthCare.gov*.

Comment: A few commenters supported HHS adopting an active purchaser model in future years. Several commenters supported it as part of a larger strategy that they stated should also include both standardized plan options and a meaningful difference standard. Some of these commenters also stated that the State of California's use of this approach illustrates the benefits of limiting the number of plan offerings, lowering costs for consumers, setting standards for plan quality, and fostering robust competition among plans seeking entry into the Exchange.

However, multiple commenters opposed HHS adopting an active purchaser model for the Federal Exchanges, mainly due to concerns that doing so would put too much control over plan offerings in the hands of the Exchange, as opposed to allowing issuers the flexibility to design plans based on consumer preferences and needs. These commenters were also concerned that an active purchaser model could reduce the number of issuers willing to participate in Exchanges on the Federal platform by requiring issuers who are not selected for a given year to pause their individual market operations and later expend time and resources to apply in a future year.

Response: As noted in the proposed rule, HHS acknowledges that a number of State Exchanges have successfully employed an active purchaser model and that we intend to consider whether such a model would be appropriate in future PYs to further streamline the plan selection process for consumers on the Exchanges. HHS appreciates comments considering the advantages and disadvantages of such a model, and we will take this feedback into consideration as part of future decision-making processes.

F. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Reimbursement for Clinical Services Provided to Enrollees (§ 158.140)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 691), we proposed to amend § 158.140(b)(2)(iii) to clarify that only provider incentives and bonuses that are tied to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes. We are finalizing this proposal as proposed.

Section 2718(a) of the PHS Act requires health insurance issuers offering group or individual health insurance coverage (including a grandfathered health plan) to separately report the percentage of total premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees for activities that improve health care quality, as well as all other non-claim (administrative) costs. Section 2718(b) of the PHS Act requires a health insurance issuer to provide an annual rebate to each enrollee if the issuer's MLR falls below the applicable MLR standard. Section 158.140 sets forth the MLR reporting requirements related to reimbursement for clinical services provided to enrollees, including a requirement in § 158.140(b)(2)(iii) that issuers must include the amount of incentive and bonus payments made to providers with incurred claims. Due to the lack of clarity and specificity in the regulations, some issuers include an overly broad variety of incentive and bonus payments made to providers. The inclusion of many types of provider incentives and bonuses in incurred claims is appropriate and consistent with the purpose of the statute, but only to the extent that such bonuses incentivize providers to deliver objectively measurable higher-quality care and value for enrollees.

In the course of conducting MLR examinations pursuant to §§ 158.401 and 158.402, we observed some issuers reporting incentive or bonus payments to providers that are not based on quality or performance metrics, but rather, involve transferring excess premium revenue to providers to circumvent MLR rebate requirements and avoid paying MLR rebates when issuers do not meet the applicable MLR standard. The incentive for such arrangements is particularly high for integrated medical systems where the issuer is the subsidiary, owner, or affiliate of a provider group or a hospital system. Further, in some cases, these ''incentives'' or ''bonuses'' are not even paid to the clinical providers, but rather to the non-clinical parent holding company of the hospital or provider group and the issuer.

We summarize and respond to public comments received on the proposal to clarify the inclusion of provider incentives and bonuses in incurred claims (§ 158.140) below.

Comment: The overwhelming majority of commenters supported the proposed clarification and accompanying regulatory amendment. Commenters stated that this regulatory provision needs to be clarified and tightened to ensure the faithful execution of the MLR requirements. Commenters further stated that the proposed clarification is necessary to prevent issuers from evading compliance by inappropriately using the MLR standard itself to trigger ''incentive'' or ''bonus'' payments and to prevent issuers from inflating their MLRs by including any such payments that are not based on quality or performance metrics.

Response: We appreciate the supportive comments and agree that it is important to look beyond the labels used (for example, provider ''incentive'' or ''bonus'' payments) to confirm that the provider payments meet the applicable standards for inclusion in incurred claims for MLR reporting purposes. After considering public comments, we are finalizing the amendment to § 158.140(b)(2)(iii), as proposed, to explicitly clarify in regulation that to be included in incurred claims ''incentive'' or ''bonus'' payments to providers must be tied to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers. Any provider payment that is based on the financial condition or actions of the issuer may not be reported as incurred claims. For example, we generally believe that payment arrangements between issuers and providers that result in there being no scenario in which an MLR rebate would ever be paid to consumers or that are tied to the financial condition or actions of the issuer would violate both the letter and the spirit of the law. It is inappropriate to include such provider payments—even if labeled as ''incentive'' or ''bonus'' payments—as incurred claims in issuers' MLR calculations. This includes arrangements where the MLR standard itself is used as the threshold to determine whether such a payment is due, or because some other metric, such as issuer profit or surplus, is used, or if the arrangement is otherwise designed to substantially avoid compliance with the MLR rebate requirements.

Comment: One commenter that supported the proposal recommended that HHS also clarify that provider incentives and bonuses are not required to be excluded from incurred claims solely because they incorporate shared savings elements or cost efficiency requirements in addition to clinical quality requirements. This commenter further recommended a safe harbor for provider incentives that do not exceed a specified cap (such as 20 percent), make the incentive contingent on meeting objective clinical measurements, and require disclosure to any beneficiary that requests it.

Response: We confirm that under the proposal, the fact that a provider incentive or bonus program has a shared saving or other cost efficiency element does not disqualify the entire incentive or bonus from being classified as incurred claims, as long as the incentive or bonus is tied to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers. We do not believe that a safe harbor proposed by the commenter is necessary and decline to adopt one at this time.

Comment: Several commenters requested that HHS distinguish alternative payment models such as Accountable Care Organization (ACO) initiatives, arrangements where the issuer shares savings with providers, and value-based contracting (VBC) from the types of arrangements that were the cause for concern, and requested that HHS allow all bonuses and incentives paid under such alternative payment models to be reported as incurred claims. These commenters expressed concern that the proposal would inhibit issuers' ability to pursue such cost containment strategies and suggested that the proposal is inconsistent with HHS' support of value-based payment models. Some of these commenters asserted that purely financial savings that reduce the total cost of care are an appropriate basis for provider bonuses or incentives. Other commenters suggested that such alternative payment models reduce utilization needs and lead to better health outcomes, or at least lower costs while continuing to provide quality care.

Response: HHS continues to support innovative alternative payment models that deliver efficient and high-quality care. We further note that the MLR statute and HHS implementing

regulations in 45 CFR part 158 do not prohibit issuers from adopting a wide range of value-based payment models, including ones that may not be tied to clinical or quality standards. The clarification and accompanying amendment to § 158.140(b)(2)(iii), which we are finalizing as proposed, is instead limited in applicability to the treatment and reporting of these amounts for MLR purposes. As explained in the proposed rule (87 FR 691), in the course of conducting MLR audits, we uncovered several instances where provider payments labeled as ''incentive'' or ''bonus'' that were triggered based on the financial condition or actions of the issuer [347] were included in the issuer's incurred claims. This violates the spirit of the statute by artificially inflating the issuer's MLR and depriving consumers of the rebates they would otherwise be owed under section 2718(b) of the PHS Act. It is also inconsistent with the requirements that dictate separate reporting and treatment of the percentage of total premium review (after certain adjustments) expended on reimbursement for clinical services and activities that improve health care quality, and on all other non-claims (administrative) costs.[348] In order to increase compliance and improve program integrity, we are finalizing as proposed, the regulatory amendment to codify the agency's existing policy and interpretation of the statute regarding the treatment of provider ''incentives'' and ''bonuses'' that are not tied to clinical or quality standards for MLR reporting and rebate purposes. This will further ensure that consumers receive value for their premium payments and the rebates they are owed under the statute.

We agree with the commenter who suggested that value-based payment models can reduce utilization and lead to better outcomes, or lower costs, without compromising the quality of care. Issuers employing such models or arrangements should be able to demonstrate this through the use and documentation of appropriate clinical or quality metrics and thus such incentive or bonus payments would be eligible for inclusion in incurred claims. Further, we are not aware of any CMS value-based payment initiatives (such as Medicare shared savings initiatives and alternative payment models) that do not include clinical or quality standard requirements and generally disagree the adoption of the amendment to § 158.140(b)(2)(iii) is inconsistent HHS' support of innovative, value-based payment models.

Comment: One commenter expressed concern that the proposed clarification could potentially place (unspecified) burdens on physicians to earn the incentive and bonus money.

Response: While we acknowledge the comment, as the commenter did not provide any specifics regarding potential burdens, the substance of the commenter's concern is not clear. We note that this provision will not impact every provider incentive and bonus arrangement since, for example, it is unlikely to impact the majority of issuers that exceed MLR standards or existing arrangements, the majority of which are tied to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards applicable to providers. In addition, as discussed above, this provision does not prohibit issuers from adopting value-based payment models that may not be tied to clinical or quality standards. Nor does this provision require issuers to add clinical or quality documentation requirements on providers to existing value-based payment models.[349] Rather, the amendment to § 158.140(b)(2)(iii), which we are finalizing as proposed, is limited in applicability to the treatment and reporting of these amounts for MLR purposes. As explained above, the inclusion of provider incentives and bonuses in incurred claims when the incentives and bonuses fail to incorporate clinical or quality standards could create incentives to inappropriately reduce or even withhold medical care and would reduce the value consumers receive for their premium dollars.

Comment: One commenter recommended that we adopt a narrow exception to the reporting requirement under § 158.140(b)(2)(iii) for issuer payments to providers at risk of becoming insolvent due to extraordinary circumstances, such as the COVID pandemic, subject to prior approval of the applicable State regulator. According to this commenter, such payments in extraordinary circumstances may be necessary to enable providers to continue providing medical care and to ensure that issuers were able to comply with network adequacy requirements.

Response: We understand and commend issuers that made cash payments to help prevent at-risk providers from becoming insolvent due to the COVID pandemic in order to ensure that consumers had access to medical care. However, we did not propose and are not finalizing the exception suggested by the commenter. We intend to further consider the treatment of such payments in extraordinary circumstances under the MLR framework codified in 45 CFR part 158, and would address any policies in this regard in future guidance or rulemaking, as applicable.

Comment: One commenter urged HHS to exercise greater oversight of insurance companies that own or are owned by companies that also own networks of providers and other health care services. The commenter described a number of reporting or business practices made possible by vertical integration in health care that have the potential to erode the PHS Act MLR protections. According to the commenter, these include issuers channeling more health care dollars to their own provider groups, encouraging enrollment in an HDHP and contributing to an HSA offered by an affiliate, and reporting as QIA the expenses for utilization management programs that may not actually benefit enrollees or improve their health. Another commenter agreed that the examples of provider incentives described in the proposed rule are troubling but recommended that the more appropriate remedy is stronger enforcement rather than clarifying the regulations.

Response: We understand the commenter's concern regarding issuers that are integrated with health care providers and agree with the suggestions and will continue to focus our oversight and enforcement on ensuring issuer compliance with MLR reporting requirements for all of the different types of provider arrangements or payment models issuers may employ. As part of this effort, we intend to consider the impact of vertical integration on the reporting and treatment of provider payments under the MLR framework codified in 45 CFR part 158, including the impact on rebates owed to consumers. However, we note that our ability to identify non-

[347] This included arrangements under which payments were made to providers any time the issuer's MLR fell below a specified threshold, such as the applicable standard established in section 2718(b)(1)(A)(i) and (ii) of the PHS Act. Other arrangements of this nature used a metric tied to when the issuer's profitability exceeded a specified threshold. Payments were sometimes made to clinical providers or hospitals and other times were made to non-clinical parent holding companies.

[348] See section 2718(a) of the PHS Act and 45 CFR 158.110, *et seq.*

[349] We further note that to the extent the issuer elects to impose documentation requirements on its providers under a value-based payment model or other arrangements, those types of requirements would fall outside of the MLR calculation and rebate framework under section 2718 of the PHS Act and the implementing regulations at 45 CFR part 158.

compliant reporting of provider incentives and bonuses for targeted enforcement is limited as the MLR rules require issuers to aggregate by State and market the amounts they incurred for any such incentives and bonuses. Additionally, the MLR reporting requirements require issuers to report only the amounts incurred for provider incentives and bonuses and do not require them to describe or provide details about the incentive or bonus program itself. Thus, the level of detail that is available does not support easily identifying errant practices. In addition, we believe that clarification of the requirements in regulation is necessary and appropriate to increase awareness and ensure broad and uniform compliance. We also emphasize our intention to combine this regulatory clarification with heightened oversight and monitoring of compliance with MLR reporting and rebate requirements with respect to these types of arrangements to ensure consumers receive value for their premium payments, consistent with the statute.

Comment: A few commenters requested that the clarification be prospective to give issuers sufficient time to come into compliance.

Response: As explained above and in the proposed rule, the clarification and amendment to § 158.140(b)(2)(iii), which we are finalizing as proposed, codifies the Department's existing policy and interpretation of the statute. Including provider ''incentive'' or ''bonus'' payments that are not based on clearly defined, objectively measurable, and well-documented clinical or quality improvement standards in incurred claims artificially inflates the issuer's MLR and deprives consumers of the rebates they would otherwise be owed. This practice is also inconsistent with the statutory requirements that dictate separate reporting and treatment of the percentage of total premium review (after certain adjustments) expended on reimbursement for clinical services and activities that improve health care quality, and on all other non-claims (administrative) costs. We further note that the MLR requirements established under section 2718 of the PHS Act have generally been effective since 2011. Finally, as noted above, the adoption of this regulatory amendment does not require issuers to modify existing arrangements with providers. Instead, it is limited in applicability to the treatment and reporting of these amounts for MLR purposes. The next annual MLR report is not due until July 31, 2022.[350] For all of these reasons, we disagree that additional time is needed or should be provided for issuers to come into compliance.

After consideration of the comments received on this proposal, we are finalizing the regulatory amendment to § 158.140(b)(2)(iii) as proposed.

2. Activities That Improve Health Care Quality (§ 158.150)

In the HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 584, 691 through 692), we proposed to amend § 158.150(a) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses for MLR reporting and rebate calculation purposes. In order to ensure reporting consistency among issuers and ensure that QIA expenses included in the MLR numerator represent the actual value provided for consumers' premium dollars, consistent with the purpose of section 2718 of the PHS Act, we are finalizing the proposal to amend § 158.150(a) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses.

As discussed in the proposed rule (87 FR 691 through 692), section 2718(a) of the PHS Act requires health insurance issuers offering group or individual health insurance coverage (including a grandfathered health plan) to report the percentage of total premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees under such coverage, for activities that improve health care quality, as well as all other non-claims costs. Section 158.221 defines the numerator of an issuer's MLR to include the issuer's incurred claims plus the issuer's expenditures for activities that improve health care quality, as defined in §§ 158.150 and 158.151. Section 158.150 describes the types of activities that qualify as QIA, but does not specify the types of expenses that may be included as QIA expenses, or the extent to which such expenses must relate to the activity. The lack of clarity in existing regulations has caused wide discrepancies in the types of expenses that issuers include in QIA expenses and creates an unequal playing field among issuers.

Some issuers appropriately include only direct expenses, such as the salaries of the staff performing actual QIA functions in QIA expenses. However, other issuers additionally allocate indirect expenses such as overhead, marketing, lobbying, corporate or holding group overhead, and vendor profits in QIA expenses. For example, some issuers allocate to QIA fixed costs—such as office space or IT infrastructure—that would, for the most part, exist even if the issuer did not engage in any QIA. Some issuers include in QIA expenses amounts exceeding the cost of providing the actual QIA service. In addition, some issuers include the promotion or marketing of their QIA services to group policyholders or enrollees as QIA expenses. Some issuers also include the cost of developing the prices of QIA services sold to group policyholders, or costs associated with calculating and reporting QIA expenses. Further, some issuers are not able to precisely determine what portion of indirect costs is tied to QIA, as many issuers do not have an accurate method to quantify the actual cost of each expense category as it relates to each QIA, and thus issuers are often arbitrarily reporting or apportioning indirect expenses without adequate documentation or support.

We sought comment on this proposal.

We summarize and respond to public comments received on the activities that improve health care quality proposal (§ 158.150). We note that we received a few comments and suggestions that were outside the scope of the proposed rule, which are not addressed in this final rule.

Comment: The majority of commenters supported the proposal to amend § 158.150(a) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses. These commenters agreed that it is reasonable, appropriate, and necessary to prevent issuer MLRs from being inflated.

Most commenters generally agreed that overhead costs should not be allowed to be reported as QIA. A few commenters requested that certain non-salary expenses associated with employees performing QIA functions be allowed in QIA expenses. These commenters noted that employee benefits are part of compensation, and that expenses related to office space, equipment, and IT infrastructure are necessary for such employees to perform QIA. Several of these commenters stated that issuers should be allowed to allocate a portion of indirect costs to QIA on a pro rata basis. Several commenters requested that we provide a specific list of examples of expenses that are or are not permitted as direct expenses. Another commenter suggested that HHS should convene stakeholders to discuss an appropriate methodology for allocating indirect costs to QIA expenses rather than adopting the proposed amendment to

[350] See 45 CFR 158.110(b).

§ 158.150(a) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses.

Response: We appreciate the supportive comments on this proposal. We agree with commenters that non-salary benefits of employees performing QIA functions that are part of compensation packages are directly tied to QIA, and we clarify that we consider the cost of such employee benefits to be a direct QIA expense. Thus, the issuer's cost of health coverage, retirement contributions, life insurance, or similar benefits provided to employees actually performing QIA may be included in QIA expenses under § 158.150(a), as amended. However, similar to salary costs, such costs may only be included up to the percentage that reflects the percentage of the employees' time actually spent on QIA. Issuers that report such costs as QIA should take care to both document and retain records supporting the amount(s) reported and the determination of what portion of these costs are a direct QIA expense.[351]

However, as explained in the proposed rule, many of the other indirect expenses identified by these commenters[352] would be incurred even if issuers did not engage in QIA. For example, it is unlikely that an issuer's cost of purchasing, renting, and maintaining an office building or equipment is meaningfully impacted by the engagement of some of its employees in QIA. Therefore, we disagree that expenses for items such as office space, equipment, and IT infrastructure are directly or in some cases even indirectly related to QIA, or that they are incurred in the furtherance of quality improvement. As such, for MLR reporting and rebate purposes, these expenses are classified as non-claims, administrative costs and should not be included in the MLR numerator. Allowing issuers to report these same expenses as expenditures on QIA is inappropriate. It would undermine the purpose and intent of section 2718 of the PHS Act and would allow issuers to inflate QIA costs (and the MLR numerator) by including fixed costs that would be incurred regardless of whether the issuer engages in QIA. We also do not believe that there is a compelling policy rationale to allow issuers to automatically shift a *pro rata* portion of such costs to consumers. For the same reasons, we do not believe that convening stakeholders to discuss an appropriate methodology for allocating such expenses is necessary.

We provided multiple examples of the types of expenses that we consider to be indirect expense that should not be reported as QIA in both the proposed rule and this rule. Examples include: Office space (including rent or depreciation, facility maintenance, janitorial, utilities, property taxes, insurance, wall art), human resources, salaries of counsel and executives, computer and telephone usage, travel and entertainment, company parties and retreats, IT systems, and marketing of issuers' products. This list, however, is not intended to be exhaustive or all-inclusive. As a general matter, expenses for items or services that have no direct or quantifiable relationship to health care quality cannot reported as QIA and will not be considered direct QIA expenses. Conversely, expenses for items or services that primarily or exclusively support QIA as opposed to regular business or other functions, when reasonable and quantifiable,[353] are likely to constitute direct expenses that are properly included in QIA expenses. We intend to continue to monitor issuer QIA reporting and will issue further guidance, as may be necessary, and welcome stakeholder feedback on which other types of expenses they would like us to address in technical guidance on direct versus indirect expenses.

Comment: Two commenters expressed concern that, under the proposal, HHS appears to take the position that health information technology (HIT) expenses, which are specifically allowed by §§ 158.150 and 158.151, cannot be reported as QIA if they are determined to be indirect.

Response: We do not believe that the amendment to § 158.150(a) to specify that only direct expenses related to activities that improve health care quality can be included in QIA expenses for MLR reporting and rebate purposes conflicts with the definition of HIT at § 158.151. Section 158.151 defines HIT as specifically being ''designed for use by health plans, health care providers, or enrollees for the electronic creation, maintenance, access, or exchange of health information, as well as those consistent with Medicare and/or Medicaid meaningful use requirements.'' This definition recognizes that some information technology is HIT; while also recognizing that not all information technology is HIT. We affirm and clarify that HIT expenses that meet the applicable requirements in §§ 158.150 and 158.151 are permissible costs that can be included as QIA expenses. For example, the cost of software designed and used primarily for QIA purposes, such as HEDIS reporting, constitutes a direct expense related to activities that improve health care quality and can be included in QIA expenses for MLR reporting and rebate purposes. In contrast, as explained above and in the proposed rule, the costs of IT infrastructure that primarily supports regular business functions such as billing, enrollment, claims processing, financial analysis, and cost containment, even when the same IT infrastructure also happens to support QIA activities in addition to regular business functions, do not constitute a direct expense related to activities that improve health care quality and cannot be included in QIA expenses for MLR reporting and rebate purposes. As a simple example, the cost of the computer software license for an employee that works part of the time on QIA should not be allocated to QIA expenses for MLR reporting purposes. The fact that the employee uses this software to write QIA documents in addition to other documents does not convert this otherwise general non-claims, administrative cost into one of the types of expenses eligible to be included in the MLR numerator as QIA expenses.

Comment: A few commenters that opposed the proposal disagreed with the classification of the administrative expenses and profits of issuers' QIA vendors as indirect expenses. These commenters stated that this approach will disincentivize issuers from engaging vendors with appropriate expertise. Some commenters stated that vendors' administrative expenses and profits should be treated in the same manner regardless of whether vendors perform clinical services or QIA.

Response: We disagree that clinical providers' administrative costs and profits are analogous to non-clinical providers' administrative costs and profits. Clinical services are a provider function. QIA, on the other hand, is an issuer function. Where an issuer performs its own QIA without engaging a vendor, any ''profit'' that it makes on such QIA cannot be included in the MLR calculation. Accordingly, where an issuer chooses to outsource its QIA to a third party, rather than developing the necessary skills in-house, as it does for other issuer functions such as claims

[351] See 45 CFR 158.502.

[352] Examples of other indirect expenses identified by commenters include costs related to office space, equipment, and IT infrastructure.

[353] Consistent with 45 CFR 158.502, issuers must maintain all documents and other evidence necessary to enable HHS to verify that the data reported complied with the applicable definitions and criteria.

processing, network development, clinical policies, and case and utilization management, for example, for MLR reporting and rebate purposes that vendor stands in the shoes of the issuer. Consequently, the vendor's indirect costs, as well as any profit, cannot be reported as a QIA expense that is included in the MLR calculation.[354] We also disagree with the assertion that disallowing issuers to include QIA vendor administrative expenses and profits in QIA will disincentivize issuers from engaging with vendors with the appropriate expertise because, as noted, if the issuer were to perform the QIA itself, those same administrative expenses and profits would still not be a permissible inclusion in QIA. Further, many issuers have not been dissuaded from outsourcing claims processing, network development, clinical policies, and case and utilization management (UM) to vendors who have the respective, requisite expertise even though they cannot include the vendor's administrative expenses and profits in their MLR calculations.

Comment: A commenter urged us to review how insurers are categorizing their UM expenses and set clear guardrails around when, if ever, such activities can be categorized as QIA.

Response: We agree with the commenter that certain UM activities are designed to target cost-containment rather than quality improvement. To that end, under current regulations at § 158.150(c), issuers cannot include in QIA any prospective or concurrent UM costs or any retrospective UM costs that do not meet the definition of a QIA. Additionally, in the course of performing MLR examinations, HHS routinely reviews the UM program expenses that issuers report as QIA to ensure they comply with the regulatory requirements. We believe the current regulations provide sufficient guardrails on the reporting of UM expenses and therefore did not propose, and are not finalizing, any such changes at this time.

Comment: One commenter requested that we allow health equity accreditation costs in QIA.

Response: Issuers are currently permitted by § 158.150(b)(2)(i)(A)(5) to include in QIA expenses the costs associated with accreditation fees that are directly related to the quality of care activities. Therefore, to the extent, a health equity activity requiring accreditation meets the definition of a QIA at § 158.150, such accreditation fees can be reported as QIA expenses.

Comment: One commenter requested that the definition of QIA be revised to explicitly include issuer payments to providers for quality or clinical improvements directed at people with disabilities, such as the purchase of accessible medical and examination equipment.

Response: We did not propose and are not finalizing regulatory changes to address issuer payments to providers for quality or clinical improvements directed at people with disabilities. As such, modifying the regulation to specifically allow issuers to include expenses such as payments to clinical providers to purchase accessible medical office equipment for people with disabilities is out of the scope of this rulemaking. However, we note that to the extent such equipment purchases meet the requirements of § 158.150, § 158.151, or § 158.162(c), they may be included as QIA expenses in issuers' MLR calculations.

Comment: A few commenters requested that we clarify in which MLR reporting year the clarification is effective and requested that the effective date be prospective, suggesting that it should be effective beginning with the 2023 MLR reporting year to allow for contract renegotiation.

Response: We note that in the course of conducting MLR examinations, we have consistently disallowed some of the more egregious types of indirect expenses that issuers have reported and which we believe are unambiguously inconsistent with the spirit and intent of the law. Therefore, we are clarifying that this change is effective beginning with the 2021 MLR reporting year (reports due July 31, 2022). However, to allow issuers additional time to revise their reporting processes or undergo contract negotiations (and renegotiations), we intend to maintain the existing enforcement posture with respect to the MLR reports filed for the 2021 MLR reporting year, and will otherwise exercise enforcement discretion to not penalize issuers who make good faith efforts to comply and report QIA consistent with the clarifications in this rule until the 2022 MLR reporting year (reports due July 31, 2023). Issuers should not interpret this enforcement approach to justify reporting any and all indirect QIA expenses on their 2021 Annual MLR Reporting Forms; instead it is intended to provide a transition in the limited situations, such as those identified by the commenter, that present barriers to adjusting the issuer's reporting practices for the 2021 MLR reporting year.

After consideration of the comments received on this proposal, we are finalizing the amendment to § 158.150(a) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses, as proposed.

3. Allocation of Expenses (§ 158.170)

As noted in part 2 of the 2022 Payment Notice final rule, on March 4, 2021, the United States District Court for the District of Maryland decided *City of Columbus, et al.* v. *Cochran,* 523 F. Supp. 3d 731 (D. Md. 2021). Among other things, the court vacated § 158.221(b)(8), which provided that beginning with the 2017 MLR reporting year, an issuer had the option of reporting an amount equal to 0.8 percent of earned premium in the relevant State and market in lieu of reporting the issuer's actual expenditures for activities that improve health care quality, as defined in §§ 158.150 and 158.151.[355] Accordingly, in part 2 of the 2022 Payment Notice final rule, we finalized the deletion of § 158.221(b)(8) and removed the option allowing issuers to report the fixed, standardized amount of QIA and reverted to requiring issuers to itemize QIA expenditures, beginning with the 2020 MLR reporting year (MLR reports that were due by July 31, 2021). However, we inadvertently failed to make a conforming amendment to § 158.170(b). Section 158.170 addresses allocation of expenses in relation to MLR reporting in general. Section 158.170(b) requires issuers to describe the methods used to allocate expenses. Specifically, § 158.170(b) requires the report required in § 158.110 to include a detailed description of the methods used to allocate, among other things, ''quality improvement expenses (unless the report utilizes the percentage of the premium option described in § 158.221(b)(8), in which case the allocation method description should state so),'' to each health insurance market in each State. Given the deletion of § 158.221(b)(8) in part 2 of the 2022 Payment Notice final rule, the reference in § 158.170(b) to the percentage of premium QIA reporting option described in § 158.221(b)(8) is no longer applicable. Accordingly, we proposed to make a technical amendment to § 158.170(b) to correct this oversight and remove the reference to the percentage

[354] *See* 45 CFR 158.140(3)(ii) and CCIIO Technical Guidance (CCIIO 2011–002): Questions and Answer Regarding the Medical Loss Ratio Interim Final Rule, May 13, 2011, Q&As 10–14, at *https://wayback.archive-it.org/2744/20200125161941/https://www.cms.gov/CCIIO/Resources/Files/Downloads/mlr-guidance-20110513.pdf.*

[355] 86 FR 24140.

of premium QIA reporting option described in § 158.221(b)(8).

We summarize and respond to public comments received on the allocation of expenses proposed technical amendment (§ 158.170).

Comment: No commenters commented on this technical correction, but a commenter requested we reconsider and permit the previous allowance for plans to report 0.8 percent of earned premium as QIA in the MLR numerator to reduce the effort required of issuers to identify, track, and report QIA.

Response: While we appreciate the comment, as stated above, this change aligns § 158.170(b) with the vacatur of § 158.221(b)(8) by the United States District Court for the District of Maryland in *City of Columbus.* We are therefore finalizing this technical correction as proposed.

G. Solicitation of Comments on Health Equity, Climate Health, and Qualified Health Plans

To further HHS' aims to proactively advance health equity and improve the health of all Americans, including racial and ethnic minorities, sexual and gender minorities, people with disabilities, individuals with limited English proficiency, rural populations, and historically underserved communities, HHS is considering other ways to incorporate health equity standards through HHS' authority to enhance criteria for the certification of QHPs or by leveraging existing QHP requirements such as the Network Adequacy Standards at § 156.230 and Accreditation of QHP Issuers at § 156.275. We also sought input on additional ways to incentivize QHP issuers to improve health equity and improve conditions in enrollees' environments, as well as to address other SDOH outside of the QHP certification process.

We also sought comment on ways HHS might improve its understanding of the existing landscape of issuer collection of health equity data, including demographic information, as well as comment on how HHS might assess data sources that focus on population-level factors made available by governments, quasi-governmental entities, data vendors and other organizations. Specifically, we sought input on, among other things, health equity assessment tools, the challenges QHP issuers could face implementing a new accreditation product on health equity; [356] and information on the demographic or SDOH data QHP issuers currently collect from enrollees. We summarize and respond to public comments received on HHS' solicitation of comments on health equity and climate health.

Comment: Commenters supported CMS' suggestion for QHP issuers to obtain a health equity accreditation, and some specified support for the National Committee for Quality Assurance (NCQA) Health Equity Accreditation to encourage issuers to take meaningful steps to advance health equity. Some commenters expressed concerns that the scope of the NCQA's Heath Equity Accreditation was too narrow, noting that the NCQA does not explicitly discuss disability status in their accreditation language and that the accreditation is still new while other commenters found the NCQA's Health Equity Accreditation requirements too broad. In addition, commenters noted that NCQA may have not collaborated with the historically marginalized groups that are disproportionately impacted by health disparities when they developed the parameters of the accreditation. Furthermore, some commenters expressed concern with CMS sourcing a health equity accreditation from one accrediting body, suggesting that other organizations' accreditations may also provide useful parameters and requirements. A few commenters expressed that requiring any additional QHP accreditations would create significant cost and burdens for issuers.

Response: We appreciate commenters' input on potentially requiring issuers to obtain a health equity accreditation and the challenges QHP issuers could face implementing a new accreditation product. We will consider the feedback as we continue to explore options for advancing health equity in the Exchanges.

Comment: Commenters supported the idea of collecting demographic or SDOH data, including information on enrollees' race, ethnicity, gender, sexual orientation, primary language, and disabilities, while also acknowledging the challenges of collecting data.

Commenters encouraged HHS to set standards for how issuers and other stakeholders should collect demographic data and suggested that recommendations from the Institute of Medicine, the Williams Institute at the University of California, Los Angeles, and forthcoming recommendations from the National Academies of Sciences, Engineering, and Medicine could offer foundational guidance. Commenters also suggested that HHS set an example for improving data collection.

While noting the importance of collecting accurate demographic data, some commenters identified data sharing and use agreements, Federal privacy and data protection laws, State laws, and a lack of formal standards for collecting data as barriers that may impede issuers' abilities to meaningfully collect and use SDOH and demographic data.

Response: We appreciate the commenters' insight into the current landscape of demographic data and SDOH. We will take these comments into consideration when considering ways to advance health equity through QHPs.

Comment: Commenters provided examples of datasets related to population factors that CMS could leverage to analyze whether QHP networks are providing adequate access to health care services for members within specific geographic areas, such as social vulnerability index scores, provider and consumer data, Provider Master Index/Shared Provider Profile (PMI/SPP), and census data.

Response: We will consider the use of these data sources to analyze and evaluate QHPs' performance related to providing equitable access to health care services.

Comment: Some commenters commented on the ability of QHP issuers to tailor provider networks based on the health needs of enrollees in specific geographic areas. Commenters were supportive of tailored provider networks, noting that issuers could contract with and develop networks based on the health needs of their enrollees, which issuers could identify through improved data collection. Commenters suggested QHP issuers could conduct this work in concert with CMS' ECP requirements.

Response: We appreciate the input and will consider the feedback as we continue to explore ways to promote health equity.

Comment: Commenters discussed health conditions and outcomes variables for which analysis and measurement may help CMS promote health equity. While many of these commenters encouraged CMS to use appropriate variables to promote health equity without providing specific feedback, some commenters identified populations that were vulnerable and may require target interventions to improve health outcomes. Some examples of the populations identified

[356] *Health Equity.* National Committee for Quality Assurance. *https://store.ncqa.org/accreditation/health-equity-he.html.*

were minority mothers, individuals with diagnosed opioid use disorder or substance use disorders, individuals with special immigrant juvenile status, and individuals with behavioral health conditions.

Some commenters also suggested options that CMS could consider to effectively use outcome variables for analysis and measurement, which included relying on network adequacy standards to ensure that adequate health care services are available and provided, adding Value-Based Insurance Designs into the Exchanges, increasing the ratio of required Essential Community Provider contracts, and educating providers on the use of ICD–10 z-codes.

Response: We appreciate the suggestions for the use of health conditions and outcomes variables for which analysis and measurement may help CMS promote health equity. HHS understands the importance of addressing vulnerable populations as it continues to explore ways to promote health equity.

Comment: Several commenters offered feedback on ways in which CMS could encourage QHP issuers to be accountable for improving health outcomes across all populations equitably. Commenters suggested that CMS encourage QHP issuers to engage with local organizations and become more integrated with providers and other community partners. Commenters also suggested that CMS could hold QHP issuers financially accountable for integrating with the communities they serve or for a small number of clinical measures.

Response: We will consider these suggestions as ways to advance health equity through QHPs.

Comment: Some commenters suggested that CMS could incentivize QHP issuers to advance health equity outside of the QHP certification requirement by considering activities that promote health equity as a QIA within MLR calculations or tie equity to plans' quality ratings. Several commenters recommended that we define QIA to explicitly include expenses related to coverage of SDOH and interventions that address social barriers to care or other health disparities. One commenter requested that we specify what types of SDOH expenses qualify as QIA.

Response: We appreciate these comments and supports issuers' efforts to design plans that improve health equity and address SDOH and will consider these suggestions as ways to promote health equity. While modifying the MLR regulation and framework to explicitly allow issuers to include investments in SDOH is outside the scope of this rulemaking, we will consider these comments for future rulemaking or guidance. We note that under the current MLR regulation at § 158.140, issuers can include SDOH costs in incurred claims if the SDOH expenses are for a covered policy benefit. Issuers can also include SDOH expenses that do not relate to covered benefits in QIA if the underlying activity meets the definition and applicable criteria for QIA at § 158.150. Additionally, issuers exempt from Federal income tax or not subject to State premium taxes can, pursuant to §§ 158.162(b)(1)(vii) or 158.162(b)(1)(viii), respectively, deduct the expense from earned premium to the extent their SDOH expenses meet the regulatory definition of Community Benefit Expenditures under § 158.162(c).

Comment: Commenters discussed challenges that QHP issuers face in promoting and advancing health equity, but did not specify strategies that could overcome these challenges. Challenges included lack of Federal guidance and standardization for data collection.

Response: We appreciate the feedback and will consider these suggestions as we explore ways to promote health equity.

Comment: Commenters suggested several health equity tools that may help CMS address health disparities within QHPs, for example, Area Deprivation Index, Population Health Assessment, Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey, additional NCQA resources, and updated HEDIS health equity measures. In addition, commenters noted the Institute of Medicine, the Williams Institute at UCLA, and the National Academies on race, ethnicity, and language (REL) could offer models for health equity tools that CMS may want to consider.

Response: We will consider these health equity tools as a way to advance health equity through QHPs.

HHS also sought comment on how Exchanges and related health care system organizations can more readily prepare for the impacts of climate change. HHS believes that it is critical to study and prepare for these impacts given mounting evidence linking climate change to catastrophic natural events and chronic disease disproportionately harming at-risk populations including groups already suffering serious health disparities.

Comment: Of the 52 total comments received by HHS, all commenters acknowledged the threats climate change presents to human health and supported health care stakeholders considering the impact of climate change on their enrollees, providers, and employees. Twenty-five commenters supported the collection and public reporting of greenhouse gas emissions data by providers and, in fewer cases, issuers. Thirteen commenters noted the importance of preparing health care systems for climate health threats by identifying at-risk enrollees prior to climate change events to better assist them with access to cooling and clean air resources. Twelve commenters suggested tying health care system and provider reimbursement to action on climate change and emissions reduction. Some commenters suggested incentives tied to action, and others suggested fines due to lack of commitment. Twelve commenters discussed the relationship between climate change and social determinants of health, noting the importance of anticipating and managing climate change's impact on the health of certain marginalized and high-risk populations. Nine commenters suggested that issuers or health care systems should further educate providers and enrollees about the health effects of climate change. Three commenters noted the importance of creating or updating measures sensitive to climate health impacts. Two commenters noted the strong connection between climate change and respiratory health problems. Additional commenters noted the impact of climate change on maternal and child health; women's health; skin cancers; and maintaining care quality. Commenters also mentioned the need to develop better forecasting tools to anticipate climate disasters and threats; maintaining care quality, and consider supply chain contributions to overall health care sector emissions.

Specific insight was shared on possible actions health care systems and issuers could take to better support preparedness for climate disasters and related impacts, especially for at-risk populations, and the opportunity for issuers to provide education and technical assistance on climate resilience and emissions reduction to providers and enrollees.

Response: These comments will inform HHS in determining how best to support the health care system and benefit delivery changes in response to climate change. These comments also will inform HHS through its Office of Climate Change and Health Equity, as well as other Federal agencies pursuing policies on climate change.

We will consider these comments as we consider ways QHPs can be more effective in addressing climate health.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. This final rule contains information collection requirements that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Tables 18 and 19. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

We summarize general comments on the Collection of Information Requirements (ICR) below:

Comment: A few commenters provided general comments regarding the ICR section of the proposed rule. These commenters urged HHS to consider the impact of the various data collection requirements on impacted entities. One commenter noted that the burden estimates contained in the ICR compound, and urged HHS to consider their total impact on the affected entities. Another commenter requested that HHS suspend new data collection on the proposed policies during the COVID–19 PHE to relieve the operational burden on impacted entities.

Response: We have carefully considered the burden of the information collection requirements associated with the proposed policies, including their combined impact, which is quantified in the Final Annual Recordkeeping and Reporting Requirements Tables, and the Accounting Table. While we appreciate the burden placed on all systems during the COVID–19 PHE, we believe that the new information collections for the finalized policies are necessary to carry out the proper functions of the agency.

A. Wage Estimates

To derive wage estimates, we generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.[357] Table 17 in this final rule presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage. As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 17: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr.)	Fringe Benefits and Overhead ($/hr.)	Adjusted Hourly Wage ($/hr.)
Management Analyst	13-1111	$48.33	$48.33	$96.66
Business Operations Specialist	13-1199	$38.10	$38.10	$76.20
Operations Manager	11-1021	$55.41	$55.41	$110.82
Computer and Information Systems Manager	11-3021	$78.33	$78.33	$156.66
Eligibility Interviewers, Government Programs	43-4061	$23.35	$23.35	$46.70
Computer System Analyst	15-1211	$49.14	$49.14	$98.28
Computer Programmer	15-1251	$46.46	$46.46	$92.92
Computer & Information Systems Manager	11-3021	$78.33	$78.33	$156.66
Compliance Officer	13-1041	$36.45	$36.45	$72.90
Web and Digital Interface Designer	15-1255	$45.90	$45.90	$91.80

B. ICRs Regarding State Flexibility for Risk Adjustment (§ 153.320)

We are finalizing the proposal to repeal the risk adjustment State flexibility to request reductions to risk adjustment State transfer payments for the 2024 benefit year and beyond, as proposed. We are also finalizing, as proposed, to provide an exception for the States that previously submitted State flexibility requests under § 153.320(d) to allow those States to continue to request this flexibility in the 2024 benefit year and beyond. As part of this policy, we are also finalizing, as proposed, the removal of the option for States applying under this exception in the 2024 benefit year and beyond to demonstrate the State-specific factors that warrant an adjustment to more precisely account for relative risk differences in the State individual catastrophic, individual non-catastrophic, small group, or merged market risk pool as a justification for the State's request and the criteria for HHS

[357] May 2021 National Occupational Employment and Wage Estimates. Available at *Occupational Employment Statistics.* (2022, March 31). Bureau of Labor Statistics. *https://www.bls.gov/oes/current/oes_stru.htm.*

approval. This retains the *de minimis* standard as the only option for prior participants to justify the reduction and for HHS to approve a request and is designed to help ensure that consumers would not experience an increase in premiums greater than 1 percent as the result of a State requested reduction in transfers. Further, we are finalizing this policy as proposed with the intention to propose in future rulemaking to repeal the exception for prior participants beginning with the 2025 benefit year to provide impacted stakeholders additional time to prepare for this proposed change and the potential elimination of this flexibility. Consistent with these policies, we finalized various amendments to the risk adjustment State flexibility regulations at § 153.320(d) to reflect the general repeal of this flexibility, with the exception of prior participants, and to remove one of the criteria for State justification and HHS approval beginning with the benefit year 2024 requests.

The burden associated with this requirement is the time and effort for the State regulator to submit its request and supporting evidence and analysis to HHS. Since publishing the proposed rule, we have updated the burden associated with this requirement based on the most recent available national occupational employment and wage estimates statistics. We estimate that submitting the request and supporting evidence and analysis will 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 will 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 insurance operations analyst and 20 hours for the senior manager). We have updated the estimated burden related to the submission of these requests because only one State, will continue to have this ability to make this request on the policy being finalized in this rule. In the 2019 Payment Notice,[358] we estimated that 25 States would submit requests and provided a total burden of approximately 1,500 hours across all States, which would total $131,610 based on current wage estimates. Since we estimate that only one State will continue to request reductions, we estimate that this burden will be reduced by $126,345.60 to a total annual cost of $5,264.40, reflecting the burden associated with one State's submission. We are finalizing this proposal to account for the burden associated with this revision, HHS submitted a reinstatement request to OMB for approval of the previously expired information collection request (OMB control number 0938–1155/CMS–10401). As noted in previous sections of this rule, HHS intends to propose in future rulemaking to fully repeal the State flexibility framework and eliminate the ability of prior participants to request reductions in risk adjustment transfers starting with the 2025 benefit year.

We did not receive any comments in response to the information collection requirements related to the proposed policy.

C. ICRs Regarding Distributed Data and Risk Adjustment Data Submission Requirements (§§ 153.610, 153.700, and 153.710)

We are finalizing the proposal to collect and extract five new data elements from issuers' EDGE servers: ZIP Code, race, ethnicity, ICHRA indicator, and subsidy indicator beginning with the 2023 benefit year. Specifically, we are finalizing that starting with the 2023 benefit year, issuers will be required to populate the ZIP Code data field, using the five-digit level based on the enrollee's mailing address, and the subsidy indicator data field, which is intended to indicate whether a particular enrollee is (or is not) receiving APTC. For the 2023 and 2024 benefit years, we are adopting a transitional period during which issuers are required to populate the fields for race and ethnicity using only data they already collect or have accessible regarding their enrollees.[359] For example, for the 2023 and 2024 benefit years, for race and ethnicity data, issuers will be deemed in compliance if they submit these data elements using data they already have or collect through existing means, including, for example, through enrollee data captured and reported to the issuer by the FFE, SBE–FPs, and State Exchanges at the time of enrollment. Then, beginning with the 2025 benefit year, the transitional approach will end, and issuers will be required to populate the fields using available sources and, in the absence of such an existing source for particular enrollees, to make a good faith effort to ensure collection and submission of the race and ethnicity data for these enrollees.

We are also finalizing, with slight modification, collection of the ICHRA indicator. For the 2023 and 2024 benefit year, similar to the transitional approach for race and ethnicity data, issuers are required to populate the field for the ICHRA indicator using only data they already collect or have accessible regarding their enrollees. Then, beginning with the 2025 benefit year, the transitional approach will end, and issuers will be required to populate the field using available sources (for example, information from Exchanges and small employers, 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 ICHRA indicator for these enrollees. HHS will provide additional details on what constitutes a good faith effort to ensure collection and submission of the race, ethnicity, and ICHRA indicator data elements beginning with 2025 benefit year data submissions in the future.[360]

In addition, as detailed earlier, we are finalizing the extraction of the three data elements that issuers already make accessible to HHS as part of the required risk adjustment data—plan ID, rating area, and subscriber indicator—but will extract plan ID and rating area beginning with the 2021 benefit year, and the subscriber indicator beginning with the 2022 benefit year. We concluded the proposals to extract these data elements will not pose an additional operational burden to issuers, since the creation and storage of the extract—which issuers do not receive—is mainly handled by HHS. Therefore, we did not propose to change the existing burden for the proposal to extract plan ID, rating area, and subscriber indicator.

For the five new data elements we proposed to collect beginning with the 2023 benefit year, we estimated that approximately 600 issuers would be subject to this new data collection. We proposed to collect these new data elements via issuers' ESES files and risk adjustment recalibration enrollment files. In the proposed rule (87 FR 584 and 695), we estimated a cost of

[358] 82 FR 51118.

[359] HHS will collect these data elements in a format that is consistent with the 2011 HHS Data Standards. We also will provide a value for the race or ethnicity data elements that allows issuers to indicate that race or ethnicity are not known for a specific enrollee in recognition of situations where the enrollee declines to provide the information and situations where the issuer does not have an available data source to populate the fields.

[360] After the transitional approach ends (beginning in the 2025 benefit year), the option to select the value to indicate race or ethnicity are not known for a specific enrollee will be available to issuers who comply with the good faith standard but are unable to populate the race or ethnicity EDGE data field for one or more enrollees.

approximately $375.28 in total labor costs for each issuer, which reflects 4 hours of work by a management analyst per issuer at an average hourly rate of $93.82 per hour. The cumulative additional cost estimate as a result of this proposal was $225,168 for 600 issuers (2,400 total hours per year for all issuers). We explained the proposals to extract these data elements would not pose an additional operational burden to issuers, since the creation and storage of the extract are mainly handled by HHS. We are finalizing the proposed collection and extraction of ZIP Code, race, ethnicity, the ICHRA indicator, and the subsidy indicator. HHS submitted a reinstatement request to OMB for approval of the previously expired information collection request (OMB control number 0938–1155/CMS–10401). Once reinstated, HHS will revise the information collection request to account for the burden associated with this policy, and will provide the applicable comment periods.

After a review of the comments received, and after incorporating the most recently updated wage estimate data, we are updating the burden estimates for this policy as described below.

We summarize and respond to public comments received on ICRs related to Distributed Data and Risk Adjustment Data Submission Requirements (§§ 153.610, 153.700, and 153.710) below.

Comment: One commenter disagreed with the estimated 4 hours of work per issuer to collect and submit additional data elements estimated in this section of the proposed rule and reflected in the regulatory impact analysis of the proposed rule. The commenter stated that the cost associated with these collection and extraction proposals would be 500 hours of work per issuer. The commenter did not provide further detail regarding the methodology used to calculate its burden estimate of 500 hours.

Response: We are finalizing the proposal to require issuers of risk adjustment covered plans to submit and make accessible five new data elements (ZIP Code, race, ethnicity, the ICHRA indicator, and the subsidy indicator) as part of the enrollee-level EDGE data to HHS in States where HHS operates the risk adjustment program beginning with the 2023 benefit year. We are also finalizing the accompanying proposal for HHS to extract these data elements once available. To better reflect the most current agency estimates, we have modified the estimates from our proposed rule. Currently, all issuers that submit data to their EDGE servers [361] have automated the creation of data files that are submitted to their EDGE servers. For successful EDGE server data submission, each issuer will need to update their file creation process to include the five new data elements, which will require a one-time administrative cost. After incorporating the most recently updated wage estimate data, we estimate this cost at $2,899.80 (reflecting 30 hours of work by a management analyst at an average hourly rate of $96.66 per hour). In addition, rather than 4 hours of work, we now estimate, based on the most current agency estimates, that the new data collection will require 5 hours of work by a management analyst (one hour of work per new data element collected), at an average hourly rate of $96.66 per hour. We have limited this estimate to the incremental information collection associated with the requirements of the new data collection. As such, although the new data collection requires that issuers transform and submit additional data elements, it does not require changes to the process or distributed data collection approach currently used by an issuer to submit and make risk adjustment data accessible to HHS, which is via issuers' ESES files and risk adjustment recalibration enrollment files on their EDGE servers. We also estimate that approximately 650 issuers, rather than 600 issuers as initially estimated, will be subject to this new data collection. Based on these modifications, we estimate approximately $483.30 in total labor costs per year for each issuer. In addition, the cumulative one-time cost to update issuers' file creation process is $1,884,870 for 650 issuers (19,500 total hours for all issuers). The cumulative additional annual cost estimate as a result of this proposal is $314,145 for 650 issuers (3,250 total hours per year for all issuers).

In addition, we are finalizing the proposed extraction of the three data elements that issuers already make accessible to HHS as part of the required risk adjustment data—plan ID, rating area, and subscriber indicator—but will extract plan ID and rating area beginning with the 2021 benefit year, and the subscriber indicator beginning with the 2022 benefit year. As explained previously in this rule and in the proposed rule, extracting these data elements will not pose an additional operational burden to issuers since the creation and storage of the extract are not received by issuers and is primarily handled by HHS. Therefore, there is no additional issuer burden associated with extracting any of the new data elements that will be collected (ZIP Code, race, ethnicity, the ICHRA indicator, and the subsidy indicator), or with extracting the data elements that are already being collected (plan ID, rating area, and subscriber indicator).

D. ICRs Regarding 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)

In this final rule, we are finalizing the proposal to revise § 155.220(c)(3)(i)(A) to include at proposed new §§ 155.220(c)(3)(i)(A)(*1*) through (*6*) [362] a list of the QHP comparative information web-broker non-Exchange websites are required to display consistent with § 155.205(b)(1). We are also finalizing the proposal to revise the disclaimer requirement in § 155.220(c)(3)(i)(A) so that web-broker non-Exchange websites would be required to prominently display a standardized disclaimer provided by HHS stating that enrollment support is available on the Exchange website and provide a web link to the Exchange website where enrollment support for a QHP is not available using the web-broker's non-Exchange website. We are finalizing as proposed.

The revised disclaimer policy should result in a very limited new burden for web-brokers. The new standardized disclaimer requires web-brokers to make minor updates to their non-Exchange websites in cases where they do not support enrollment in all available QHPs. However, in those cases, web-brokers will be displaying a disclaimer much like the plan detail disclaimer that they have historically been required to display.

We estimated the revised disclaimer policy will affect approximately 20 web-brokers based on the number of web-brokers currently approved by CMS and our internal knowledge of entities that have expressed interest in becoming

[361] Issuers that elect a risk adjustment default charge are not required to submit EDGE data. See 45 CFR 153.740(b) and 81 FR at 12237–12238. Also see, for example, *Summary Report on Permanent Risk Adjustment Transfers for the 2020 Benefit Year* (2021, June 30). CMS. *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2020.pdf.*

[362] While the preamble in the proposed rule referred to amendments to add new § 155.220(c)(3)(i)(A)(*1*) through (c)(3)(i)(A)(*5*), the discussion of the proposal and the proposed regulations made clear that the proposal would add new § 155.220(c)(3)(i)(A)(*1*) through (c)(3)(i)(A)(*6*). See, for example, 87 FR 641 through 642 and 721 through 722.

web-brokers. Given the minor modifications necessary to implement the revised disclaimer, we estimated a cost of $411 in total labor costs for each web-broker, which reflects 5 hours of work by Web Developers and Digital Interface Designers (15–1257) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of $82.20. The cumulative additional cost estimate as a result of this policy is $8,220 for 20 web-brokers in the 2022 benefit year. We have updated these estimates based on the most recent available national occupational employment and wage estimates. We estimate a cost of $459 in total labor costs for each web-broker, which reflects 5 hours of work by Web and Digital Interface Designers (15–1255) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of $91.80. The cumulative additional cost estimate as a result of the revised disclaimer policy is $9,180 for 20 web-brokers in the 2022 benefit year. We are finalizing this proposal and will revise the information collection under OMB control number 0938–1349 accordingly and provide the applicable comment periods.

We are also finalizing the proposal to amend § 155.220 to add a new paragraph (c)(3)(i)(M) that would require web-broker websites to prominently display a clear explanation of the rationale for explicit QHP recommendations and the methodology for the default display of QHPs on their websites (for example, alphabetically based on the plan name, from lowest to highest premium, etc.). We are finalizing as proposed.

This policy should result in very limited new costs for web-brokers, since the information it requires they display on their websites is limited to text-based changes that are relatively easy to implement. Some web-brokers are already providing the information, and therefore, will not have to make any website updates. Other web-broker websites do not explicitly recommend QHPs, and therefore, the impact is limited to providing similar information about the methodology for their default display of QHPs (for example, explaining QHPs are sorted from lowest to highest premium, etc.), assuming they do not already provide that information. Furthermore, the extent of those textual updates should be relatively minor in most cases. We expect explanations to be short and easy for consumers to understand. Generally, we believe that a single phrase or a few sentences will suffice.

We estimated this policy will affect approximately 20 web-brokers. Given the minor text-based changes necessary to implement the informational text detailing the rationale for QHP recommendations and the methodology for a default display of QHPs, we estimated a cost of $411 in total labor costs for each web-broker, which reflects 5 hours of work by Web Developers and Digital Interface Designers (15–1257) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of $82.20. The cumulative additional cost estimate as a result of this policy is $8,220 for 20 web-brokers in the 2022 benefit year. We have updated these estimates based on the most recently available national occupational employment and wage estimates. We estimate a cost of $459 in total labor costs for each web-broker, which reflects 5 hours of work by Web and Digital Interface Designers (15–1255) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of $91.80. The cumulative additional cost estimate as a result of this policy is $9,180 for 20 web-brokers in the 2022 benefit year. We are finalizing this proposal and will revise the information collection under OMB control number 0938–1349 accordingly and provide the applicable comment periods.

E. ICRs Regarding Verification of Eligibility for Special Enrollment Periods (§ 155.420)

Since 2017, the Exchanges on the Federal platform have implemented pre-enrollment special enrollment period verification for special enrollment period types commonly used by consumers to enroll in coverage. We proposed to amend § 155.420 to add a new paragraph (g) to State that Exchanges may conduct pre-enrollment eligibility verification for special enrollment periods at the option of the Exchange. The Exchanges on the Federal platform would verify special enrollment period eligibility for the most common special enrollment period type, loss of minimum essential coverage. This special enrollment period type comprises the majority of all special enrollment period enrollments on the Exchanges on the Federal platform.

Since consumers on Exchanges on the Federal platform currently must provide eligibility verification documentation for more special enrollment period types, the provision would decrease the burden on consumers applying for special enrollment period types that no longer require pre-enrollment verification. We expected that it takes an individual, on average, about 1 hour to gather and submit the relevant documentation needed for pre-enrollment special enrollment period eligibility verification. This estimate is based on the assumption that each individual required to submit documentation will submit, on average, two documents for review. It could take significantly less time if an individual already has the documents on hand, or more time if the individual needs to procure documentation from a government agency or other source.

Based on enrollment data for Exchanges on the Federal platform, we estimate that HHS eligibility support staff members would conduct pre-enrollment verification for 194,000 fewer individuals compared to a total of 970,000 individuals in 2019. We estimated that once individuals have submitted the required verification documents, it would take an Eligibility Interviewer approximately 12 minutes (at an hourly cost of $46.14) to review and verify submitted verification documents. We have updated these estimates to reflect the most recent wage estimates based on the most recent national occupational employment and wage estimates. We anticipate that it will take an Eligibility Interviewer approximately 12 minutes (at an hourly cost of $46.70) to review and verify submitted verification documents. In 2017, the Exchanges on the Federal platform expanded pre-enrollment special enrollment period verification to include five special enrollment period types and estimated an annual additional administrative burden of 130,000 hours at a cost of $5,306,600.[363] Limiting pre-enrollment verification to one special enrollment period type would decrease the annual administrative burden of special enrollment period verification. The proposed change would result in a decrease in the annual burden for the Federal Government of 38,800 hours at a cost of $1,811,960. It would also result in a decrease in the annual burden for consumers attesting to special enrollment period types that no longer require document verification of 194,000 hours.

We are finalizing this requirement and the related burden decrease discussed in this section will be submitted for OMB review and approval as part of a revision of the information collection currently approved under OMB control number 0938–1207 (Expiration date: February 29, 2024).[364]

[363] 82 FR 18346.

[364] Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing;

We did not receive any comments in response to the information collection requirements related to the proposed policy.

F. ICRs Regarding General Program Integrity and Oversight Requirements (§ 155.1200)

1. Programmatic Audit Requirement (§ 155.1200(c))

We proposed to add § 155.1200(e) to permit a State Exchange to meet the requirement to conduct an annual independent external programmatic audit, as described at § 155.1200(c), by completing an audit that year under the SEIPM audit process we proposed under part 155, subpart P. We estimated that there would be a burden reduction for State Exchanges related to the programmatic audit requirement under § 155.1200(c). Based on industry estimates of the average cost of contracting an auditor to conduct an independent external programmatic audit, HHS estimated that the cessation of contracting such audit entities would result in an annual cost reduction of approximately $90,000 for each State Exchange, which is described in detail in the RIA section of this rule.

Additionally, staff resources would no longer be needed to submit the results of the programmatic audit as a component the SMART. This proposal would remove the burden associated with reporting requirements, which includes the burden for a management analyst taking 3 hours (at $93.82 an hour) to pull data into a report, the time and effort necessary for a policy analyst taking 2 hours (at $93.82) to prepare the report of the audit results, and the time for a senior manager taking 1 hour (at $155.52 an hour) to review and submit to CMS. We estimated the burden of 6 hours at a cost of $624.62 for each State Exchange. Therefore, the aggregate burden for the 18 State Exchanges that manage their own eligibility and enrollment platforms is 108 hours at a cost of $11,243.16.

Based on these estimates, we expected the cost reduction associated with compiling and reporting audit data to total $11,243.16 across all 18 State Exchanges beginning in the 2024 benefit year.

We requested comment on the reduction in burden proposed, and specifically sought feedback from State Exchanges regarding the annual cost of the programmatic audit process.

We did not receive any comments in response to the information collection requirements related to the proposed policy. We are not finalizing this provision at this time. Since we are not finalizing this provision, we have not provided updated burden estimates based on the most recently published wage estimate date. We provide further details in the preamble section of this final rule.

2. Reporting on APTC Calculation Methodology (§ 155.1200(b)(2))

We are finalizing to codify the proposed APTC proration methodology to be used by the Exchanges on the Federal platform, but we are not finalizing the requirement to prorate premium or APTC amounts for State Exchanges. Rather, beginning in PY 2024 we will require State Exchanges to implement a methodology to ensure that the total monthly APTC amount does not exceed an enrollee's monthly PTC eligibility to maintain compliance with HHS and IRS regulations. We are also finalizing the requirement that State Exchanges must prospectively report to HHS through existing State Exchange oversight mechanisms described at § 155.1200(b)(2) the methodology the State Exchange plans to use in PY 2024. The requirement to report this methodology to HHS will be fulfilled through the SMART and will impose minimal burden on State Exchanges, who already report on eligibility and enrollment and compliance with other Exchange program requirements through this tool. This information collection is currently approved under OMB control number: 0938–1244 (Expiration date July 31, 2022/CMS–10507).

G. ICRs Regarding State Exchange Improper Payment Measurement Program (§§ 155.1500–155.1540)

1. Data Collection (§ 155.1510)

As described in the preamble to § 155.1510, we explain the sampling process for each SEIPM review cycle. In § 155.1510(a)(1), we proposed that HHS will provide State Exchanges with the pre-sampling data request, which State Exchanges will complete and return to HHS. Both the pre-sampling data request and the requested source data are in an electronic format. The burden associated with completion and return of the pre-sampling data request would be the time it would take each State Exchange to interpret the requirements, analyze and design the database queries based on the data elements identified in the SEIPM data request form, develop the database queries, test the data, perform verification and validation of the data, and return the form to HHS.

Once the pre-sampling data request is returned to HHS, HHS will draw the sample for each State Exchange. In § 155.1510(a)(2), we proposed that HHS will provide the sampled unit data request to the State Exchange for completion and return to HHS. The sampled unit data request will include the sampled units specific to each State Exchange. Both the sampled unit data request and the requested source data are in an electronic format. The burden associated with the completion and return of the sampled unit data request would be the time it would take each State Exchange to interpret the requirements, analyze and design the database queries based on the data elements identified in the SEIPM data request form, develop the database queries, test the data, perform verification and validation of the data, and return the form to HHS.

We expected 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 information for approximately 100 sampled units. We did not expect reporting costs to vary considerably based on sample size. We sought comment on these assumptions.

We estimated completion of the pre-sampling data request would take 12 hours per respondent at an estimated $1,364 per respondent. We estimate completion of the sampled unit data request would take 707 hours per respondent at an estimated cost of $73,054 per respondent. To compile our estimates, we referenced our experience in collecting data in our FFE pilot initiative. We identified specific personnel and the number of hours that would be involved in collecting the sampled unit 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). Additionally, to account for the time needed for any State Exchanges to convert hard copies to a digitized format, we added 20 hours for each State Exchange into the burden estimates.

HHS estimated based on May 2020 Bureau of Labor Statistics Occupational Codes and vary from $45.98 (adjusted to $91.96 to account for overhead) to $77.76 (adjusted to $155.52 to account for overhead) depending on occupation code and function. With a mean hourly rate of $103.50 for the respective occupation codes, the burden across the 18 State Exchanges equals 12,942 hours for a total cost of up to $1,339,523.

Exchanges: Eligibility and Enrollment (CMS–10468).

2. Determination of Error Findings Decision and Appeal Redetermination (§§ 155.1525 and 155.1530)

As described in the preamble to § 155.1525, Redetermination of Error Findings Decision, a State Exchange may file a request with HHS to resolve issues with HHS' findings within the deadline prescribed in the annual program schedule.

The burden associated with the information collection requirements contained in §§ 155.1525 and 155.1530 is the time and effort necessary to draft and submit a request for a redetermination of an error findings decision and, if requested, an appeal of a redetermination decision. In accordance with 5 CFR 1320.4, information collected during the conduct of an administrative action is not subject to the PRA. As a result, we believed the burden associated with these requirements is exempt from the PRA under 44 U.S.C. 3502(3)(A)(i).

3. Corrective Action Plan (§ 155.1535)

As described in the preamble to § 155.1535, we proposed that State Exchanges may be required to develop and implement corrective action plans following a completed SEIPM measurement designed to reduce improper payments as a result of eligibility determination errors. The burden associated with this requirement is the time and effort put forth by State Exchanges to develop and submit a corrective action plan to HHS. We estimated that it would take each selected State Exchange up to 1,000 hours to develop a CAP. We estimated that the total annual burden associated with this requirement for up to 18 State Exchange respondents would be up to 18,000 hours. Assuming the management analyst average hourly rate of $93.82 per hour, we estimated that the cost of a corrective action plan per State Exchange could be up to $93,820, and for all 18 State Exchanges, up to $1,688,760.

After reviewing the public comments received for the SEIPM program proposal, we will not finalize this provision at this time. We have not provided updated burden estimates for any of the elements associated with the SEIPM program policy to reflect the most recent wage estimate data, as we are not finalizing this provision and the final estimated burden will not be included in the Accounting Table (Table 20). We summarize and respond to public comments received on ICRs Regarding State Exchange Improper Payment Measurement program (§§ 155.1500 through 155.1540) below.

Comment: One commenter stated their State Exchange currently expends approximately $280,000 annually on other audit requirements. The commenter noted the SEIPM program will require significant changes to their reporting systems, as well as providing access to certain data. The commenter noted that CMS' estimated annual cost of the SEIPM program at $3 million is over 10 times what their State Exchange spends on all of its current audits. Other commenters did not estimate the dollar amount of the burden cost to their State Exchanges but expressed concern about duplicative data collection and needed IT investments.

Response: After considering the public comments received, we will not finalize the SEIPM program proposal at this time. We will solicit public comments on the SEIPM program in future rulemaking.

H. ICRs Regarding State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

We proposed to eliminate the requirement at § 156.111(d) and (f) to require States to annually notify HHS in a form and manner specified by HHS, and by a date determined by HHS, of any State-required benefits applicable to QHPs in the individual or small group market that are considered to be in addition to EHB in accordance with § 155.170(a)(3) and any benefits the State has identified as not in addition to EHB and not subject to defrayal, describing the basis for the State's determination.

Under this proposal, States would no longer be required to submit an annual report that complies with each requirement listed at § 156.111(f)(1) through (6), nor would HHS identify which benefits are in addition to EHB for the applicable PY in the State if a State does not submit an annual reporting package.

As States are already required under § 155.170 to identify which State-required benefits are in addition to EHB and to defray the cost of QHP coverage of those benefits, the 2021 Payment Notice estimated that a majority of States, approximately 41, would submit annual reports and that 10 States would not submit annual reports.[365]

The 2021 Payment Notice estimated that the burden for each State to meet this reporting requirement in the first year would be 30 hours, with an equivalent cost of approximately $2,459, with a total first year burden for all 41 States of 1,230 hours and an associated total first year cost of approximately $100,829. Because the first year of annual reporting was intended to set the baseline list of State-required benefits which States would update as necessary in future annual reporting cycles, the 2021 Payment Notice explained that the burden associated with each annual reporting thereafter would be lower than the first year. The 2021 Payment Notice therefore estimated that for each annual reporting cycle after the first year the burden for each State to meet the annual reporting requirement would be 13 hours with an equivalent cost of approximately $1,117, with a total annual burden for all 41 States of 533 hours and an associated total annual cost of approximately $45,817. The average annual burden over 3 years was estimated at approximately 765 hours with an equivalent average annual cost of approximately $64,154.

Given that we did not require States to submit annual reports in 2021 pursuant to our enforcement posture in part 2 of the 2022 Payment Notice final rule,[366] repealing the annual reporting requirement will also remove the associated ICRs and the anticipated burden on States submitting such reports. Thus, as we are finalizing as proposed, we will request discontinuation of the ICRs associated with the repealed annual reporting requirement (OMB control number: 0938–1174 Essential Health Benefits Benchmark Plans (CMS–10448)/ Expiration date: February 29, 2024).

After reviewing the public comments, we are finalizing the repeal of the annual reporting policy at § 156.111(d) and (f), including revising the section heading to § 156.111 to instead read, ''State selection of EHB-benchmark plan for PYs beginning on or after January 1, 2020.''

I. ICRs Regarding Differential Display of Standardized Plan Options on the Websites of Web-Brokers (§ 155.220) and QHP Issuers (§ 156.265)

As detailed above, we are resuming enforcement of the standardized plan option differential 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, beginning with the PY 2023 open enrollment period.

We estimated that a total of 110 web-brokers and QHP issuers participating in the FFEs and SBE–FPs would be

[365] See 85 FR 29164, 29244.

[366] 86 FR 24140.

required to comply with these requirements. We estimated that it would take a web developer/digital interface designer (OES occupational code 15–1257) 2 hours annually, at an average hourly cost of $82.20 per hour, to implement these changes, at a total annual cost of $164.40 per entity. Therefore, we estimated a total annual burden of 220 hours at a cost of $18,804 for all applicable web-brokers and QHP issuers. Since the proposed rule, we have updated these estimates to reflect the most recently available national occupational employment and wage data. We estimated that it would take a web digital interface designer (OES occupational code 15–1255) 2 hours annually, at an average hourly cost of $91.80 per hour, to implement these changes, at a total annual cost of $183.60 per entity. Therefore, we estimated a total annual burden of 220 hours at a cost of $20,196 for all applicable web-brokers and QHP issuers.

Consistent with the approach finalized in the 2018 Payment Notice,[367] we continue to recognize that system constraints may prevent web-broker and QHP issuers from mirroring the *HealthCare.gov* display. We therefore will continue to permit web-brokers and QHP issuers that use a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP to submit a request to deviate from the display on *HealthCare.gov,* with approval from HHS. Any requests from web-brokers and QHP issuers seeking approval for an alternate differentiation format would be reviewed based on whether the same level of differentiation and clarity is being provided under the requested deviation as is provided on *HealthCare.gov.*

We estimated that 55 of the above web-brokers and QHP issuers would submit a request to deviate from the manner in which standardized plan options are differentially displayed on *HealthCare.gov*. We estimated it would take a compliance officer (OES occupational code 13–1041) approximately 1 hour annually, at a rate of $72.70 per hour, to complete the request to deviate from the display on *HealthCare.gov,* as well as the justification for the request. Therefore, we estimated a total annual burden for all web-brokers and issuers subject to the differential display requirements submitting a request to deviate of approximately $3,998.50 beginning in 2023. Since the proposed rule, we have updated these estimates to reflect the most recently available national occupational employment and wage estimates. We estimate it would take a compliance officer (OES occupational code 13–1041) approximately 1 hour annually, at a rate of $72.90 per hour, to complete the request to deviate from the display on *HealthCare.gov,* as well as the justification for the request. Therefore, we estimated a total annual burden for all web-brokers and issuers subject to the differential display requirements submitting a request to deviate of approximately $4009.50 beginning in 2023.

To account for the burden associated with this ICR, (Non-Exchange Entities—OMB control number 0938–1329 (CMS–10666)) HHS submitted a reinstatement request to OMB for approval to restore the previously discontinued request.

We did not receive any comments in response to the information collection requirements related to the proposed policies.

J. ICRs Regarding Network Adequacy and Essential Community Providers (§§ 156.230 and 156.235)

We are finalizing amendments to § 156.230, including the adoption of standards related to time and distance and appointment wait time to assess QHP issuers' fulfillment of the reasonable access network adequacy standard. HHS finalized raising the ECP provider participation standard from 20 percent to 35 percent. Issuers will continue to submit provider facility information and geographic location of participating ECPs participating in an issuer's provider network or other documentation necessary to demonstrate that an issuer has a sufficient number and geographic distribution of ECPs for the intended service areas. This is done to ensure QHP enrollees have reasonable and timely access to providers that serve predominantly low-income, medically underserved individuals in accordance with ECP inclusion requirements found at § 156.235.

Additionally, issuers must collect and submit provider information necessary to demonstrate satisfaction of time and distance standards and appointment wait time standards to ensure that an issuer's network has fulfilled the network adequacy reasonable access standard found at § 156.230. Reviews of appointment wait time standards will begin in the QHP certification cycle for PY 2024. Lastly, an issuer must report the offering of telehealth services for each provider to help inform the future development of telehealth standards. We provided the definition of telehealth in the draft PY 2023 Letter to Issuers. Issuers will be required to respond yes or no as to whether each network provider offers telehealth. As described in the preamble, issuers who do not have the information available by the time of the QHP certification process can respond that they have requested the information from the provider and are awaiting the response.

HHS anticipates burden for completing the ECP/NA template will increase based on the changes in this final rule to an estimated 20 hours in total for each medical QHP submitted by issuers and 4 hours in total for each SADP submitted by issuers. This estimate is inclusive of the requirement to report provider facility information and the geographic location of ECPs in an issuer's provider network. Since we are finalizing raising the ECP threshold from 20 percent to 35 percent, QHP issuers will need to submit information on a sufficient number of their contracted ECPs to meet the higher threshold.[368] Some issuers have previously only included enough contracted ECPs on the template in order to meet the current threshold for that year's certification process. For those issuers, the increase in the ECP threshold would somewhat increase the burden in completing the ECP/NA template as they would need to include more contracted ECPs on the template to meet the standard. Notwithstanding, HHS estimates that the burden associated with showing compliance with the increased ECP threshold will account for 3 hours of the total 20 hours we estimate for completing the ECP/NA template for medical QHPs and 1 hour of the total 4 hours we estimate for SADPs.

The 20-hour burden estimate for the ECP/NA template also includes the burden resulting from the requirement that QHP issuers report information relevant to compliance with time and distance standards and appointment wait time standards. For PYs 2018–2022, HHS deferred reviews of network adequacy for QHPs to States that HHS determined to have a sufficient network adequacy review process, which was all FFE States for that time period. As HHS resumes network adequacy reviews, we finalized a broader provider specialty list for time and distance standards than was evaluated for PYs 2015–2017. We also added appointment wait time standards and will begin implementing network adequacy reviews of appointment wait time standards in PY 2024. HHS estimates that the burden

[367] 81 FR 94118.

[368] The ECP/NA template requires QHP issuers to report only that number of providers sufficient to demonstrate compliance with relevant requirements.

associated with the requirement that QHPs report information sufficient to show compliance with the proposed network adequacy standards would account for 12 of the total 20 hours we estimate for completing the ECP/NA template for medical QHPs, and 1 hour of the total 4 hours we estimate for SADPs.

The 20-hour estimate also includes the burden associated with the requirement that issuers report whether network providers provide telehealth services. HHS believes that many QHP issuers already collect and maintain information on whether network providers furnish telehealth services. Approximately half of the parent companies of issuers on the FFEs also offer Medicare Advantage plans. Since Medicare Advantage offers a telehealth credit for network adequacy, we expect those issuers would already have telehealth information available for their providers. HHS further is of the view that those QHP issuers that do not currently collect this information may do so using the same means and methods by which they already collect information from their network providers relevant to time and distance standards and provider directory information. For these reasons, HHS estimates that any additional burden relative to the requirement that QHP issuers report whether each network provider is furnishing telehealth services would lead to a minimal increase in burden for many issuers. The requirement to report whether providers offer telehealth services would account for 4 of the total 20 hours we estimate for completing the ECP/NA template for medical QHPs and 1 of the total 4 hours we estimate for SADPs. Finally, we estimate it will take 1 hour for issuers, including both medical QHPs and SADPs, to submit the ECP/NA template and complete the portions of the Issuer Module that are relevant to these reviews.

We estimated that the total annual burden associated with completing the additional requirements proposed within the ECP/NA template for medical QHPs for up to 215 issuers would be up to 4,300 hours. Assuming the compliance officer's average hourly rate of $36.35 per hour, plus a 100% fringe benefit rate of $36.45, we estimated that the cost of completing the ECP/NA template for an individual medical QHP could be up to $1,454, and for all 215 issuers, up to $312,610. We estimated that the total annual burden associated with this requirement for SADPs for up to 270 issuers would be up to 1,080 hours. Assuming the compliance officer's average hourly rate of $36.35 per hour, plus a 100 percent fringe benefit rate of $36.35, we estimated that the cost of completing the ECP/NA template for an individual SADP could be up to $290.80, and for all 270 issuers, up to $78,516. The total estimated cost for the annual burden associated with completing the ECP/NA template across both medical QHP and SADP issuers is $391,126.

Since publishing the proposed rule, we have updated these estimates to reflect the most recently available national occupational employment and wage estimates. We currently estimate that the total annual burden associated with completing the additional requirements proposed within the ECP/NA template for medical QHPs for up to 215 issuers would be up to 4,300 hours. Assuming the compliance officer's average adjusted hourly rate of $72.90 per hour, we estimate that the cost of completing the ECP/NA template for an individual medical QHP could be up to $1,458 and for all 215 issuers, up to $313,470. We estimate that the total annual burden associated with this requirement for SADPs for up to 270 issuers would be up to 1,080 hours. Assuming the compliance officer's average adjusted hourly rate of $72.90 per hour, we estimate that the cost of completing the ECP/NA template for an individual SADP could be up to $291.60, and for all 270 issuers, up to $78,732. The total estimated cost for the annual burden associated with completing the ECP/NA template across both medical QHP and SADP issuers is $392,202.

HHS submitted the Essential Community Provider-Network Adequacy (ECP/NA) Data Collection to Support QHP Certification information collection request (OMB control number 0938–NEW/CMS–10803) to OMB to request approval for data collections related to essential community provider and network adequacy requirements, which includes the changes finalized in this final rule. The existing information collection for QHP certification (OMB control number: 0938–1187 (CMS–10433)/Expiration date: June 30, 2022) includes the data collection and burden information for the ECP/NA template, outside of what is in this rule.

We summarize and respond to public comments received on ICR regarding network adequacy and essential community providers (§§ 156.230 and 156.235) below.

Comment: Commenters submitted two remarks regarding the burden estimates associated with the addition of telehealth data collection reporting for SADPs. Commenters expressed concern that the burden was underestimated for SADPs and should be reassessed. The commenters shared that they believe the burden is underestimated because: SADPs do not currently collect data on telehealth; the estimate does not include costs for a second reviewer; and the hourly rate and total estimated hours are too low.

Response: We appreciate the feedback received on the burden estimates for SADPs. HHS is aware that the actual burden will vary for each QHP based on a variety of factors. We acknowledge that telehealth data collection may increase the burden for some QHPs, including SADPs. We are also aware that some QHPs already have telehealth data available, from sources like claims data or provider surveys. We have reflected the telehealth data collection requirement in our burden estimates and believe these estimates are reasonable. For issuers that have not yet received responses from providers regarding telehealth availability and do not have that information available from other sources, like claims data, they can select the response on the template that they are awaiting a response from that provider.

For QHP certification data collection and reporting, we use the mean hourly wages for a compliance officer to estimate costs. This data was retrieved from the Bureau of Labor Statistics website.[369] HHS believes that this job title and associated hourly wage provide a reasonable basis for our estimates. We understand that multiple staff at different levels may be involved and the total number of anticipated hours reflects that. It is up to each issuer to determine their process for collecting and reporting ECP/NA data and how many staff are involved. We will collect user experience data regarding the information collection requirements related to network adequacy and will reassess burden estimates for future years as needed.

Comment: Two commenters expressed concern that the burden estimate was too low.

Response: HHS believes the burden estimates accurately reflect the time it takes for an issuer to complete the activities described in this package and bases its estimates on extrapolation from experience in prior plan years.

Comment: One commenter stated that updates made to ECP/NA data collection are necessary and should be approved.

Response: HHS agrees that the ECP/NA data collection is necessary to

[369] *Occupational Employment and Wages, May 2021.* (2022, March 31). Bureau of Labor Statistics. *https://www.bls.gov/oes/current/oes131041.htm.*

support the ECP/NA portions of the QHP certification review process.

Comment: Some commenters recommended that HHS defer to States that have similar network adequacy standards as the Federal network adequacy standards, and coordinate with States and NAIC where possible.

Response: As described in the preamble of this rule, HHS will defer to States performing plan management that elect to perform their own reviews during QHP certification, provided that the State applies and enforces network adequacy standards that are at least as stringent as the Federal standards. HHS will continue to coordinate with States and NAIC.

Comment: A commenter encouraged HHS to identify plans that use very narrow networks as a discriminatory enrollment selection process rather than to control costs.

Response: HHS appreciates this suggestion and will consider the possibility of identifying plans that use narrow networks as a method to deter consumers with greater health needs from enrollment.

Comment: Some commenters recommended that HHS align network adequacy standards with NCQA and Utilization Review Accreditation Commission (URAC) standards.

Response: HHS reviewed the NCQA and URAC standards regarding network adequacy. We believe it is appropriate to align with NCQA in its use of business days to measure appointment wait time standards, which will be finalized in the final PY 2023 Letter to Issuers. We will also finalize that the appointment wait time standard for the behavioral health category will align with NCQA's standards. NCQA and URAC do not have quantitative parameters for the other categories we are finalizing for appointment wait times nor do they have quantitative standards for time and distance.

Comment: One commenter requested HHS allow providers from multiple network tiers to be considered when assessing network adequacy.

Response: HHS is not finalizing the network tiering policy for network adequacy.

Comment: Some commenters requested that HHS defer network adequacy standards until PY 2024 and defer appointment wait time standards until COVID-related provider staffing issues are addressed.

Response: HHS is finalizing appointment wait time standards and delaying implementation until PY 2024.

Comment: Some commenters shared concerns that plans will not have enough time to implement changes required by the proposed network adequacy policies and that plans do not have sufficient details on the implementation plans for these policies. Some commenters offered feedback on specific provider types and requested more detail on how provider types are defined. One commenter requested clarification about aspects of the ECP/NA template, such as telehealth data collection, provider specialty codes, and time and distance parameters.

Response: HHS included details on the implementation of network adequacy policies in the draft 2023 Letter to Issuers and believes issuers will have sufficient time to comply with time and distance standards for PY 2023 and appointment wait time standards beginning in PY 2024. Further information, including detail on definitions of provider types and clarification requested regarding aspects of the ECP/NA template, will be included in the ECP/NA template, FAQs, QHP Application Instructions, and other related documents.

Comment: One commenter requested deferral of telehealth data collection.

Response: HHS will collect data from issuers on which providers offer telehealth as many issuers already have this information, can gather it during the required timeframe, or can select that they have requested information from the provider and are awaiting their response.

Comment: Two commenters recommended a clear network adequacy justification process.

Response: HHS has developed streamlined justification processes for network adequacy and ECP that are described in the preamble.

Comment: Some commenters requested that HHS use a phased-in approach to increasing the ECP threshold or that HHS defer raising the ECP threshold until PY 2024.

Response: HHS is finalizing the ECP threshold for PY 2023 as proposed as we anticipate the majority of issuers will be able to meet the standard and the justification process can be used by issuers that are working to come into compliance with the ECP standards.

Comment: One commenter requested HHS consider a different approach to assess network adequacy in rural areas.

Response: HHS believes the time and distance standards for rural areas are reasonable based on our review of industry standards. We will assess time and distance standards at the county level. Rural counties and counties with extreme access considerations will have time and distance parameters that are longer than more metropolitan areas.

Comment: A commenter asked HHS to exclude SADPs from appointment wait time standards requirement.

Response: HHS does not agree that SADPs should be exempt from compliance with appointment wait time standards. HHS believes it is important that timely access to care is ensured, regardless of plan type. HHS will evaluate all plans seeking QHP certification, including SADPs, for compliance with appointment wait times beginning in PY 2024.

Comment: One commenter recommended that HHS provide additional opportunities for stakeholder feedback on the implementation of network adequacy policies.

Response: HHS will continue seeking stakeholder feedback on network adequacy policies on an ongoing basis.

HHS received one out-of-scope comment to which we have not responded in this final rule.

K. ICRs Regarding Payment for Cost-Sharing Reductions (§ 156.430)

We proposed several amendments to § 156.430 to clarify that CSR data submission is mandatory for those issuers that received CSR payments from HHS for any part of the benefit year and voluntary for other issuers. The currently approved burden estimate is a total cost of $235,683 (2,362.50 hours) across 150 issuers ($1,571.22 per issuer), which accounts for 0.75 hours per issuer to complete and submit the Issuer Summary Report to HHS each year and 15 hours per issuer to complete and submit the Standard Methodology Plan and Policy Report to HHS each year.[370] We expected that these proposals will reduce the burden associated with the CSR data submission process when HHS is not making CSR payments to QHP issuers, as we expect that the number of issuers submitting CSR data each year will decrease due to these proposals. We have revised the information collection currently approved under OMB control number: 0938–1266 (Cost-Sharing Reduction Reconciliation (CMS–10526)/ Expiration date: July 31, 2024) to account for this decreased burden when HHS is not making CSR payments to QHP issuers.

We did not receive any comments in response to the information collection requirements related to the proposed policy.

L. ICRs Regarding Quality Improvement Strategy (§ 156.1130)

We did not propose and are not finalizing any amendments to the

[370] OMB control number 0938–1266 (Cost-Sharing Reduction Reconciliation (CMS–10526)/ Expiration date: July 31, 2024).

regulatory text in 45 CFR 156.1130, which outlines QIS data collection and submission framework established in the 2016 Payment Notice.[371] The information collections associated with QIS data collection and submission requirements are currently approved under OMB control number 0938–1286 (Quality Improvement Strategy Implementation Plan and Progress Report (CMS–10540)/Expiration date: February 25, 2024) and encompasses the estimated burden and costs associated with a QIS submission that may include several QIS topic areas. In this rule, we are finalizing, as proposed, that beginning with QIS submissions in calendar year 2023 (for the PY 2024 coverage), a QHP issuer would be required to address reducing health and health care disparities as one of the QIS topic areas in addition to at least one other topic area outlined in section 1311(g)(1) of the ACA, including: Improving health outcomes of plan enrollees, preventing hospital readmissions, improving patient safety and reducing medical errors, and promoting wellness and health. We did not estimate additional burden to be accounted for since the current QIS submission form already encompasses the estimated burden and costs associated with a QIS submission that may include several QIS topic areas.

We did not receive any comments in response to the information collection requirements related to the proposed policy.

M. ICRs Regarding Medical Loss Ratio (§§ 158.140, 158.150, 158.170)

We are finalizing the proposed amendments to § 158.140 to codify in regulation that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes. We are also finalizing amendments to § 158.150 to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses for MLR reporting and rebate calculation purposes. We are also finalizing the proposed technical amendment to § 158.170(b) to correct an oversight and remove the reference to the percentage of premium QIA reporting option described in § 158.221(b)(8), which was deleted in part 2 of the 2022 Payment Notice final rule.[372] We anticipate that implementing these provisions will require minor changes to the MLR Annual Reporting Form Instructions but will not significantly increase the associated reporting burden. The burden related to this information collection is currently approved under OMB control number: 0938–1164 (Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping Requirements (CMS–10418)). The control number is currently set to expire on July 31, 2024.

We did not receive any comments in response to the information collection requirements related to the proposed policies.

N. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 18: Final Annual Recordkeeping and Reporting Requirements (New Burden)

Regulation Section(s)	OMB control number	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($)	Total Cost ($)
§§ 153.610 and 153.710	0938-1155	650	650	30	19,500	$1,884,870	$1,884,870
§ 155.220	0938-1349	20	40	5	200	$18,360	$18,360
§§ 156.230 and 156.235	0938-NEW	270 (SADPs)	270	4	1,080	$78,732	$78,732
§§ 156.230 and 156.235	0938-NEW	215 (Medical QHPs)	215	20	4,300	$313,470	$313,470
§§ 155.220 and 156.265	0938-1329	55 (deviation request)	55	1	55	$4,009.50	$4,009.50
§§ 155.220 and 156.265	0938-1329	110 (differential display)	110	2	220	$20,196	$20,196
Total				62	25,355	$2,259,858.50	$2,259,858.50

[371] 80 FR 10750, 10844 through 10848.

[372] 86 FR 24261.

TABLE 19: Final Annual Recordkeeping and Reporting Requirements (Reduction)

Regulation Section(s)	OMB control number	Original Number of Respondents	Number of Respondents (if reduced)	Burden per Response (hours)	Reduced Total Annual Burden (hours)	Labor Cost of Reporting ($)	Total Cost ($)
§ 153.320	0938-1155	25	1	60	-1,440	-$126,345	-$126,345
§ 155.420*	0938-1207	n>10		.2	-38,800	-$1,811,960	-$1,811,960
§156.111	0938-1174	41	0	13	-533	-$45,817	-$45,817
Total				73.2	-40,773	-$1,984,122	-$1,984,122

*This proposal estimates a decrease in annual burden for consumers attesting to special enrollment period types that no longer require document verification, because the number of consumers enrolling through a loss of minimum essential coverage is represented as n>10 since the number is undefined.

This final rule includes several policies with information collection requirements for which we use this rulemaking as the **Federal Register** notice through which to receive comment on their proposed revisions to or submissions of ICRs. These proposals include Verification of Eligibility for Special Enrollment Periods (§ 155.420), and the proposals on Network Adequacy and Essential Community Providers (§§ 156.230 and 156.235) and the proposal regarding Differential Display of Standardized Plan Options (§§ 155.220) and 156.265).

The following policies with associated information collection requests that require revision to align with policies in this rule, including State Flexibility for Risk Adjustment (§ 153.320), Risk Adjustment Distributed Data and Risk Adjustment Data Submission Requirements (§§ 153.610, 153.700 and 153.710), and the 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) will be submitted for OMB approval outside of this rulemaking, through a separate **Federal Register** notice.

The policies for Quality Improvement Strategy (§ 156.1130), Medical Loss Ratio (§§ 158.140, 158.150, 158.170), Payment for Cost-Sharing Reductions (§ 156.430), and Reporting APTC Calculation Methodology (§ 155.1200(b)(2)) contain information collections which are currently approved by OMB that do not require revision. One policy, the State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111), as finalized, will discontinue the associated information collections and remove them from the ICRs, and the information collected in the Determination of Error Findings Decision and Appeal Redetermination (§§ 155.1525 and 155.1530) policy is exempt from the PRA.

We have submitted a copy of this final rule to OMB for its review of the rule's information collection requirements. These requirements are not effective until they have been approved by OMB.

V. Regulatory Impact Analysis

A. Statement of Need

This rule finalizes standards related to the risk adjustment program for the 2023 benefit year and beyond, as well as standards for the HHS–RADV program beginning with the 2021 benefit year. This rule finalizes additional standards related to eligibility redetermination, special enrollment periods, requirements for agents, brokers, web-brokers, and issuers assisting consumers with enrollment through Exchanges that use the Federal platform; State selection of EHB-benchmark plan and annual reporting of State-required benefits, termination of coverage, the MLR program, and 2023 FFE and SBE–FP user fees. This rule also finalizes to remove the annual reporting requirement on States to report State-required benefits to HHS. The rule also finalizes refinements to the EHB nondiscrimination framework by including examples of presumptively discriminatory benefit designs. The rule also finalizes the requirement that issuers in FFEs and SBE–FPs offer standardized plan options. This rule finalizes to expand QIS standards and requires QHP issuers to address health and health care disparities in their QIS submissions in addition to at least one other topic area outlined in section 1311(g)(1) of the ACA. Finally, this final rule would implement the PIIA requirements for State Exchanges.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4) and 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any one year).

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the

President's priorities, or the principles set forth in the Executive Order. An RIA must be prepared for major rules with economically significant effects ($100 million or more in any one year), and a ''significant'' regulatory action is subject to review by OMB. HHS has concluded that this rule is likely to have economic impacts of $100 million or more in at least 1 year. Based on HHS estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

The provisions in this final rule aim to ensure that consumers continue to have access to affordable coverage and quality health care. Although there is still some uncertainty regarding the net effect on premiums, we anticipated that the provisions of this final rule would help further HHS' goal of ensuring that all consumers have access to quality and affordable health care and are able to make informed choices. In accordance with Executive Order 12866, HHS believed that the benefits of this regulatory action justify the costs.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular A–4, Table 20 depicts an accounting statement summarizing HHS' assessment of the benefits, costs, and transfers associated with this regulatory action.

This final rule implements standards for programs that will have numerous effects, including providing consumers with access to affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify all benefits and costs of this final rule. The effects in Table 20 reflect the qualitative assessment of impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for health insurance issuers and consumers. The annual monetized transfers described in Table 20 include changes to costs associated with the risk adjustment user fee paid to HHS by issuers and the potential increase in rebates from issuers to consumers due to amendments to MLR requirements.

We are finalizing the risk adjustment user fee of $0.22 PMPM for the 2023 benefit year to operate the risk adjustment program on behalf of States, which we estimated to cost approximately $60 million in the benefit year 2023.[373] We expect risk adjustment user fee transfers from issuers to the Federal Government to remain steady at $60 million, the same as estimated for the 2022 benefit year; this is included in Table 20.

Additionally, for 2023, we are maintaining the FFE and the SBE–FP user fee rates at current levels, 2.75 and 2.25 percent of premiums, respectively.

[373] As noted previously in this final rule, no State has elected to operate the risk adjustment program for the 2023 benefit year; therefore, HHS will operate the program for all 50 States and the District of Columbia.

TABLE 20: Accounting Table

Benefits:

Qualitative:

- Increased access to health insurance coverage for individuals who are currently unable to enroll in coverage because of past-due premiums.
- Greater market stability resulting from updates to the risk adjustment models.
- Increased access to the health insurance coverage due to the proposal to decrease the scope of special enrollment period verification.
- Greater consistency in protections based on EHB nondiscrimination.
- Increased access to more comprehensive provider networks and enhanced health equity[1] due to the network adequacy and ECP finalized policies, which will 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.
- Enhanced access to behavioral health providers who provide key services for vulnerable populations via the network adequacy and ECP finalized policies.
- Greater access to primary care and OB/GYN providers in recognition of the importance of preventive care for underserved populations through the network adequacy and ECP finalized policies.
- Encourage continuous quality improvement among QHP issuers to help strengthen health care system-wide efforts to improve health outcomes, lower costs, and advance health equity.

Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	-$119.0 Million	2021	7 percent	2022-2026
	-$120.3 Million	2021	3 percent	2022-2026

Quantitative:

- Reduction in costs for States related to annual reporting of State-required benefits, estimated to be one-time savings of $100,829 in PY 2022 and annual savings of $45,817 each year thereafter.
- Reduction in potential costs to Exchanges since they would not be required to conduct random sampling as a verification process for enrollment in or eligibility for employer-based insurance when the Exchange reasonably expects that it will not obtain sufficient verification data, estimated to be one-time savings of $63 million in 2022 and annual savings of $134 million in 2023 and onwards.
- Increased costs to Exchanges to design a risk-based verification process for enrollment in or eligibility for employer sponsored coverage based on a risk assessment for inappropriate subsidy payments estimated to be about $5.3 million in one-time costs in 2022.
- Annual cost savings of $5.2 million related to the proposal to decrease the scope of special enrollment period verification beginning in 2023.
- Reduction of $126,345 in reporting costs to reflect the number of States participating in the State flexibility to request a reduction in risk adjustment State transfers in any market risk pool, which starting with the 2024 benefit year, will only be available to one prior participating State.
- Cumulative one-time implementation cost associated with the collection of five new data elements for risk adjustment is estimated to be approximately $1,884,870 for 650 issuers, or $2,899 per issuer in the 2023 benefit year.
- Cumulative additional cost estimate for the collection of five new data elements for risk adjustment is estimated to be approximately $314,145 for 650 issuers, or $483.30 per issuer annually, beginning in the 2023 benefit year.
- Increased cost to web-brokers to implement minor text-based changes to their websites to add or modify a disclaimer. Estimated $9,180 in one-time costs for 20 web-brokers in the 2022 benefit year.
- Increased cost to web-brokers to implement minor text-based changes to their websites to add text-based explanations for how they display QHPs. Estimated $9,180 in one-time costs for 20 web-brokers in the 2022 benefit year.

- Increased annual cost of $20,196 across all web- brokers and QHP issuers utilizing the Classic DE and EDE Pathways to comply with the standardized plan option differential display requirements in the 2023 benefit year.
- Increased annual cost of $4,009.50 across the subset of web-brokers and issuers subject to the differential display requirements submitting a request to deviate from the requirements beginning in the 2023 benefit year.
- Increased cost to issuers for completing the updated ECP/NA template that includes a longer provider specialty list for network adequacy, appointment wait time standards (beginning in PY 2024), and a question on providers offering telehealth. The total estimated annual burden for medical QHP and SADP issuers to complete the updated ECP/NA template is $392,202 beginning in PY 2023.
- Increased costs to State Exchanges associated with one-time operational builds to comply with the APTC methodological requirements estimated at $500,000 for each of 8 State Exchanges, or $4 million in PY 2024.

Qualitative:

- Potential reduction in costs to enrollees who are currently unable to enroll in coverage because of past-due premiums related to searching for a new plan from another issuer when seeking to enroll in health care coverage.
- Potential administrative burden on States and regulated entities that would need to take action to come into compliance with the updated nondiscrimination policies (for example, regulated entities under § 156.125).
- Potential administrative burden on States if they choose to align their network adequacy standards with the new Federal standards (instead of having HHS complete the reviews).

Transfers:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	$631.9 Million	2021	7 percent	2022-2026
	$645.3 Million	2021	3 percent	2022-2026

Quantitative:

- Federal Transfers to Consumers: Increase in PTC payments due to changes in the AV *de minimis* range, estimated to be approximately $0.73 billion in 2023, $0.77 billion in 2024, $0.77 billion in 2025, and $0.76 billion in 2026.
- Other Transfers: Increase in rebate payments from issuers to consumers due to the clarification regarding the reporting of provider incentives and bonuses and the removal of indirect expenses from QIA in MLR and rebate calculations, estimated to be $61.8 million annually, beginning in 2023.

Qualitative:

- Potential transfers from issuers who would have been able to recoup unpaid premiums from enrollees to those enrollees who would now be able to enroll in coverage from the same issuer or another issuer in the same controlled group without having to pay past-due premiums.
- Potential transfer from consumers to issuers: An estimated 2 percent premium increase for individuals not eligible for PTC due to the proposal to require individual market silver QHPs to provide an AV between 70-72 percent and associated income-based CSR plan variations to follow a *de minimis* range of +1/0 (impact on approximately 248,000 enrollees in HealthCare.gov silver plans below 70 percent AV, with approximately 4.2 million enrollees in corresponding CSR plan variations).

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 collection, and insurance enrollment. Table 21 summarizes the effects of the risk adjustment program on the Federal budget from fiscal years 2023 through 2027, with the additional, societal effects of this final rule discussed in this RIA. We did not expect the provisions of this final rule to significantly alter CBO's estimates of the budget impact of the premium stabilization programs that are described in Table 21.

[1] Healthy People 2030 defines health equity as ''the attainment of the highest level of health for all people.'' *Healthy People 2030 Questions & Answers.* (2022, March 9). Office of Disease Prevention and Health Promotion. *https://health.gov/our-work/national-health-initiatives/healthy-people/healthy-people-2030/questions-answers.*

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on these internal analyses, we anticipated that, quantitatively, the effects of the provisions proposed in this rule are consistent with our previous estimates in the 2022 Payment Notice [375] for the impacts associated with the APTC, the premium stabilization programs, and FFE (including SBE–FP) user fee requirements.

TABLE 21: Estimated Federal Government Outlays and Receipts for the Risk Adjustment and Reinsurance Programs from Fiscal Year 2023-2027, in billions of dollars[376]

Year	2023	2024	2025	2026	2027	2023-2027
Risk Adjustment and Reinsurance Program Payments	6	6	6	7	7	32
Risk Adjustment and Reinsurance Program Collections	6	6	7	7	7	33

Note: Risk adjustment program payments and receipts lag by one quarter. The receipt will fully offset payments over time.
Source: Congressional Budget Office. Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2020 to 2030 Table A-2. September 29, 2020. Available at https://www.cbo.gov/system/files/2020-09/56571-federal-health-subsidies.pdf.https://www.cbo.gov/system/files/2020-09/56571-federal-health-subsidies.pdf.

1. Guaranteed Availability of Coverage (§ 147.104(i))

This rule finalizes amendments to § 147.104(i), which reverse the current policy allowing an issuer to attribute a premium payment made for new coverage to any past-due premiums owed for coverage from the same issuer or another issuer in the same controlled group within the prior 12-month period preceding the effective date of coverage before effectuating enrollment in new coverage. Under the current policy, individuals may have had to pay up to 3 months of past-due premiums plus a binder payment before enrolling in coverage.[377] HHS lacks information on the frequency with which consumers miss payments or the frequency with which binder payments are made, and sought data or information related to past-due premiums in the proposed rule (87 FR 584 and 706). HHS was also interested in learning more about the population and characteristics of individuals with past-due premiums.

Individuals often stop making premium payments or forgo health insurance because they are unable to afford the premium payments. In a 2022 survey, 36 percent of insured adults reported being worried about being able to afford their monthly health insurance premium, with 12 percent being ''very worried'' and 23 percent being ''somewhat worried.'' [378] In a 2021 survey, 27 percent of insured adults reported having a difficult time covering the cost of health insurance each month.[379] In 2019, 73.7 percent of uninsured adults pointed to the high cost of coverage as the reason for being uninsured.[380]

Based on internal analysis, we estimate that approximately 7.8 percent of enrollees in Exchanges using the Federal platform had their coverage terminated in 2020 for non-payment of premiums. That figure was 10.7 percent in 2019, 12.4 percent in 2018, and 17.3 percent in 2017.[381] Among those enrollees who had their coverage terminated in 2019 and lived in an area where their issuer (or a different issuer in the same controlled group) had plans available the next year, we estimated that 16.9 percent enrolled with the same issuer (or a different issuer in the same controlled group) the following year. That figure was 16.5 percent in 2018 and 16.8 percent in 2017.[382] For those enrollees with household incomes below the Federal poverty level, 15.3 percent of enrollees who had their coverage terminated in 2019 and lived in an area where their issuer (or a different issuer in the same controlled group) was available the next year enrolled with the same issuer (or a different issuer in the same controlled group) the following year. [383] That figure was 13.5 percent in 2018 and 13.2 percent in 2017. Our analysis also suggested that those enrollees with lower household incomes (specifically, household incomes below the Federal poverty level) were less likely to enroll in coverage from the same issuer or another issuer in the same controlled group the following year. In 2017, 2018, and 2019, those enrollees who were less than 35 years old were also less likely to enroll in coverage from the same issuer or another issuer in the same controlled group the following year than those aged 35 to 54.

Due to data limitations, we are unable to directly attribute any changes in enrollment behavior in the Exchanges using the Federal platform to the

[375] 86 FR 6166 through 6173 and 24270 through 24282.

[376] Reinsurance collections ended in FY 2018 and outlays is subsequent years reflect remaining payments, refunds, and allowable activities.

[377] Section 156.270(d) requires issuers to observe a 3-consecutive month grace period before terminating coverage for those enrollees who upon failing to timely pay their premiums are receiving APTC. Section 155.430(d)(4) requires that when coverage is terminated following this grace period, the last day of enrollment in a QHP through the Exchange is the last day of the first month of the grace period. Therefore, individuals whose coverage is terminated at the conclusion of a grace period would owe at most 1 month of premiums, net of any APTC paid on their behalf to the issuer. Individuals who attempt to enroll in new coverage while in a grace period (and whose coverage has not yet been terminated) could owe up to 3 months of premiums, net of any APTC paid on their behalf to the issuer.

[378] Kirzinger, A., Kearney, A., Quasem, M., Stokes, M., Hamel, L., & Brodie, M. (2022). ''KFF Health Tracking Poll—March 2022: Economic Concerns and Health Policy, The ACA, and Views of Long-term Care Facilities.'' *KFF, https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-march-2022/.*

[379] Data Note: Kearney, A., Hamel, L., Stokes, M., & Brodie, M. (2021). Americans' Challenges with Health Care Costs. *KFF, https://www.kff.org/health-costs/issue-brief/data-note-americans-challenges-health-care-costs/.*

[380] Tolbert, J., Orgera, K., & Damico, A. (2020). Key Facts about the Uninsured Population. *KFF. https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/.*

[381] The annual figures presented in this section should not necessarily be interpreted as trends, as some States moved from Exchanges using the Federal platform to State Exchanges and the overall composition of the dataset may have changed.

[382] As we reported in the April 18, 2017 **Federal Register** (82 FR 18346), that figure was approximately 16 percent in 2016.

[383] Of the 936,637 enrollees who had their coverage terminated in 2019 and lived in an area where their issuer (or a different issuer in the same controlled group) was available the next year, 24,784 (or 2.6 percent) had incomes below the Federal poverty level. Many, but not all, of these enrollees lived in States that did not expand Medicaid eligibility following the implementation of the ACA.

interpretation of the guaranteed availability requirement stated in the Market Stabilization final rule. However, this final rule will increase access to health insurance coverage for individuals who stop paying premiums due to reasons such as financial hardship or affordability and who are currently unable to enroll in coverage because they cannot afford to pay past-due premiums. This increased access may lead to better health outcomes, if these individuals are able to maintain coverage.[384] This final rule will also increase the ability for enrollees to access coverage with the same issuer or another issuer in the same controlled group in the next year. This will be of particular benefit to those Exchange enrollees living in counties with only one or two participating issuers.[385] It may also reduce the costs and burden to enrollees related to searching for a new plan from another issuer or an issuer in a different controlled group when seeking to enroll in health care coverage. Being able to enroll with the same issuer will support access to the same network of services and providers, which could improve continuity of care.

This final rule may result in transfers from issuers who would have been able to recoup unpaid premiums from enrollees to those enrollees who will now be able to enroll in coverage from the same issuer or another issuer in the same controlled group without having to pay past-due premiums. However, we anticipate that these transfers will be minimal, as issuers generally are not permitted to waive past-due premiums and would be expected to pursue other means of collecting them.

We sought comment on the potential costs, benefits, and transfers associated with this provision. We also sought data related to past-due premiums, missed binder payments, and information on the population and characteristics of individuals with past-due premiums.

We summarize and respond to public comments received regarding the impact of the proposed change to the guaranteed availability of coverage (§ 147.104(i)) requirement below.

Comment: Many commenters stated that this provision will increase access to health insurance coverage and care for individuals who stop paying premiums and are currently unable to enroll in coverage because they cannot afford to pay past-due premiums. Commenters provided a number of reasons why individuals stop paying premiums, such as financial hardship or affordability, not receiving a notice of past-due premiums, or mistakenly forgetting to cancel coverage when becoming eligible for other forms of coverage. Commenters also provided various reasons for financial hardship such as periodic unemployment, chronic conditions, serious illnesses, addiction, domestic violence, crime, environmental disaster, and medical emergencies. Commenters mentioned high rates of being uninsured among individuals in minority and underserved communities and women and children and the risks associated with being uninsured. One commenter cited studies that found a correlation between the lack of health insurance coverage and preventable deaths.

Many commenters stated that the current policy creates a barrier to coverage for and has a negative impact on low- or middle-income individuals and individuals experiencing financial hardship. Several commenters also stated that the current policy has a disproportionate impact on underserved populations, such as immigrants, people of color, disabled women, and the LGBTQI+ community, that continue to face cultural and financial barriers to coverage and care.

A few commenters also stated that if individuals are better able to maintain coverage because of this provision, it will improve continuity of care and lead to better health outcomes. One of these commenters noted in particular that enabling individuals to enroll with the same issuer the next plan year increases the likelihood that they will maintain relationships with their providers. Several commenters also highlighted the importance of continuous coverage during the COVID–19 pandemic.

Response: We agree with the commenters that this change improves health equity by removing a barrier to health insurance coverage and health care that disproportionately affects low-income, minority and underserved communities.

Comment: A few commenters stated that this provision will have a negative impact on consumers. Some commenters suggested that the provision will lead to higher costs for issuers and result in higher premiums for consumers. One commenter speculated that the increase in premiums could range from 0.3 percent to more than 3 percent. A few commenters also stated that the proposed rule will reduce access to coverage if issuers exit the market. A few commenters stated that the proposed rule could negatively affect risk pools. A commenter also expressed concern about the potential financial impact on providers who may not receive payments when individuals fail to pay their premiums. One commenter also stated that it may negatively affect MLRs.

On the other hand, some commenters suggested that the proposed rule could improve the stability of risk pools, for instance, by reducing adverse selection. One of these commenters noted that the current policy may have deterred enrollment among younger, healthier individuals. A few commenters stated that the current policy worsened the risk pool and led to higher premiums, since individuals with significant health care costs are more likely to pay past-due premiums. One commenter noted that restrictions on enrollment outside of open enrollment periods limit adverse selection. In addition, one commenter stated that few issuers chose to implement the current policy because the implementation costs outweighed the premium losses. A commenter also speculated that the change would lead to reduced administrative costs for issuers. Several commenters stated that the amount of past-due premiums is minimal relative to issuers' profits. Several commenters also stated that issuers would be able to recoup past-due premiums by other means. One commenter noted that the financial risk to the individual from not having continuous coverage outweighs the cost to the risk pool from individuals not paying premiums (which could be recouped by issuers).

Response: We disagree that this rule is likely to result in an increase in premiums, have a negative financial impact on issuers or providers, or cause issuers to exit the market. There is no evidence that suggests that premiums would noticeably change because of a shift in how the guaranteed availability requirement is interpreted. As one commentator stated, few issuers have implemented the current policy of

[384] We requested comment on whether there would be any impact on premiums, affordability, and access for the individuals who reliably pay. We solicited comments regarding whether issuers who implemented policies requiring payment of past due premiums prior to reenrollment experienced declines in administrative costs related to the collection of past-due premiums.

[385] According to recent figures from KFF, in 2021, there were only two issuers participating in the ACA Exchanges in 44 percent of counties, and there was only one issuer participating in the ACA Exchanges in 10 percent of counties. Source: McDermott, D. & Cox, C. (2020). *Insurer Participation on the ACA Marketplaces, 2014–2021. KFF. https://www.kff.org/private-insurance/issue-brief/insurer-participation-on-the-aca-marketplaces-2014-2021/* This was noted by Sandy Ahn and JoAnn Volk in their analysis of the current interpretation of the guaranteed availability requirement. Source: Ahn, S. & Volk, J. (2017). *Relaxing the Affordable Care Act's Guaranteed Issue Protection: Issues for Consumers and State Options.* CHIRblog. *http://chirblog.org/relaxing-the-affordable-care-acts-guaranteed-issue-protection-issues-for-consumers-and-state-options/.*

attributing payment made for new coverage to past-due premiums before effectuating new enrollment. In addition, as another commenter stated, issuers that did adopt the current policy are likely to experience a reduction in administrative costs due to this change. Issuers also have other means to recoup past-due premiums. We also agree with commenters that stated that this change may result in an improved risk pool by removing barriers to enrollment for young and relatively healthy individuals.

2. Nondiscrimination Based on Sexual Orientation and Gender Identity (§§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b)), and EHB Nondiscrimination Policy for Health Plan Designs (§ 156.125)

In the 2023 Payment Notice proposed rule, HHS proposed amendments to certain regulations prohibiting discrimination in health insurance coverage, including discrimination in the design and implementation of health plan designs, under §§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), 156.1230(b), and 156.125. HHS proposed to amend these regulations so that they explicitly identify and recognize sexual orientation and gender identity as prohibited forms of discrimination based on sex consistent with pre-2020 HHS discrimination policy. HHS also proposed refinements to its EHB nondiscrimination policy for health plan benefit designs through proposed amendments to § 156.125 regulation text that would require that a nondiscriminatory health plan design that provides EHB to be clinically based, incorporate evidence-based guidelines into coverage and programmatic decisions, and rely on a current and relevant peer-reviewed medical journal articles, practice guidelines, or recommendations from reputable governing bodies, or similar sources. We provided examples of presumptively discriminatory benefit designs to provide further clarity on our refined EHB nondiscrimination policy. HHS proposed that its refined EHB nondiscrimination policy under § 156.125, as reflected in the examples of presumptively discriminatory health plan designs, would be applicable starting on the earlier of PY 2023 or upon renewal of any plan subject to the EHB requirements.

We sought comment on the potential costs, benefits, and transfers associated with the proposals in these provisions.

As explained in the Supplementary Information section earlier in this preamble, HHS will address in future rulemaking the proposed amendments to §§ 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b) that would have explicitly identified and recognized sexual orientation and gender identity as prohibited forms of sex discrimination.

HHS is finalizing the proposed revisions to § 156.125(a) to state that a nondiscriminatory benefit design that provides EHB is one that is clinically based. However, HHS does not finalize the proposed revisions to § 156.125(a) that would have provided that a nondiscriminatory benefit design is one that incorporates evidence-based guidelines into coverage and programmatic decisions and relies on a current and relevant peer-reviewed medical journal articles, practice guidelines, or recommendations from reputable governing bodies, or similar sources.

HHS finalizes all but one of the examples of presumptively discriminatory benefit designs. Specifically, consistent with the explanation in the Supplementary Information section earlier in this preamble, HHS will address in future rulemaking the example related to gender-affirming care that illustrated a benefit design that presumptively discriminates against enrollees based on gender identity under § 156.125.

We summarize and respond to public comments received on the regulatory impact and burden analysis relevant to our proposals under § 156.125 that we finalize in this final rule. Accordingly, we do not respond to comments that relate to the proposal to specifically identify sexual orientation and gender identity as prohibited forms of sex discrimination, nor do we respond to comments that relate to the gender-affirming care example in the 2023 Payment Notice proposed rule.

Comment: One commenter questioned what the regulatory impact and burden would be on issuers and enrollees to declare a class of treatment based on ''presumptive nondiscrimination.'' Another commenter stated the policy refining the nondiscrimination standard would unintentionally impose costs that far exceed any benefits by limiting the ability of issuers to develop cost-effective formulary plan designs and by compelling plans to ignore the standard use of clinical evidence as a factor in determining the appropriate tier for drugs.

A commenter also asserted that the lack of a cost-benefit analysis makes the rule arbitrary and capricious (noting CMS does not cite how many plans already cover the procedures, how many individuals will seek them, their cost, and increased costs to issuers and insured). Other commenters expressed concern that health plans may see increased utilization and higher costs due to an unintended adverse impact on issuers' ability to administer packages of benefits under the refined framework. Yet another commenter recommended that HHS should conduct and publish the results of a detailed cost study demonstrating premium impacts of refining the nondiscrimination standard for consumers prior to finalizing the proposal.

Response: With regards to the EHB nondiscrimination policy we are finalizing at § 156.125, we reiterate that the nondiscrimination requirements at § 156.125 apply only to benefit designs or implementation of a benefit designs to the extent that those benefits are EHB. The policy at § 156.125 does not apply to benefits that are not EHB. As mentioned in the proposed rule, the clarifications and changes we are finalizing to § 156.125 will most likely affect the vast majority of State EHB-benchmark plans. Because some current EHB-benchmark plans continue to be based on plan year 2014 plans, some of the EHB-benchmark plan designs may not comply with current Federal requirements such as nondiscrimination requirements at § 156.125. Therefore, when designing plans that are substantially equal to the EHB-benchmark plan, issuers may need to further conform plan benefits covered as EHB, including coverage and limitations, to comply with current Federal requirements, such as the nondiscrimination requirement of § 156.125.

If a State EHB-benchmark plan has a discriminatory benefit design, the State may prohibit plans providing benefits that are substantially equal to the EHB-benchmark plan from replicating that discriminatory benefit design. However, we clarify that we will not consider State EHB-benchmark plan designs to be out of compliance with EHB-benchmark plan requirements at § 156.110(d) or § 156.111(b)(2)(v) if the State provides such guidance or otherwise directs issuers to comply with these refined nondiscrimination standards notwithstanding any aspects of the EHB-benchmark plan that are not otherwise consistent with these refined nondiscrimination standards. Therefore, under this approach, States are not required at this time to go through the formal process at § 156.111 to update their EHB-benchmark plans solely for the purpose of removing any such discriminatory benefit designs on EHBs, but States that do elect to update their

EHB-benchmark plans at any point going forward will be expected to ensure their new EHB-benchmark plans are compliant.

To the extent that States take actions necessary to come into compliance with the refined EHB nondiscrimination policy such actions may have a small impact on premiums. States making changes to their EHB-benchmark plans for plan years after 2020 have the flexibility to design their EHB-benchmark plans consistent with § 156.111, which provides more options in plan designs. Several States have already used this flexibility to update their EHB-benchmark plans. CMS provides States with greater flexibility to select their EHB-benchmark plans by providing three new options for selection in PY 2020 and beyond, including: (1) Selecting the EHB-benchmark plan that another State used for PY 2017, (2) replacing one or more categories of EHBs under its EHB-benchmark plan used for PY 2017 with the same category or categories of EHB from the EHB-benchmark plan that another State used for PY 2017, or (3) otherwise selecting a set of benefits that would become the State's EHB-benchmark plan. Under each of these three options, the new EHB-benchmark also must comply with additional requirements, including the scope of benefits requirements, under § 156.111(b).[386]

Plans subject to the EHB requirement have always been required to comply with the nondiscrimination requirements in § 156.125 regardless of the presence of any noncompliant discriminatory language in the relevant EHB-benchmark plan. We therefore further recognize that issuers subject to § 156.125 requirements may choose to carefully review the refined EHB nondiscrimination final rule to ensure compliance. We also recognize that such reviews may take time and that issuers may experience added burden to the extent that issuers make additional changes to their plans designs for benefits covered as EHB in response to those reviews. Although we expect that issuers are already compliant with current § 156.125 requirements, we also believe that finalizing the refined EHB nondiscrimination policy at § 156.125 to be applicable on the earlier of PY 2023 or upon renewal of any plan subject to the EHB requirements will lessen any burden on issuers to make any necessary conforming changes than if we had finalized a mid-year effect date as proposed.

Further, we are declining to finalize that a nondiscriminatory benefit design that provides EHB must incorporate evidence-based guidelines into coverage and programmatic decisions, and rely on current and relevant peer-reviewed medical journal articles, practice guidelines, recommendations from reputable governing bodies, or similar sources. By instead finalizing only that plan designs providing EHB must be clinically based, we believe we are better balancing the need to protect consumers from discriminatory benefit designs without unreasonably limiting the sources that may be relied upon to assess whether a benefit design or its implementation are discriminatory. We will continually assess this policy to evaluate whether changes or further refinements are warranted.

3. Risk Adjustment (§§ 153.320, 153.610, 153.620, 153.700, 153.710, and 153.730)

We are finalizing two of the three proposed model specifications. Beginning with the 2023 benefit year, we are finalizing, as proposed, to remove the existing severity illness factors in the adult models and add interacted HCC counts factors to the adult and child risk adjustment models and to revise the enrollment duration factors for the adult models. However, we are not finalizing the proposed addition of a two-stage weighted model specification to the adult and child models. By prioritizing simplicity and limiting the number of changes to the current model structure, we minimize administrative burden for HHS, and as HHS runs risk adjustment in all 50 States and the District of Columbia, we do not expect these policies to place an additional burden on State governments. The model specifications finalized in this rule result in limited changes to the number and type of risk adjustment model factors; therefore, we do not expect these changes to impact issuer burden beyond the current burden for the HHS-operated risk adjustment program.[387] To further assist issuers in understanding the potential impact of these changes on risk adjustment transfers, we released the 2021 RA Technical Paper and conducted an EDGE transfer simulation that estimated the impact on risk scores and transfers with and without the proposed changes using 2020 benefit year risk adjustment data.[388]

Additionally, we are finalizing, as proposed, the use of the 2017, 2018, and 2019 enrollee-level EDGE data to recalibrate the HHS risk adjustment models for the 2023 benefit year. We believe that the approach of blending (or averaging) 3 years of separately solved coefficients will provide stability within the risk adjustment program and minimize volatility in changes to risk scores from the 2022 benefit year to the 2023 benefit year. We are also finalizing, as proposed, to continue applying a market pricing adjustment to the plan liability associated with Hepatitis C drugs in the risk adjustment models, consistent with the approach adopted beginning with the 2020 models. For the 2023 benefit year, we are finalizing, as proposed, to recalibrate the models using the final, fourth quarter (Q4) RXC mapping document that was applicable for the 2018 and 2019 benefit year, with the exception of the 2017 enrollee-level EDGE data year, for which we will use the most recent RXC mapping document that was available when we first processed the 2017 enrollee-level EDGE data (that is, Q2 2018) for consistency with prior model year recalibrations, as we did not include RXCs in the adult risk adjustment models until 2018.[389] For the 2024 benefit year and beyond, we will recalibrate the models using the final, fourth quarter (Q4) RXC mapping document that was applicable for each benefit year of data that is included in the current year's model recalibration (except under the extenuating circumstances that are described previously in this rule). We removed the mapping of hydroxychloroquine sulfate to RXC 09 (Immune Suppressants and Immunomodulators) and the related RXC 09 interactions for the 2018 and 2019 benefit years' enrollee-level EDGE data used for model recalibration.[390] For the 2023 benefit year, we are finalizing, as proposed, to maintain the CSR adjustment factors finalized in the

[386] Section 156.111(b). *https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-B/part-156.*

[387] See current burden estimates in the Supporting Statement of OMB control number 0938–1155 (Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment (CMS–10401)), which is currently being updated. The previous version of the Supporting Statement is *Supporting Statement A.* (2017, December 22). OIRA. *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201712-0938-015.*

[388] See the *2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf* and the *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes: Summary Results for Transfer Simulations.* (2021, December 28). CMS. *https://www.cms.gov/files/document/report-summary-results-transfer-simulations.pdf.* Issuers that participated in the simulation also received detailed issuer-specific data, including risk score and transfer estimates for the simulated results.

[389] See 81 FR 94075.

[390] The same concerns were not present for the 2017 enrollee-level EDGE data because hydroxychloroquine sulfate was not included in the RXC crosswalk until 2018.

2019–2022 Payment Notices.[391] Overall, we do not estimate that these policies will impact issuer burden beyond the current burden for the HHS-operated risk adjustment program.

For the 2023 benefit year, HHS will operate a risk adjustment program in every State and the District of Columbia. For the 2023 benefit year, we are finalizing, as proposed, to use the same methodology that we finalized in the 2022 Payment Notice to estimate our administrative expenses to operate the program. We estimate that the total cost for HHS to operate the risk adjustment program on behalf of States for 2023 will be approximately $60 million, and therefore, the 2023 risk adjustment user fee will be $0.22 PMPM. Because overall risk adjustment costs estimated for the 2023 benefit year are similar to 2022 costs, we do not expect the risk adjustment user fee for the 2023 benefit year to materially impact the transfer amounts collected or paid by issuers of risk adjustment covered plans.

We will also repeal, as proposed, the ability for States to request a reduction in risk adjustment State transfers of up to 50 percent in all State market risk pools beginning with the 2024 benefit year, with an exception for prior participants. We provide an exception for States that have previously submitted risk adjustment State flexibility requests, so only such States may continue to request this flexibility beginning with the 2024 benefit year. We also removed, as proposed, as a criterion for State justification and HHS review and approval of these requests the demonstration of State-specific factors that warrant an adjustment to more precisely account for relative risk differences in the State individual catastrophic, individual non-catastrophic, small group, or merged market risk pool. We will retain as the sole requirement for State justification and criterion for HHS review and approval the demonstration that the requested reduction would have a *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.

We anticipate that the changes to risk adjustment State flexibility request framework will have a minimal impact on States and other interested parties. Only one State, Alabama, has requested a reduction in risk adjustment State transfers since this flexibility was first made available beginning in the 2020 benefit year, and under this policy, Alabama would be considered a prior participant and could continue to request such reductions. However, we note that we intend to propose in future rulemaking to repeal the exception for prior participants beginning with the 2025 benefit year to provide impacted stakeholders additional time to prepare for this proposed change and the potential elimination of this flexibility. We did not anticipate any new burden or costs as a result of this policy.

We finalize the collection and extraction of five new data elements from issuers' EDGE servers through issuers' ESES files and risk adjustment recalibration enrollment files: ZIP Code, race, ethnicity, subsidy indicator, and ICHRA indicator beginning with the 2023 benefit year. Specifically, we are finalizing that starting with the 2023 benefit year, issuers will be required to populate the ZIP Code data field, using the five-digit level based on the enrollee's mailing address, and the subsidy indicator data field, which is intended to indicate whether a particular enrollee is (or is not) receiving APTC. For the 2023 and 2024 benefit years, we are adopting a transitional period during which issuers are required to populate the fields for race and ethnicity using only data they already collect or have accessible regarding their enrollees.[392] For example, for the 2023 and 2024 benefit years, for race and ethnicity data, issuers will be deemed in compliance if they submit these data elements using data they already have or collect through existing means, including, for example, through enrollee data captured and reported to the issuer by the FFE, SBE–FPs, and State Exchanges at the time of enrollment. Then, beginning with the 2025 benefit year, the transitional approach will end, and issuers will be required to populate the fields using available sources and, in the absence of such an existing source for particular enrollees, to make a good faith effort to ensure collection and submission of the race and ethnicity data for these enrollees.

We are also finalizing, with slight modification, collection of the ICHRA indicator. For the 2023 and 2024 benefit year, similar to the transitional approach for race and ethnicity data, issuers are required to populate the field for the ICHRA indicator using only data they already collect or have accessible regarding their enrollees. Then, beginning with the 2025 benefit year, the transitional approach will end, and issuers will be required to populate the field using available sources (for example, information from Exchanges and small employers, 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 ICHRA indicator for these enrollees. HHS will provide additional details on what constitutes a good faith effort to ensure collection and submission of the race, ethnicity, and ICHRA indicator data elements beginning with 2025 benefit year data submissions in the future.[393]

In addition, we will begin extracting three data elements issuers already report to their EDGE servers—plan ID, rating area, and subscriber indicator—as part of the enrollee-level EDGE data. We will extract plan ID and rating area beginning with the 2021 benefit year, and the subscriber indicator beginning with the 2022 benefit year. The extraction of plan ID, rating area, and subscriber indicator will pose a minimal burden on issuers (only the burden associated with the running of a command) since the creation and storage of the extract—which issuers do not receive—is mainly handled by HHS.

For the collection of the five new data elements, we estimated in the proposed rule that the cumulative additional cost estimate would be $225,168 for 600 issuers (87 FR 584, 695). However, to reflect the most current agency estimates, we have modified the estimates from the proposed rule to reflect new wage data, and estimate that the cumulative additional cost estimate will be $314,145 for 650 issuers, and that the addition of these five new data elements to the risk adjustment data submission requirements will be $483.30 per issuer. In addition, we estimate a cumulative one-time administrative cost estimate to update the issuer's file creation process of $1,884,870 for 650 issuers, reflecting a one-time cost of $2,8992 per issuer, which is further explained in the Collection of Information section of this final rule. The extraction of these data elements will pose a minimal burden on issuers (only the burden associated with

[391] 83 FR 16953; 84 FR 17479; 85 FR 29190; and 86 FR 24181.

[392] HHS will collect these data elements in a format that is consistent with the 2011 HHS Data Standards. We also will provide a value for the race or ethnicity data elements that allows issuers to indicate that race or ethnicity are not known for a specific enrollee in recognition of situations where the enrollee declines to provide the information and situations where the issuer does not have an available data source to populate the fields.

[393] After the transitional approach ends (beginning in the 2025 benefit year), the option to select the value to indicate race or ethnicity are not known for a specific enrollee will be available to issuers who comply with the good faith standard but are unable to populate the race or ethnicity EDGE data field for one or more enrollees.

the running of a command) since the creation and storage of the extract—which issuers do not receive—is mainly handled by HHS. We expected minimal costs to HHS as a result of these new collections and extractions.

We are also finalizing, as proposed, to amend § 153.730 to clarify that in situations where the April 30 deadline for issuers to submit risk adjustment data to HHS in States where HHS is operating the risk adjustment program falls on a non-business day, the deadline for issuers to submit the required data would be the next applicable business day. We believe this proposal will not pose an additional burden since it does not change any of the data submission requirements and only clarifies the deadline when April 30 falls on a non-business day.

We sought comment on estimated costs and transfers and potential benefits associated with these provisions.

We received one comment related to the burden associated with the requirement that issuers of risk adjustment covered plans to submit and make accessible the five new data elements as part of the enrollee-level EDGE data to HHS in States where HHS operates the risk adjustment program beginning with the 2023 benefit year, which we summarized and responded to in the Information Collection Requirements section of the rule.

4. Risk Adjustment Data Validation (§§ 153.350 and 153.630)

In this final rule, we finalize updates to the HHS–RADV error rate calculation methodology beginning with the 2021 benefit year to (1) extend the application of Super HCCs from their current application only in the sorting step that assigns HCCs to failure rate groups to broader application throughout the HHS–RADV error rate calculation processes, (2) specify that Super HCCs will be defined separately according to the age group model to which an enrollee is subject, and (3) constrain to zero any negative failure rate outlier in a failure rate group, regardless of whether the outlier issuer has a negative or positive error rate. Although we anticipate the changes will have a small impact on issuers' HHS–RADV risk adjustment transfer adjustments, risk adjustment is a budget neutral program and we expect these policies to refine the HHS–RADV error rate calculation methodology will not have an impact on the administrative burden to issuers subject to the current HHS–RADV process because HHS is responsible for calculating error rates and applying error rates to adjust risk scores and State market risk pool transfers. Furthermore, we expect these changes will have minimal impacts on administrative costs to the Federal Government as the described changes do not impact the underlying HHS–RADV data, the amount of data HHS collects, or the SVA, which is conducted by an entity HHS retains.

We sought comment on these burden estimates. We did not receive any comments in response to the burden estimates for the HHS–RADV policies in this rule.

5. Agents, Brokers, and Web-Brokers (§ 155.220)

a. Required QHP Comparative Information on Web-Broker Websites and Related Disclaimer

In this final rule, we are finalizing the proposal to amend § 155.220(c)(3)(i)(A) to include at proposed new §§ 155.220(c)(3)(i)(A)(*1*) through (c)(3)(i)(A)(*6*) a list of the QHP comparative information web-broker non-Exchange websites are required to display consistent with § 155.205(b)(1). We are also finalizing the proposal to revise the disclaimer requirement in § 155.220(c)(3)(i)(A) so that web-broker non-Exchange websites would be required to prominently display a standardized disclaimer provided by HHS stating that enrollment support is available on the Exchange website and provide a web link to the Exchange website where enrollment support for a QHP is not available using the web-broker's non-Exchange website. We are finalizing as proposed.

This policy should result in very limited new burden for web-brokers. As we explained in the proposed rule (87 FR 584, 709), given CMS' current enforcement policies relative to these requirements, the QHP comparative information we are requiring web-broker websites to display is consistent with previously established requirements. As a result, these requirements would not present a new burden to web-brokers.

The new disclaimer will require web-brokers to make minor updates to their websites in cases when they do not support enrollment in all available QHPs. However, in those cases, they will be displaying a standardized disclaimer much like the plan detail disclaimer that they have historically been required to display.

We estimated this policy will affect approximately 20 web-brokers. Given the minor modifications necessary to implement the revised disclaimer, we estimated a cost of $411 in total labor costs for each web-broker, which reflects 5 hours of work by Web Developers and Digital Interface Designers (15–1257) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of $82.20. The cumulative additional cost estimated as a result of this policy is $8,220 for 20 web-brokers in the 2022 benefit year. We have updated these estimates based on the most recently available national occupational employment and wage estimates. We estimate a cost of $459 in total labor costs for each web-broker, which reflects 5 hours of work by Web and Digital Interface Designers (15–1255) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of $91.80. The cumulative additional cost estimate as a result of this policy is $9,180 for 20 web-brokers in the 2022 benefit year.

We sought comment on the estimated burden associated with these proposals.

We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

b. Prohibition of QHP Advertising on Web-Broker Websites

Section 155.220(c)(3)(i)(L) prohibits web-broker non-Exchange websites from displaying QHP recommendations based on compensation an agent, broker, or web-broker receives from QHP issuers. We are finalizing the proposal to amend § 155.220(c)(3)(i)(L) to make clear that web-broker non-Exchange websites are also prohibited from displaying QHP advertisements, or otherwise providing favored or preferred placement in the display of QHPs, based on compensation agents, brokers, or web-brokers receive from QHP issuers. We are finalizing this proposal as proposed.

This policy should impose no new costs on web-brokers so long as they are not displaying QHP advertisements on their websites. We believe that very few web-brokers are currently doing so. However, for those few web-brokers that are displaying QHP advertisements on their websites, they must update their websites to remove those advertisements and will lose any advertising revenue associated with such placements. Since advertisements on websites are inherently subject to change, even for those web-brokers that are required to make updates to their websites, the costs may be very limited, although we acknowledge that there may be loss of advertising revenue. We also realized, to the extent advertising revenue is lost, web-brokers may seek to recoup the lost revenue from other sources resulting in a transfer of costs. For example, web-brokers may seek to increase fees received from agents and

brokers using their websites or may pursue increased commissions from QHP issuers.

We sought comment on the potential costs, benefits, and transfers associated with this proposal. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

c. Explanation of Rationale for QHP Recommendations on Web-Broker Websites

We are finalizing the proposal to amend § 155.220 to add a proposed new paragraph (c)(3)(i)(M) that would require web-broker websites to prominently display a clear explanation of the rationale for explicit QHP recommendations and the methodology for the default display of QHPs on their websites (for example, alphabetically based on plan name, from lowest to highest premium, etc.). We are finalizing this proposal as proposed.

This policy should result in very limited new costs for web-brokers, since the information it requires they display on their websites is limited to text-based changes that are relatively easy to implement. Furthermore, the extent of those textual updates should be relatively minor in most cases. We expect explanations to be short and easy for consumers to understand. Generally, we believe that a single phrase or a few sentences will suffice. Some web-brokers are already providing the required information, and therefore, will not have to make any website updates. Other web-broker websites do not explicitly recommend QHPs, and therefore, the impact of this policy is limited to providing similar information about the methodology for their default display of QHPs (for example, explaining QHPs are sorted from lowest to highest premium, etc.), assuming they do not already provide that information.

We estimated this policy will affect approximately 20 web-brokers. Given the minor text-based changes necessary to implement the informational text detailing the rationale for QHP recommendations and the methodology for a default display of QHPs, we estimated a cost of $411 in total labor costs for each web-broker, which reflects 5 hours of work by Web Developers and Digital Interface Designers (15–1257) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of $82.20. The cumulative additional cost estimate as a result of this policy is $8,220 for 20 web-brokers in the 2022 benefit year. We have updated these estimates based on the most recently available national occupational employment and wage estimates. We estimate a cost of $459 in total labor costs for each web-broker, which reflects 5 hours of work by Web and Digital Interface Designers (15–1255) per web-broker (100 hours across all web-brokers annually) at an average hourly rate of $91.80. The cumulative additional cost estimate as a result of this policy is $9,180 for 20 web-brokers in the 2022 benefit year.

We sought comment on the potential costs and benefits associated with this proposal. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

d. Providing Correct Information to the FFEs and Prohibited Business Practices

The proposed revisions to § 155.220(j)(2) are focused on addressing various areas where HHS has thus far identified a need for more direct and clear guidance, including ensuring that correct consumer information is entered onto Exchange applications. This includes contact information, such as the consumer's email address, telephone number, and mailing address, as well as information related to projected consumer household income. They also set forth prohibited business practices, such as using automation when interacting with CMS Systems or the DE Pathways without CMS' advance written approval and failing to properly identity proof Exchange applicants. These proposed changes will clarify HHS' expectations in these areas, and create clear, enforceable standards and bases for taking enforcement action for violations of these requirements.

HHS believed these proposals would not impose any burden on any of the parties the proposals would impact, including agents, brokers, and web-brokers. None of these proposals sought to impose new requirements. Rather, these proposals are intended to address common problems that HHS has observed, and provide clear, enforceable standards intended to protect consumers and support the efficient operation of Exchanges by substantially reducing the occurrence of those problems.

We sought comment on any potential costs or benefits associated with these proposals. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

6. Verification Process Related to Eligibility for Insurance Affordability Programs (§ 155.320)

We proposed to amend § 155.320(d)(4) to remove the requirement that Exchanges that do not reasonably expect to obtain sufficient verification data related to enrollment in or eligibility for employer sponsored coverage conduct random sampling to verify whether an applicant is eligible for or enrolled in an eligible employer sponsored plan in favor of a verification process that is based on risk for inappropriate APTC/CSRs. We believed this proposal would benefit employers, employees, Exchanges using the Federal platform, and State Exchanges that operate their own eligibility and enrollment platform, as this proposal would relieve them from the burden of investing resources to conduct and respond to random sampling, as applicable.

In the 2019 Payment Notice final rule (82 FR 51128), we discussed a study that HHS conducted in 2016 and the burden associated with sampling based in part on the alternative process used for the Exchanges. HHS incurred approximately $750,000 in costs to design and operationalize this study, and the study indicated that $353,581 of APTC was potentially incorrectly granted to individuals in the sampled population who inaccurately attested to their enrollment in or eligibility for a qualifying eligible employer sponsored plan. We placed calls to employers to verify 15,125 cases but were only able to verify 1,948 cases. A large number of employers either could not be reached or were unable to verify a consumer's information, resulting in a verification rate of approximately 13 percent. The sample size involved in the 2016 study did not represent a random sample of the target population and did not fulfill all regulatory requirements for sampling under § 155.320(d)(4)(i).

Taking additional costs into account—namely, the cost of sending notices to employees as required under § 155.320(d)(4)(i)(A), the cost of building the infrastructure and implementing the first year of operationalizing this process, and the cost of expanding the number of cases to a random sample size of approximately 1 million cases—we estimated that the overall one-time cost of implementing sampling would have been approximately $8 million for the Exchanges using the Federal platform, and between $2 million and $7 million for other Exchanges, depending on their enrollment volume and existing infrastructure. Therefore, we estimated that the average per-Exchange cost of implementing sampling that resembles the approach taken by the Exchanges using the Federal platform would have been approximately $4.5 million for State Exchanges that operate their own

eligibility and enrollment platform, for a total cost of $67.5 million for the 15 State Exchanges that operate their own eligibility and enrollment platform (operating in 14 States and the District of Columbia). However, we are aware that 4 State Exchanges that operate their own eligibility and enrollment platform have already incurred costs to implement sampling and estimate that they have incurred one-time costs of approximately $4.5 million per Exchange with a total of $18 million and will only experience savings related to recurring costs. Therefore, the one-time savings for Exchanges using the Federal platform and the remaining State Exchanges that operate their own eligibility and enrollment platform will be approximately $49.5 million.

We estimated the annual costs to conduct sampling on a random sample size of approximately 1 million cases to be approximately $8 million for the Exchanges using the Federal platform and $7 million on average for each State Exchange that operates its own eligibility and enrollment platform. This estimate includes operational activities such as noticing, inbound and outbound calls to the Marketplace call center, and adjudicating consumer appeals. The total annual cost to conduct sampling would have been $105 million for 15 State Exchanges. Therefore, the total annual cost for the Exchanges using the Federal platform and the 15 State Exchanges that operate their own eligibility and enrollment platform would have been $113 million in 2022 and onward.

Eliminating these estimated costs would be offset by the costs of designing and implementing an appropriate verification process. We estimated that the cost to conduct research for Exchanges using the Federal platform to be approximately $295,000 and for the 15 State Exchanges that operate their own eligibility and enrollment platform to be approximately $4.4 million. In addition to significant cost savings, this proposal would provide more flexibility for States to design and implement a verification process for employer sponsored coverage that is tailored to their unique populations and would protect the integrity of States' respective individual markets. Furthermore, we believe that this proposal would reduce the burden on employers and employees, as compliance with the current random sampling, notification, and information gathering processes require significant time and resources, which likely would be reduced if this proposal is finalized.

HHS requested a comment on the estimated and potential costs and impacts of this proposal.

We summarize and respond to public comments received on the verification process related to eligibility for insurance affordability programs (§ 155.320) below.

HHS wishes to note that since the publication of the proposed rule, three States have transitioned from having State Exchanges using the Federal eligibility and enrollment platform to operating as State Exchanges that operate their own eligibility and enrollment platform, therefore, we are revising our previous estimated cost and saving estimates. We revise the per-Exchange cost of implementing sampling that resembles the approach taken by the Exchanges using the Federal platform would have been approximately $4.5 million for State Exchanges that operate their own eligibility and enrollment platform, for a total cost of $81 million for the 18 State Exchanges that operate their own eligibility and enrollment platform (operating in 17 States and the District of Columbia). We are still aware that 4 State Exchanges that operate their own eligibility and enrollment platform have already incurred costs to implement sampling and estimate that they have incurred one-time costs of approximately $4.5 million per Exchange with a total of $18 million and will only experience savings related to recurring costs. Therefore, the one-time savings for Exchanges using the Federal platform and the remaining State Exchanges that operate their own eligibility and enrollment platform will be approximately $63 million. The total annual cost to conduct sampling has been revised to $126 million for the 18 State Exchanges. Therefore, the total annual cost for the Exchanges using the Federal platform and the 18 State Exchanges that operate their own eligibility and enrollment platform has been revised to $134 million in 2023 and onward. Finally, we revised the estimated cost to conduct research for Exchanges using the Federal platform to be approximately $295,000 and for the 18 State Exchanges that operate their own eligibility and enrollment platform to be approximately $5.3 million.

Comment: While not directly related to the cost estimates, one commenter expressed concern with the proposed risk-based approach for designing and developing processes for employer sponsored coverage verification as it could lead to increased APTC/CSR improper payments. The commenter noted that the Congressional Budget Office estimated that approximately $83 billion will be spent on APTC/CSR in 2022. The commenter stated that based on HHS' own analysis that about two percent of consumers may have an incentive to enroll in Exchange coverage rather than coverage offered through an employer, this could result in about $1.7 billion in APTC/CSR payments, which is larger than HHS' estimates to operationalize the random sampling requirement.

Response: HHS disagrees with the commenter's estimate because there are many other factors to take into consideration when estimating potential inappropriate payments of APTC/CSR, such as the average number of months an enrollee would have received APTC/CSR after HHS took action to end APTC/CSR. HHS believes using a flat estimate based on CBO projections, which doesn't take these factors into consideration, is misleading.

After reviewing the public comments, we are finalizing as proposed.

7. Proration of Advance Premium Tax Credit and Premium (§§ 155.240(e), 155.305(f)(5), and 155.340)

HHS proposed amendments to part 155, specifically at §§ 155.240(e), 155.305(f)(5), and 155.340 to establish the requirement that all Exchanges prorate both premiums and APTC for enrollees enrolled in a particular policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month, using a specified methodology. This method of administering APTC would reduce instances of payments of APTC in excess of an applicable taxpayer's monthly PTC eligibility for a month in which an enrollee is enrolled in multiple policies within a month, each lasting less than the full calendar month, and thus would protect the applicable taxpayer from incurring income tax liability due to excess APTC.

HHS noted that this would benefit both issuers and enrollees by reducing instances of APTC over-payment and eliminating wasted resources dedicated to resolving over-payment issues. While the FFEs and SBE–FPs already prorate APTC and premium amounts, some State Exchanges do not currently prorate consistently the amount of applied APTC administered to issuers in their applicable States.

HHS acknowledged that those State Exchanges that do not currently prorate APTC or premium amounts would be financially impacted by the proposed requirement to implement this methodology, and this proposal would likely require operational systems

builds to support this new proration requirement.

Based on historical cost data for State Exchanges to implement changes to their IT systems and operations related to premium processing functionality and similar functionality, such as functionality for processing consumer failures to reconcile APTC received for a previous plan year, HHS estimated that State Exchanges that currently do not implement proration of APTC or premium amounts according to the proposed methodology could expect to incur one-time implementation costs. HHS anticipated that each affected State Exchange that does not already prorate APTC or premium amounts according to the proposed methodology would expect an estimated $1 million one-time burden to account for the IT build to support the new calculation and reporting systems associated with this requirement.

HHS estimated that 8 State Exchanges currently prorate premium amounts but do not prorate APTC amounts. HHS anticipated that those State Exchanges which already prorate premium amounts would have the operational and systems capacity to calculate the prorated premium and APTC amounts as required in the proposed policy.

Currently, State Exchanges vary in their approaches to implementing the proposed APTC and premium proration. In order to provide an upper bound estimate of this proposal's burden, HHS assumed that 10 State Exchanges, including State Exchanges that newly transitioned to being State Exchanges by the time of this rulemaking, would incur the highest level of implementation cost detailed earlier in this final rule ($1 million in one-time implementation burden per State Exchange) for a total estimated impact of $10,000,000 in the 2024 benefit year across all State Exchanges. HHS sought comment on the estimated costs and benefits described in this section.

We summarize and respond to public comments received on the proration of APTC and premium (§§ 155.240(e), 155.305(f)(5), and 155.340) below.

Comment: We received several comments on the estimated costs for a State Exchange to implement the proposed APTC and premium proration methodology. A few commenters stated that the estimated one-time implementation cost of $1 million dollars per State Exchange was unreasonably burdensome, particularly considering competing programmatic demands and the ongoing COVID–19 PHE. Another commenter noted that HHS severely underestimated the implementation cost and estimated that it would cost approximately four times the burden estimate detailed in the proposed rule to implement the proposed proration methodology within their Exchange.

Response: HHS appreciates the comments on the estimated burden associated with the proposed policy. The estimates in the proposed rule were made using the best available information that HHS could access, and the comments received helped to clarify the impact that the proposed policy could have State Exchanges. In an effort to be responsive to comments regarding implementation costs, HHS is finalizing this policy with modifications that will significantly reduce the burden on State Exchanges. We are not finalizing the requirement to prorate premium or APTC amounts for State Exchanges. Rather, we are finalizing a requirement that, beginning in PY 2024, State Exchanges must implement a methodology to ensure that APTC calculations do not cause an enrollee's total monthly APTC amount from exceeding their PTC, in compliance with HHS and IRS regulations. Further, State Exchanges must prospectively report to HHS through existing State Exchange oversight mechanisms the methodology the State intends to use in PY 2024.

While many State Exchanges already have a methodology that meets the requirement of preventing an enrollee's monthly APTC amount from exceeding their monthly PTC eligibility, we note that some States will likely require operational IT systems changes to implement a compliant methodology. HHS estimates that 8 State Exchanges will require some form of operational investment to comply with this policy. The cost of a systems builds may vary among State Exchanges depending on their elected methodology, but we estimate $500,000 in one-time contact labor cost per State Exchange. This cost estimate is lower than that in the proposed rule to reflect that State Exchanges will have the flexibility to implement any methodology that ensures an enrollee's monthly APTC does not exceed their PTC eligibility. We estimate that the one-time financial impact of this requirement to be approximately $500,000 for 8 State Exchanges, or $4 million in PY 2024.

The burden to report this information to HHS will be negligible, as State Exchanges will use existing oversight mechanisms. This reporting requirement will be included within the reporting requirements described at § 155.1200(b)(2) and the information collected will be addressed by the State Based Marketplace Annual Report Tool (SMART) PRA (OMB Control Number 0938–1244) which we explain earlier in the ICR section of this rule.

After reviewing the public comments, we are finalizing with modifications.

10. Special Enrollment Periods—Special Enrollment Period Verification (§ 155.420)

We proposed to amend § 155.420 to add a new paragraph (g) to state that Exchanges may conduct pre-enrollment verification of eligibility for special enrollment periods, at the option of the Exchange, and that Exchanges may provide an exception to pre-enrollment special enrollment period verification for special circumstances. Exchanges on the Federal platform would conduct pre-enrollment special enrollment period eligibility verification for new consumers who attest to losing minimum essential coverage.

We did not anticipate that revisions to § 155.420 would impose regulatory burden or costs on the Exchanges on the Federal platform because these Exchanges will decrease the number of special enrollment period types that require pre-enrollment verification to only include special enrollment periods for new consumers who attest to losing minimum essential coverage. The provisions proposed in this rule would decrease the scope of pre-enrollment special enrollment period verification in all States with Exchanges served by the Federal platform. We anticipated that this would result in 194,000 fewer individuals having their enrollment delayed or ''pended'' annually until eligibility verification is completed, which would result in a $5,150,700 (or 20 percent) decrease in annual ongoing costs to the Federal Government.

There may be State Exchanges that also decide to reduce the scope of their current pre-enrollment special enrollment period verification, which would also decrease annual ongoing costs for State Exchanges. State Exchanges that are currently conducting pre-enrollment verification of eligibility for more special enrollment period types than those that the Exchanges on the Federal platform would be verifying under this proposal could experience a decrease in burden and costs if they choose to align their approaches with the Exchanges on the Federal platform. State Exchanges that are currently conducting pre-enrollment verification of eligibility for fewer types of special enrollment periods than the proposed special enrollment period that the Exchanges on the Federal platform would be verifying under this proposal could experience an increase in burden and costs if they choose to align with

the Exchanges on the Federal platform, but State Exchanges will not be required to align with the Exchanges on the Federal platform.

We did not anticipate that this would increase administrative costs on QHP issuers. Additionally, our data suggest that SEP documentation deters younger, likely healthier individuals from enrolling, but there could be an increase in claims costs to QHP issuers since the Exchanges on the Federal platform will be requiring document submission prior to enrollment for fewer special enrollment period types.

We sought comment on the potential costs, benefits, and transfers associated with this proposal.

We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision. Therefore, we are finalizing these provisions as proposed.

11. General Program Integrity and Oversight Requirements (§ 155.1200)

As explained earlier in this preamble, we are not finalizing this provision related to general program integrity and oversight requirements at this time. We estimated that there would be a general reduction in reporting and contracting costs to State Exchanges related to meeting auditing requirements under § 155.1200. We anticipated the combined cost in contracting and reporting would result in an average annual reduction of approximately $90,624.62 for each State Exchange beginning in the benefit year 2024. The total cost annual reduction across 18 State Exchanges would be approximately $1,631,243.16.

We sought comment on the potential costs, benefits, and transfers associated with this provision.

Comment: A few commenters expressed general concern regarding the estimated burden reduction associated with this proposal.

Response: We address these comments in the General Program Integrity and Oversight 155.1200 preamble discussion earlier in this rule. Based on public comments received, we are not finalizing this provision at this time.

12. State Exchange Improper Payment Measurement Program (§§ 155.1500 Through 155.1540)

As we explained earlier in section III. of the preamble, HHS is not finalizing the regulations we proposed to govern implementation of the SEIPM program could have the direct effect of reducing improper payments. We sought comment on the estimated costs and benefits and potential transfers associated with these provisions but did not receive any responsive comments.

13. FFE and SBE–FP User Fees (§ 156.50)

We are finalizing an FFE user fee rate of 2.75 percent of monthly premiums charged by the FFE issuer for the 2023 benefit year, which is the same as the 2.75 percent FFE user fee rate finalized in part 3 of the 2022 Payment Notice.[394] We are finalizing an SBE–FP user fee rate of 2.25 percent of monthly premiums charged by the SBE–FP issuer for the 2023 benefit year, which is the same as the 2.25 percent SBE–FP user fee rate finalized in part 3 of the 2022 Payment Notice.[395] Therefore, we do not believe that these user fee rates will have any additional impact on premiums compared to the 2022 benefit year. We also finalize an amendment to § 156.50 to conform the user fee regulations with the repeal of the Exchange DE option finalized in part 3 of the 2022 Payment Notice.[396] We do not expect that it will have any additional regulatory impact

We sought comment on the potential costs, benefits, and transfers associated with this provision. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

14. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

We proposed to eliminate the requirement at § 156.111(d) and (f) to require States to annually notify HHS in a form and manner specified by HHS, and by a date determined by HHS, of any State-required benefits applicable to QHPs in the individual or small group market that are considered to be in addition to EHB in accordance with § 155.170(a)(3) and any benefits the State has identified as not in addition to EHB and not subject to defrayal, describing the basis for the State's determination.

Under this proposal, States would no longer be required to submit an annual report that complies with each requirement listed at § 156.111(f)(1) through (6), nor would HHS identify which benefits are in addition to EHB for the applicable PY in the State if a State does not submit an annual reporting package.

The 2021 Payment Notice acknowledged that requiring States to annually report to HHS would require that States submit additional paperwork to HHS on an annual basis but noted that, as States are already required under § 155.170 to identify which State-required benefits are in addition to EHB and to defray the cost of those benefits, any such burden experienced by States would be minimal.[397] The 2021 Payment Notice also stated that this reporting requirement would be complementary to the process the State should already have in place for tracking and analyzing State-required benefits. The 2021 Payment Notice further explained that States may opt not to report this information and instead let HHS make this determination for them. In the 2021 Payment Notice, we also discussed that any State burden associated with this policy would be limited to the completion of the HHS templates, validation of that information, and submission of the templates to HHS. Repealing the annual reporting requirement would remove the burden associated with that policy, detailed in 2021 Payment Notice and summarized previously in the Collection of Information Requirements section in this final rule.

Although this proposal would relieve States of the annual reporting requirements and any associated burden with submission and validation of the information on the annual reporting templates, it would not pend or otherwise impact the defrayal requirements under section 1311(d)(3)(B) of the ACA, as implemented at § 155.170. Under this proposal, States remain responsible for making payments to defray the cost of additional required benefits and issuers are still responsible for quantifying the cost of these benefits and reporting the cost to the State. We also noted that the obligation for a State to defray the cost of QHP coverage of State-required benefits in addition to EHB is an independent statutory requirement from the annual reporting policy finalized at § 156.111(d) and (f).

We sought comment on the potential costs, benefits, and transfers associated with this provision.

After reviewing the public comments, we are finalizing repeal of the annual reporting policy at § 156.111(d) and (f), including revising the section heading to § 156.111 to instead read, ''State selection of EHB-benchmark plan for PYs beginning on or after January 1, 2020.''

We summarize and respond to public comments received repealing the annual reporting of State-required benefits below.

[394] 86 FR 53412, 53445.

[395] Ibid.

[396] Ibid.

[397] 85 FR 29164, 29252.

Comment: Many commenters supported the repeal of the annual reporting policy and noted that the policy is an unnecessary new administrative burden on States without adequate justification. One commenter explained that the reporting structure would have required State officials to either procure consultants or divert existing staff from other work to comply with an entirely new reporting process. Commenters stated that the elimination of this reporting requirement would remove a needless administrative burden while maintaining States' responsibility to comply with the defrayal rule.

Other commenters objected to the repeal of the annual reporting policy and challenged the claims that the policy was overly burdensome. Such commenters noted that States should already have determined the status and cost of State-required benefits and that the reporting requirement should not place a burden on States of conducting new analyses. Commenters further noted that, after the initial reporting cycle, the administrative burden on States would be even more minimal.

Response: We maintain that the annual reporting policy would have imposed a minimal burden on States as the information that States would have been required to report to HHS should already be readily accessible to States, as every State should already be identifying which State-required benefits are in addition to EHB and should be defraying any such costs. States should already have ready access to the information the annual reports would have required as States should already have in place a process for tracking and analyzing State-required benefits. However, even if the State burden would have been minimal, we still believe that taking a more targeted approach of engaging with individual States on questions of compliance with the defrayal requirement will yield similar results to the annual reporting policy without requiring all States, including even compliant States, to expend additional time and resources submitting a report with this detailed information.

15. Levels of Coverage (Actuarial Value) (§ 156.140, 156.200, 156.400)

We proposed to change the *de minimis* range for levels of coverage at § 156.140(c) to a variation of +2/−2 percentage points for all standard bronze plans, gold plans, platinum plans, individual market off-Exchange silver plans, and all small group market silver plans (on- and off-Exchange), as well as proposed to change the *de minimis* for expanded bronze plans to +5/−2, that are required to comply with AV standards for PYs beginning in 2023. In addition, we proposed to change the *de minimis* under § 156.200 to +2/0 percentage points for individual market silver QHPs and for the income-based silver CSR plan variations under § 156.400 to +1/0.

In the 2017 Market Stabilization rule (82 FR 18346), we acknowledged that in the short run, expanding the standard *de minimis* range to +2/−4 would generate a transfer of costs from consumers to issuers in the form of decreased APTC and increased premiums, but stated our belief that the additional flexibility for issuers would have positive effects for consumers over the long term as premiums stabilized, issuer participation increased, and coverage options at the silver level and above increased, which would attract more young and healthy enrollees into such plans. As discussed above, since we finalized the expanded *de minimis* ranges, we have observed decreased enrollment in silver plans (from 963,241 enrollees in PY 2018 to 424,345 enrollees in PY 2021), despite the number of standard silver plans available on *HealthCare.gov* steadily increasing from 811 silver plans in PY 2018 to 1,386 silver plans in PY 2021. Thus, we cannot justify the decreased APTC with evidence of increased enrollment of younger and healthier enrollees in silver plans.

Changing the *de minimis* ranges for standard metal level plans would generate a transfer of costs from the government and issuers to consumers in the form of increased APTC and decreased premiums, because narrowing the *de minimis* range for silver plans can affect the generosity of the SLCSP. The SLCSP is the benchmark plan used to determine an individual's PTC. A subsidized enrollee in any county that has an SLCSP that is currently below 70 percent AV would see the generosity of their current SLCSP increase, resulting in an increase in PTC. Not all counties would see the SLCSP change as a result of this proposal. In States using *HealthCare.gov,* approximately 87 percent of counties across 23 States have an SLCSP that is below 70 percent AV.

For this proposal, the CMS Office of the Actuary estimates a nationwide increase in PTCs through PY 2032, as shown in Table 22.

TABLE 22: PTC Impact of +2/0 Silver *De Minimis* Plan AVs, 2023-2032

Calendar Year	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
PTC Impact ($ Billions)	0.73	0.77	0.77	0.76	0.77	0.78	0.82	0.83	0.87	0.92
Fiscal Year	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
PTC Impact ($ Billions)	0.55	0.76	0.77	0.76	0.77	0.78	0.81	0.83	0.86	0.91

This proposal would impact those consumers currently enrolled in standard silver plans that are currently in the −4 to −0.01 percent *de minimis* range that would be out of compliance under this proposal, as well as consumers currently enrolled in individual market silver QHPs that are currently in the −4 to −0.01 percent *de minimis* range and associated income-based CSR silver plan variations currently enrolled in the −1 to −0.01 percent *de minimis* range. Of the plans on *HealthCare.gov,* we estimate that there are approximately 150,000 enrollees in gold plans below 78 percent AV, and 3,500 enrollees in platinum plans below 88 percent AV.[398] Additionally, we estimate there are approximately 248,000 enrollees in *HealthCare.gov* silver QHPs below 70 percent AV, with approximately 4.2 million enrollees in corresponding income-based CSR plan variations. Under these proposals, those enrollees would need to select a different plan for PY 2023 if the issuer chooses to discontinue the plan rather than revise the plan's cost sharing. Additionally, these proposals would similarly affect enrollees in such plans that are not available on *HealthCare.gov,* such as plans sold on State Exchanges, for

[398] There are no enrollees in bronze plans below 58% AV.

which we do not have data to make an informed estimate.

We estimated the premiums for these plans would increase approximately 2 percent on average because of benefit changes required for plans to meet a +2/0 *de minimis* threshold. However, for Exchange enrollees, we stated that we expect this premium increase to be substantially offset by the corresponding increase in PTC because of the proposal's impact on the SLCSP. Similarly, the proposal to change the *de minimis* range for CSR variants to +1/0 would lead to improved cost sharing due to the higher relative AV compared to the current +1/−1 range, along with increased gross premiums that would be substantially offset by increased PTC payments. After implementation of the ARP enhanced financial subsidies, subsidized enrollees make up the majority of *HealthCare.gov* silver QHP enrollees—only 91,000 of approximately 248,000 individual market silver QHP enrollees in plans with AV between 66.00 and 69.99 percent plan AV remain unsubsidized. By comparison, enrollment within the corresponding income-based silver CSR variations of the above silver QHPs has increased to approximately 4.2 million. We stated that we expect the increased PTC payments due to the premium increase to incentivize healthier subsidy-eligible enrollees to participate in the Marketplace, and that the improved risk pool as a result of increased healthier enrollees would mitigate the net cost burden of covering a decreasing population of unsubsidized enrollees.

In addition, changing the *de minimis* range for standard silver plans would impact ICHRAs, which use the Lowest Cost Silver Plan (LCSP) as the benchmark to determine whether an ICHRA is considered affordable to an employee. Under this proposal, as silver plans become more generous and premiums increase, an employer would have to contribute more to an ICHRA to have it be considered affordable. This change could discourage large employer use of ICHRAs because large employers need to offer affordable coverage to satisfy the employer shared responsibility provisions.[399] Additionally, if coverage is considered unaffordable to the employee, the employee can opt out of the ICHRA and instead purchase coverage on the Exchange with APTC, if otherwise eligible; and increasing the LCSP premiums could make employer-sponsored coverage unaffordable to more employees. We estimated silver plans with an AV below 70 percent will see premiums increase by approximately 2 percent on average due to more generous benefits. We stated that we do not believe this would have a significant impact on the number of employers willing to offer ICHRAs or whether an ICHRA is considered affordable to most employees, but we invited comments to refute or refine this understanding on these issues in particular.

We sought comment on the estimated costs, benefits, and transfers associated with this provision. However, we did not receive comments that specifically addressed the accuracy of the burden estimates included in the proposed rule; instead, the comments received addressed the merits of the proposal itself, which we have addressed in the preamble. Thus, we are finalizing these burden estimates as proposed.

16. Standardized Plan Options (§ 156.201)

Section 156.201 finalizes the provision to require QHP issuers to offer standardized QHP options. Though these requirements necessitate the creation of new plans, HHS explained that it believes the burden imposed on issuers would be minimal because these new plans' benefits, networks, and formularies would not differ substantially from the benefits, networks, and formularies of a majority of plans that issuers currently offer and because HHS designed the cost-sharing parameters, MOOPs, and deductibles for these new plans. Additionally, HHS designed these standardized plan options to resemble the most popular QHPs in the individual market FFEs and SBE–FPs in PY 2021, making these standardized plan options comparable to plans that the majority of issuers already offer. Furthermore, since HHS is requiring QHP issuers to offer standardized plan options at every product network type, at every metal level, and throughout every service area they also offer non-standardized QHPs (but not at different product network types, metal levels, and service areas that they do not also offer non-standardized QHPs), issuers are not required to extend plan offerings beyond their existing service areas.

Additionally, since HHS did not finalize any provision to limit the number of non-standardized QHP options that issuers can offer in PY 2023, HHS explained that it believes the majority of enrollees will remain enrolled in their current non-standardized plan options. Moreover, since HHS did not finalize any provisions to require issuers to offer a higher number of QHPs than what they currently offer, issuers would still be able to determine how many QHPs they wish to offer. As a result, HHS explained that it does not expect the total number of plans that issuers are offering to change substantially subsequent to the imposition of the requirement. Thus, though these new plans will have to be submitted for approval, certification, and display, we expected that the overall burden for issuers and States alike would not substantially increase because we do not expect the number of overall plan offerings to substantially increase—due in part to issuers discontinuing some old non-standardized offerings.

As noted earlier in the preamble, HHS noted that it is resuming the differential display of standardized plan options per the existing authority at § 155.205(b)(1). HHS is assuming burden for the differential display of standardized plan options on *HealthCare.gov,* meaning FFE and SBE–FP issuers are not subject to this burden.

In addition, as noted in the preamble, HHS noted that it is resuming 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 explained that it believes that resuming enforcement of these differential display requirements will not require significant modification of these entities' platforms and non-Exchange websites. Further, since HHS is allowing these entities to submit requests to deviate from the manner in which standardized plan options are differentially displayed on *HealthCare.gov,* the potential burden for these for these entities is further reduced. HHS also noted that it intends to provide access to information on standardized plan options to web-brokers through the Health Insurance Marketplace PUFs and QHP Landscape file to further minimize the burden. The specific burden estimates for these requirements can be found in the corresponding ICR sections for §§ 155.220 and 156.265.

We sought comment on the potential costs, benefits, and transfers associated with this provision. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision. We are finalizing these burden estimates as proposed.

[399] See section 4980H of the Code; 26 CFR 54.4980H–1–26 CFR 54.4980H–6.

17. Network Adequacy (§ 156.230)

Section 156.230(a)(2) currently requires a QHP issuer to maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorders, to ensure that all services will be accessible without unreasonable delay. In this final rule, HHS is finalizing that for PY 2023 and future PYs that all QHPs or QHP candidates that use a provider network must comply with network adequacy standards.

HHS finalized the proposal to conduct prospective quantitative network adequacy reviews for all FFEs in all FFE States except in States performing plan management functions that adhere to a standard as stringent as the Federal standard, conduct reviews prospectively, and choose to conduct their own reviews. HHS finalized for PY 2023 and future PYs to adopt time and distance standards to assess whether FFE QHPs or QHP candidates fulfill network standards based on numbers and types of providers and providers' geographic locations. Time and distance standards will be calculated at the county level using information from the ECP/NA template. HHS also proposed to adopt appointment wait time standards to assess whether FFE QHPs or QHP candidates fulfill network adequacy standards. HHS will begin implementation of reviews for appointment wait time standards in PY 2024. Issuers that are unable to meet the specified standards for time and distance or appointment wait times must submit a justification to account for such variances.

HHS did not finalize the proposal that, for plans that use tiered networks to count toward the issuer's satisfaction of the network adequacy standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation.

Finally, HHS finalized the proposal to collect information about providers who offer telehealth services via the ECP/NA template to inform network adequacy and provider access standards for future PYs. As discussed previously in the Collection of Information Requirements section, this may increase related administrative costs for issuers who do not already possess this data, though many issuers already collect and submit this information for network adequacy submissions in other markets. While we anticipate that the increased burden related to telehealth data collection would be minimal for many issuers, the increased burden could ultimately lead to an increase in premiums for consumers. As noted previously, we believe that the potential benefits of obtaining telehealth information and using it to inform future network adequacy standards are in the best interests of both QHP enrollees and QHP issuers. As such, we anticipate that the additional burden would be mitigated by the expected benefits.

We sought comment on the potential costs, benefits, and transfers associated with this provision. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

18. Essential Community Providers (§ 156.235)

Section 156.235(a)(2)(i) provides that a plan has a sufficient number and geographic distribution of ECPs if the issuer demonstrates, among other things, that a QHP or QHP candidate provides access to a network of providers that includes at least a minimum percentage of ECPs, as specified by HHS.

For PY 2023 and future PYs, HHS proposes to raise the ECP threshold applicable to QHPs and QHP candidates from 20 percent to 35 percent. For this increased threshold, HHS would consider issuers to have satisfied the regulatory threshold requirement if the issuer contracts with at least 35 percent of available ECPs in each plan's service area to participate in the plan's provider network.

We noted that in PYs 2015–2017, all FFE QHP issuers satisfied the 30 percent threshold with minimal reliance on ECP write-ins and justifications. In PYs 2018 through 2021, when the ECP threshold was 20 percent, all QHP issuers satisfied the lower threshold with ease and very little reliance on ECP write-ins and justifications.

Consequently, HHS anticipates that issuers can meet the proposed 35 percent threshold using ECP write-ins and justifications as needed. We believed that increasing the ECP threshold would lead to greater ECP access for low-income and medically underserved individuals. HHS anticipates that costs may not increase since HHS' data analysis shows most issuers could easily meet this standard or use the justification process. HHS expected that administrative cost changes would likely be minimal for most issuers.

HHS proposed that, for plans that use tiered networks to count toward the issuer's satisfaction of 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 would be counted towards ECP standards.

We sought comment on the potential costs, benefits, and transfers associated with this provision. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

19. Standards for Delegated and Downstream Entities (§ 156.340)

In this final rule, we are finalizing the proposal to amend and add language to § 156.340, to extend its applicability to QHP issuers on all Exchange models. We are finalizing changes to capture the delegated and downstream entity standards that would apply to QHP issuers on State Exchanges and State Exchange SHOPs, as well as QHP issuers providing coverage on Exchange models that use the Federal platform, including, but not limited to, FFEs, FF–SHOPs, SBE–FPs, and SBE–FP–SHOPs. HHS is also finalizing the proposal to add a requirement that all agreements between QHP issuers and their downstream and delegated entities include language stating that the relevant Exchange authority, including State Exchanges, may demand and receive a delegated and downstream entity's records related to the QHP issuer's obligations in accordance with the minimum Federal standards related to Exchanges. These amendments are intended to hold QHP issuers in all Exchange models responsible for their downstream and delegated entities' compliance with applicable Exchange standards, and to make their oversight obligations, and the obligations of their downstream and delegated entities, explicit. We are also finalizing conforming amendments to the title of subpart D of 45 CFR part 156 from ''Standards for Qualified Health Plan Issuers on Federally Facilitated Exchanges and State-Based Exchanges on the Federal platform'' to ''Standards for Qualified Health Plan Issuers on Specific Types of Exchanges''.

We anticipated these policies will impose a minimal burden on QHP issuers and Exchange authorities impacted by them. HHS expects some QHP issuers may need to make changes to existing record retention policies and their agreements with delegated and downstream entities. The conforming amendments will become applicable to all books, contracts, computers, or other electronic systems, including medical records and documentation relating to the QHP issuer's obligations in

accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period, as of the effective date of the final rule. State Exchange authorities will retain primary enforcement authority and would be responsible for ensuring QHP issuers in State Exchanges and State Exchange SHOPs maintain oversight over downstream and delegated entities.

We sought comment on the potential costs, benefits, and transfers associated with this provision.

After reviewing the public comments and the general nature of the assertions that are unsupported by data, HHS will finalize our burden estimate and implementation date as proposed.

We summarize and respond to public comments received for standards for delegated and downstream entities.

Comment: A few commenters expressed concern that the addition of contract language proposed in paragraph (b)(5) would place a burden on downstream and delegated entities. Other commenters supported the benefits the proposed language in paragraph (b)(5) would confer by clarifying § 156.340 and its applicability.

Response: As acknowledged in our analysis, we anticipate this policy change will impose a minimal burden (that is, a limited additional burden). For example, some QHP issuers in State Exchanges may need to make changes to existing record retention policies and their agreements with delegated and downstream entities. Relatedly, some delegated and downstream entities may need to revise their record retention policies. However, we believe such changes will be relatively easy to make and implement (for example, changing a record retention policy and related agreements to retain records for 10 years instead of 7 years). We note that none of the commenters provided any data or specificity concerning the actual burdens, costs, or transfers they expected the changes to impose. We believe our analysis accounts for all burden.

20. Payment for Cost-Sharing Reductions (§ 156.430)

We are amending § 156.430 to clarify that the CSR data submission process is mandatory only for those issuers that received CSR payments from HHS for any part of the benefit year as a result of an appropriation to make CSR payments and voluntary for all other issuers. In the event HHS has not made CSR payments to issuers because there is no appropriation to do so, HHS will continue to provide those issuers that have not received CSR payments from HHS for any part of the benefit year the option to submit CSR data, but issuers will not be required to do so. We did not expect any of these provisions to increase the burden on issuers, as this amendment would codify existing practices.

We sought comment on any potential costs, benefits, and transfers associated with this provision. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

21. Quality Improvement Strategy (§ 156.1130)

We proposed that beginning in 2023, a QHP issuer would be required to address reducing health and health care disparities as one of their QIS topic areas in addition to at least one other topic area outlined in section 1311(g)(1) of the ACA, including improving health outcomes of plan enrollees, preventing hospital readmissions, improving patient safety and reducing medical errors, and promoting wellness and health. We did not propose any changes to the regulatory text. We did not estimate additional costs or burdens as a result of this proposal.

We sought comment on any potential costs, benefits, and transfers associated with this proposal. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

22. Medical Loss Ratio (§§ 158.140, 158.150, 158.170)

We are finalizing the proposal to amend § 158.140(b)(2)(iii) to clarify that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes. To the extent some issuers currently include in incurred claims payments to providers that significantly reduce or eliminate rebates while providing no value to consumers, the proposed clarification would result in transfers from such issuers to enrollees in the form of higher rebates or lower premiums. Although we do not know how many issuers currently engage in such reporting practices or the amounts improperly included in MLR calculations, we estimate the impact of the proposed clarification by assuming that provider incentive and bonus payments of 1.06 percent or more of paid claims (the top 5 percent of such observations) may represent incentives based on MLR or similar metrics. Based on this assumption and the MLR data for 2019, the proposed clarification would increase rebates paid by issuers to consumers or reduce premiums collected by issuers from consumers by approximately $12 million per year.

We are also finalizing the proposal to amend § 158.150(a) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses for MLR reporting and rebate calculation purposes. The proposed change would result in transfers from issuers that currently include indirect expenses in QIA to enrollees in the form of higher rebates or lower premiums. Although we do not know how many issuers include indirect expenses in QIA, we estimated the impact of the proposed change by assuming that indirect expenses inflate QIA by 41.5 percent (the midpoint of the 33 percent to 50 percent range we have observed during MLR examinations) for half of the issuers that report QIA expenses (based on the frequency of QIA-related findings in MLR examinations). Based on these assumptions and the MLR data for 2019, the proposed clarification would increase rebates paid by issuers to consumers or reduce premiums collected by issuers from consumers by approximately $49.8 million per year.

We are also finalizing the proposal to make a technical amendment to § 158.170(b) to correct an oversight and remove the reference to the percentage of premium QIA reporting option described in § 158.221(b)(8), a provision that was vacated by the United States District Court for the District of Maryland in *City of Columbus, et al.* v. *Cochran,*[400] and thus deleted in part 2 of the 2022 Payment Notice final rule.[401] We did not anticipate any impact on rebates or premiums as a result of this change.

We sought comment on any potential costs, benefits, and transfers associated with this provision. We did not receive any comments specific to the potential costs, benefits, and transfers associated with this provision.

D. Regulatory Alternatives Considered

In developing the policies contained in this final rule, we considered numerous alternatives to the presented proposals. Below we discuss the key regulatory alternatives that we considered.

As described in prior rulemakings and the 2021 RA Technical Paper, we considered a variety of alternatives to

[400] 523 F. Supp. 3d 731 (D. Md. 2021).

[401] 86 FR 24261.

the proposed model specifications and updated enrollment duration factors for the HHS risk adjustment models.[402] For example, we considered adding a non-linear term or HCC counts terms for all enrollees in the adult and child risk adjustment models. As detailed in the proposed 2022 Payment Notice and the 2021 RA Technical Paper,[403] we found that non-linear model specifications often failed to converge. In addition, the non-linear model specifications would significantly overhaul the current linear models, increasing the administrative burden on issuers and HHS. We also found that the aforementioned HCC counts terms approach posed gaming concerns, which would violate principle six of the HHS-operated risk adjustment program by rewarding coding proliferation.

In addition to the non-linear and HCC counts model specifications, we also considered variations to the interacted HCC counts factors and the two-stage weighted model specifications. Specifically, we tested various alternative caps for the weights based on the distribution of costs, but found the proposed caps resulted in better prediction on average. For the prediction weights, we tested various alternative forms of weights, including reciprocals of the square root of prediction, log of prediction, and residuals from the first-step estimation, but the reciprocal of the capped predictions resulted in better PRs for low-cost enrollees compared to any of the other weights.

For the interacted HCC counts factors, we tested several HCCs and considered adding and removing certain HCCs from the proposed list in Table 3 of the proposed rule (87 FR 584, 620) (shown in Table 1 of this rule). We chose the list of HCCs in Table 3 of the proposed rule (shown in Table 1 of this rule) because including these HCCs most improved prediction for enrollees with the highest costs, multiple HCCs, and with these specific HCCs. We also considered various alternatives to structure the interacted HCC counts, such as applying individual interacted HCC count factors (between 1–10 based on the number of HCCs an enrollee has) to each of the selected HCCs included in the models, instead of combining all of the selected HCCs into two severe and transplant indicator groups. We chose the proposed model specification because it would add fewer additional factors to the models, which minimizes the increased burden on issuers and HHS without sacrificing overall predictive accuracy.

For the enrollment duration factors in the adult models, we are finalizing the replacement of the enrollment duration factors with monthly duration factors of up to 6 months for enrollees with HCCs. The purpose for changing the enrollment duration factors was to address the underprediction of plan liability for partial-year adult enrollees with HCCs. As part of this assessment, we considered whether enrollment duration factors by type of partial-year enrollment (enrolling through a special enrollment period versus enrolling during the annual open enrollment period and dropping enrollment partway through the year), by market type (individual versus small group market), or by specific HCC (as well as by type of HCC—acute versus chronic) may be warranted. As previously noted, varying enrollment duration factors by partial-year enrollment type or by market produced factors that were generally very similar between partial- and full-year enrollees, which indicates they would add little value to the models while increasing complexity.[404] We chose the enrollment duration factors, contingent on the presence of at least one HCC, because these factors improve predictive accuracy for partial-year enrollees and simplify the adult risk adjustment models compared to the current models.[405]

With respect to the changes to the recalibration of the RXC mappings for the adult risk adjustment models, we considered using the latest RXC mapping document available at the time that we recalibrate the adult risk adjustment models and applying it to all three underlying EDGE data years used to recalibrate the models for the benefit year. We chose the approach of recalibrating the adult risk adjustment models using each final, Q4 RXC mapping document that was developed using the benefit year of data corresponding to that benefit year. We believe that the benefits of this approach, which include limiting the volatility of some coefficients from year-to-year, ensuring that we are capturing the utilization and costs observed for the underlying drugs in use during the data year, and improving issuers' ability to plan for downstream implications of changes to RXC mapping, outweigh the benefits of the alternative approach of using the latest RXC mapping available at the time of recalibration, which would more closely align costs between recalibration data and current benefit year data.

With respect to the changes to § 153.320(d), we considered repealing risk adjustment State flexibility for the individual catastrophic and non-catastrophic market risk pools, while retaining risk adjustment State flexibility for the small group market risk pool. Consistent with the directive in E.O. 14009[406] to prioritize protecting and strengthening the ACA and making high-quality health care accessible and affordable for all individuals, we considered whether this approach is inconsistent with policies described in Sections 1 and 3 of E.O. 14009. In prior rulemakings, we received comments stating that risk adjustment State flexibility in any market may result in risk selection, market destabilization, increased premiums, smaller networks, and worse plan options. Therefore, we also considered whether to adopt a complete repeal of the flexibility to request reductions risk adjustment State transfers.

With regard to the proposed changes to § 155.320, we considered taking no action to modify the requirement that when an Exchange does not reasonably expect to obtain sufficient verification data related to enrollment in or eligibility for employer sponsored coverage, the Exchange must select a random sample of applicants and attempt to verify their attestation with the employer listed on their Exchange application. However, based on HHS' experience conducting sampling, this manual verification process requires significant resources for a low return on investment, as using this method HHS identified only a small population of applicants who received APTC/CSR payments inappropriately. We believed the proposed change discussed earlier in the preamble to design a process to verify enrollment in or eligibility for an employer sponsored plan, informed by a risk assessment, is reasonably designed to ensure the accuracy of data, and is based on the activities or methods used by an Exchange such as studies, research, and analysis of an Exchange's own enrollment data. We also believed the proposed change would protect the integrity of the

[402] 85 FR 78572 at 78583–78586; See the *2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[403] Ibid.

[404] See, for example, 85 FR 78572 at 78585–78586 and Sections 3.3.1 and 3.3.2, *2021 HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[405] As detailed above, these new factors, which we are finalizing as proposed, will only apply to partial-year adult enrollees with up to 6 months of enrollment and at least one payment HCC.

[406] Executive Order 14009; 86 FR 7793 (2021, February 2).

individual market by allowing all Exchanges to proactively identify applicants with the greatest incentive to forego enrolling in an employer sponsored plan in favor of Exchange coverage with APTC/CSRs before which they may not be eligible, thereby potentially adding high health risk to the individual market risk pool that should be covered by the group health market, for example.

We considered several alternatives to specifying in § 155.420 that Exchanges may conduct pre-enrollment verification of eligibility for special enrollment periods, at the option of the Exchange, including requiring Exchanges to verify a certain percentage of special enrollment period enrollments and designating specific special enrollment period types for which eligibility must be verified by the Exchange. However, we believed that imposing any requirements for pre-enrollment special enrollment period verification would increase burden on consumers and Exchanges and decrease implementation flexibility to decide the best way to conduct special enrollment period verification based on Exchange type, population characteristics, and trends.

HHS considered multiple options for measuring the improper payment amounts and rates for State Exchanges to comply with its statutory mandate in the PIIA. HHS developed and pilot tested the proposed methodology with extensive collaboration from participating Exchanges during a multi-year research and demonstration period. HHS considered the following alternatives while developing this final rule:

1. Conducting No Reviews

HHS might take no preventive efforts to detect improper payments. We would wait passively until third-party investigators, private whistleblowers, qui tam relators, disgruntled relatives, or others report speculation through Inspector General channels. Advanced statistical analysis could estimate the odds of third-party prosecution and project the improper payment amount and rate for each State Exchange (with wide confidence intervals). This low intervention strategy may not fully comply with statutory intent.

2. Placing More Responsibility on State Exchanges To Conduct Reviews

HHS could require that each State Exchange determine its own improper payment rate with broad discretion on the methodology. This option would maximize regulatory flexibility while still complying with PIIA 2019 requirements. However, diverse methodology would make the State Exchanges' results difficult to compare and of variable validity. In addition, the costs resulting from higher error rates are borne by the Federal Government in the form of increased APTC and CSRs, giving State Exchanges' minimal incentive to aggressively reduce improper payments.

3. Placing More Responsibility on State Exchanges To Engage Third-Party Reviewers

HHS could require that State Exchanges engage third-party reviewers to determine the improper payment rate. As with financial reporting, the State Exchange could select among competing vendors to obtain its preferred combination of methodology, service, quality, and price. However, this approach would require more work and resources from both State Exchanges and HHS than the proposed methodology would require. The third party would need to obtain personally identifiable information from both State and Federal data systems. These processes suffer from potential record matching and data security issues. In addition, competing vendors might offer incompatible methodologies, producing non-comparable improper payment rates.

4. Conducting a Random Sample Across All State Exchanges

HHS could annually sample from the population of all State Exchange enrollees, rather than within each State Exchange. Thus, more cases would come from larger State Exchanges. This design would increase the efficiency and decrease the variance for the national estimate, but it would not provide an estimate for each State Exchange. It also would not reduce the burden on each State Exchange and may not comply with statutory intent.

With respect to standardized plan options, we considered a range of options for the proposed policy approach at § 156.201. On one end of this range, we considered resuming standardized plan options as reflected in the 2017 and 2018 Payment Notices. This approach would have allowed issuers to voluntarily offer standardized plan options and have the Exchanges on the Federal platform, web-brokers, and Classic DE and EDE Pathways differentially display these plans. We also considered gradually limiting the number of non- standardized plan options per issuer, product network type, metal level, and service area over the course of several PYs. We also considered preferentially displaying standardized plan options over non-standardized plan options. We also considered requiring issuers to offer exclusively standardized plan options in FFEs and SBE–FPs. We explained that we believe that the approach we have chosen for standardized plan options in which we finalized the provision to require issuers to offer standardized plan options but did not finalize any provision to limit the number of non-standardized offerings in PY 2023 strikes the greatest balance between simplifying the plan selection process, combatting discriminatory benefit designs, and advancing health equity, all while promoting a smooth transition to the introduction of standardized plan options.

For the proposal in §§ 155.240(e), 155.305(f)(5), and 155.340 on prorating the calculation and administration of premium and APTC, HHS considered an alternative form of implementation in which HHS would perform the proration on behalf of each State Exchange which does not already implement proration according to the proposed methodology. This approach would lessen concern regarding the burden of implementing a new proration methodology among State Exchanges. HHS already has the structures in place to prorate APTC and premium amounts in accordance with the proposed methodology and has already implemented proration in the FFEs and SBE–FPs.[407] Under this alternative, HHS would assume responsibility for prorating the amount of APTC due to each State Exchange based on the methodology HHS proposed in § 155.340 which states that when an enrollee is enrolled in a particular policy for less than the full coverage month (including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month) the amount of APTC paid to the issuer of the policy will be calculated as the product of (1) the APTC applied on the policy for one month of coverage divided by the number of days in the month, and (2) the number of days for which coverage is provided during the applicable month. However, this alternative would require State Exchanges to agree to allow HHS to use the data on the monthly SBMI to calculate the prorated amount. This would require State Exchanges to review payment reports to ensure the correct calculation of APTC and premium is reflected on each applicable State Exchanges' Form 1095–

[407] Under the SBE–FP agreement, the same method also applies in the SBE–FPs, as they rely on the Federal platform, which calculates applicable premiums in those Exchanges.

A. HHS expected that this alternative would produce additional burden of $4,500 in contract labor to update each State Exchange's SBMI and would necessitate increased data sharing and coordination back and forth between HHS and the applicable State Exchanges. In order to streamline the process of proration and allow State Exchanges greater control in the administration of APTC, HHS determined that it would propose that each State Exchange would prorate their own APTC and premium amounts for the applicable enrollees in their State. HHS sought comment on the alternative proposals considered.

Additionally, for the proposal to prorate APTC amounts with amendments to §§ 155.240, 155.305(f)(5), and 155.340, we considered proposing to implement this requirement for the 2023 benefit year. However, after analyzing the potential burden on State Exchanges to achieve operational readiness, we concluded that 2023 may not provide sufficient time. Therefore, we proposed 2024 benefit year implementation and request comments on the feasibility of 2023 benefit year implementation.

We did not receive any comments in response to the proposals in our general discussion regarding regulatory alternatives.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.'' HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this final rule, we finalize 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 believed that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for ''small entities'' established by the SBA, we did not believe that an initial regulatory flexibility analysis is required for such firms.

We believed 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.[408] We believed 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 2019 MLR reporting year, approximately 77 out of 479 issuers of health insurance coverage nationwide had total premium revenue of $41.5 million or less.[409] This estimate may overstate the actual number of small health insurance issuers that may be affected, since over 72 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. Only 10 of these 90 potentially small entities, three of them part of larger holding groups, are estimated to experience a change in rebates under the proposed amendments to the MLR provisions of this final rule in part 158. Therefore, we do not expect the MLR provisions finalized in this rule to affect a substantial number of small entities.

The proposals related to SEIPM at §§ 155.1500–155.1540 were proposed to affect only State Exchanges, and HHS is not finalizing these proposals at this time.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule under title XVIII, title XIX, or part B of title 42 of the Social Security Act may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. While this rule is not subject to section 1102 of the Act, we have determined that this final rule will not affect small rural hospitals. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule that includes any Federal mandate that may result in expenditures in any 1 year by a State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 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 an unfunded mandate.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has federalism implications.

In 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 were elected previously to operate an Exchange, those States had

[408] *Table of Size Standards.* (2019, August 19). U.S. Small Business Administration. *https://www.sba.gov/document/support—table-size-standards.*

[409] *Medical Loss Ratio Data and System Resources.* (2020). CMS. *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

the opportunity to use funds under Exchange Planning and Establishment Grants to fund the development of data. Accordingly, some of the initial cost of creating programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the State. Current State Exchanges charge user fees to issuers.

In our view, while this final rule will not impose substantial direct 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 (with an exception for prior participants) 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.

In addition, we believed this regulation has federalism implications due to the proposal for Exchanges to design a new risk-based verification process for enrollment in or eligibility for employer sponsored plan coverage that meets minimum value standards, that is based on the Exchange's assessment of risk for inappropriate APTC/CSR payments. However, the federalism implications are mitigated because the proposed requirement provides Exchanges with the flexibility to determine the best process to verify employer sponsored coverage and may choose not to implement such a risk-based verification process.

As previously noted, the proposals in this rule related to SEIPM are not being finalized. Accordingly, E.O. 13132 does not apply to this section of the final rule.

H. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to the Congress and the Comptroller for review. This final rule is a ''major rule'' as that term is defined in, because it is likely to result in an annual effect on the economy of $100 million or more.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 26, 2022.

List of Subjects

45 CFR Part 144

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Aged, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting and recordkeeping requirements, Sex discrimination.

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, Aged, Brokers, Citizenship and naturalization, Civil rights, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Taxes, Technical assistance, Women, 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, Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, under the authority at 5 U.S.C. 301, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter B, as set forth below.

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

■ 1. The authority citation for part 144 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–111 through 300gg–139, as amended.

§ 144.103 [Amended]

■ 2. Amend § 144.103 in the definition of ''large group market'' by removing the phrase '', unless otherwise provided under State law.''

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 3. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended, and section 3203, Pub. L. 116–136, 134 Stat. 281.

■ 4. Amend § 147.104 by—

■ a. Redesignating paragraph (i) as paragraph (j); and

■ b. Adding a new paragraph (i).

The addition reads as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(i) *Coverage denials for failure to pay premiums for prior coverage.* A health insurance issuer that denies coverage to an individual or employer due to the individual's or employer's failure to pay premium owed under a prior policy, certificate, or contract of insurance, including by attributing payment of premium for a new policy, certificate, or contract of insurance to the prior policy, certificate, or contract of insurance, violates paragraph (a) of this section.

* * * * *

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 5. The authority citation for part 153 continues to read as follows:

Authority: 42 U.S.C. 18031, 18041, and 18061 through 18063.

■ 6. Amend § 153.320 by—
■ a. Revising paragraphs (d) introductory text and (d)(1)(iii);
■ b. Adding paragraph (d)(1)(iv);
■ c. Revising paragraphs (d)(4)(i)(A) and (B); and
■ d. Adding paragraph (d)(5).

The revisions and additions 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. Beginning with 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) * * *

(iii) For the 2020 through 2023 benefit years, a justification for the reduction requested demonstrating the State-specific factors that warrant an adjustment to more precisely account for relative risk differences in the State individual catastrophic, individual non-catastrophic, small group, or merged market risk pool, or 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; or

(iv) Beginning with the 2024 benefit year, 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.

* * * * *

(4) * * *

(i) * * *

(A) For the 2020 through 2023 benefit years, that State-specific rules or other relevant factors warrant an adjustment to more precisely account for relative risk differences in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool and support the percentage reduction to risk adjustment transfers requested; or State-specific rules or other relevant factors warrant an adjustment to more precisely account for relative risk differences in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool and 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.

(B) Beginning with the 2024 benefit year, 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.

* * * * *

(5) *Exception for prior participants.* As used in paragraph (d) of this section, prior participants mean 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.

■ 7. Amend § 153.710 by—
■ a. Revising paragraphs (h)(1) introductory text and (h)(1)(iii) and (iv);
■ b. Adding paragraph (h)(1)(v); and
■ c. Revising paragraphs (h)(2) and (3).

The revisions and addition read as follows:

§ 153.710 Data requirements.

* * * * *

(h) * * *

(1) Notwithstanding any discrepancy report made under paragraph (d)(2) of this section, any discrepancy filed under § 153.630(d)(2), 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:

* * * * *

(iii) A cost-sharing reduction amount equal to the actual amount of cost-sharing reductions for the benefit year as calculated under § 156.430(c) of this subchapter, to the extent not reimbursed to the provider furnishing the item or service;

(iv) For medical loss ratio reporting only, the risk corridors payment to be made or charge assessed by HHS under § 153.510; and

(v) The risk adjustment data validation adjustment calculated by HHS in the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers.

(2) An issuer must report during the current MLR and risk corridors reporting year any adjustment made or approved by HHS for any risk adjustment payment or charge, including an assessment of risk adjustment user fees and risk adjustment data validation adjustments; any reinsurance payment; any cost-sharing reduction payment or charge; or any risk corridors payment or charge before August 15, or the next applicable business day, of the current MLR and risk corridors reporting year unless instructed otherwise by HHS. An issuer must report any adjustment made or approved by HHS for any risk adjustment payment or charge, including an assessment of risk adjustment user fees and risk adjustment data validation adjustments; any reinsurance payment; any cost-sharing reduction payment or charge; or any risk corridors payment or charge where such adjustment has not been accounted for in a prior MLR and Risk Corridors Annual Reporting Form, in the MLR and Risk Corridors Annual Reporting Form for the following reporting year.

(3) In cases where HHS reasonably determines that the reporting instructions in paragraph (h)(1) or (2) of this section would lead to unfair or misleading financial reporting, issuers must correct their data submissions in a form and manner to be specified by HHS.

■ 8. Revise § 153.730 to read as follows:

§ 153.730 Deadline for submission of data.

A risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must submit data to be considered for risk adjustment payments and charges and reinsurance payments for the applicable benefit year by April 30 of the year following the applicable benefit year or, if such date is not a business day, the next applicable business day.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 9. 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.

§ 155.206 [Amended]

■ 10. Amend § 155.206 in paragraph (i) by removing the phrase ''$100 for each day for each'' and adding in its place the phrase ''$100 for each day, as adjusted annually under 45 CFR part 102, for each''.

■ 11. Amend § 155.220 by—

■ a. Revising paragraphs (c)(3)(i)(A) and (L);

■ b. Adding paragraph (c)(3)(i)(M);

■ c. Revising paragraph (j)(2)(ii);

■ d. In paragraph (j)(2)(iv), removing the phrase ''described in § 155.260(b)(2); and'' and adding in its place the phrase ''described in § 155.260(b)(2);''; and

■ e. Adding paragraphs (j)(2)(vi) through (viii).

The revisions and additions read as follows:

§ 155.220 Ability of States to permit agents and brokers and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(c) * * *

(3) * * *

(i) * * *

(A) Disclose and display the following QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(c), and to the extent that enrollment support for a QHP is not available using the web-broker's website, prominently display a standardized disclaimer provided by HHS stating that enrollment support for the QHP is available on the Exchange website, and provide a Web link to the Exchange website:

(*1*) Premium and cost-sharing information;

(*2*) The summary of benefits and coverage established under section 2715 of the PHS Act;

(*3*) Identification of whether the QHP is a bronze, silver, gold, or platinum level plan as defined by section 1302(d) of the Affordable Care Act, or a catastrophic plan as defined by section 1302(e) of the Affordable Care Act;

(*4*) The results of the enrollee satisfaction survey, as described in section 1311(c)(4) of the Affordable Care Act;

(*5*) Quality ratings assigned in accordance with section 1311(c)(3) of the Affordable Care Act; and

(*6*) The provider directory made available to the Exchange in accordance with § 156.230 of this subchapter.

* * * * *

(L) Not display QHP advertisements or recommendations, or otherwise provide favored or preferred placement in the display of QHPs, based on compensation the agent, broker, or web-broker receives from QHP issuers; and

(M) Prominently display a clear explanation of the rationale for QHP recommendations and the methodology for its default display of QHPs.

* * * * *

(j) * * *

(2) * * *

(ii) Provide the Federally-facilitated Exchanges with correct information under section 1411(b) of the Affordable Care Act, including, but not limited to:

(A) Entering only an email address on an application for Exchange coverage or an application for advance payments of the premium tax credit and cost-sharing reductions for QHPs that belongs to the consumer or the consumer's authorized representative designated in compliance with § 155.227. A consumer's email address may only be entered with the consent of the consumer or the consumer's authorized representative. Properly entered email addresses must adhere to the following guidelines:

(*1*) The email address must be accessible by the consumer, or the consumer's authorized representative designated in compliance with § 155.227, and may not be accessible by the agent, broker, or web-broker assisting the consumer; and

(*2*) The email address may not have domains that belong to the agent, broker, or web-broker or their business or agency.

(B) Entering only a telephone number on an application for Exchange coverage or an application for advance payments of the premium tax credit and cost-sharing reductions for QHPs that belongs to the consumer or their authorized representative designated in compliance with § 155.227. Telephone numbers may not be the personal number or business number of the agent, broker, or web-broker assisting the consumer, or their business or agency, unless the telephone number is actually that of the consumer or their authorized representative.

(C) Entering only a mailing address on an application for Exchange coverage or an application for advance payments of the premium tax credit and cost-sharing reductions for QHPs that belongs to, or is primarily accessible by, the consumer or their authorized representative designated in compliance with § 155.227, is not for the exclusive or convenient use of the agent, broker, or web-broker, and is an actual residence or a secure location where the consumer or their authorized representative may receive correspondence, such as a P.O. Box or homeless shelter. Mailing addresses may not be that of the agent, broker, or web-broker assisting the consumer, or their business or agency, unless the address is the actual residence of the consumer or their authorized representative.

(D) When submitting household income projections used by the Exchange to determine a tax filer's eligibility for advance payments of the premium tax credit in accordance with § 155.305(f) or cost-sharing reductions in accordance with § 155.305(g), entering only a consumer's household income projection that the consumer or the consumer's authorized representative designated in compliance with § 155.227 has knowingly authorized and confirmed as accurate. Household income projections must be calculated and attested to by the consumer. The agent, broker, or web-broker assisting the consumer may answer questions posed by the consumer related to household income projection, such as helping the consumer determine what qualifies as income.

* * * * *

(vi) Not engage in scripting and other automation of interactions with CMS Systems or the Direct Enrollment Pathways, unless approved in advance in writing by CMS.

(vii) Only use an identity that belongs to the consumer when identity proofing the consumer's account on *HealthCare.gov*.

(viii) When providing information to Federally-facilitated Exchanges that may result in a determination of eligibility for a special enrollment period in accordance with § 155.420, obtain authorization from the consumer to submit the request for a determination of eligibility for a special enrollment period and make the consumer aware of the specific triggering event and special enrollment period for which the agent, broker, or web-broker will be submitting an eligibility determination request on the consumer's behalf.

* * * * *

■ 12. Amend § 155.305 by revising paragraphs (f)(1)(i) and (5) to read as follows:

§ 155.305 Eligibility standards.

* * * * *

(f) * * *

(1) * * *

(i) He or she is expected to have a household income that will qualify the tax filer as an applicable taxpayer according to 26 CFR 1.36B–2(b) for the benefit year for which coverage is requested; and

* * * * *

(5) *Calculation of advance payments of the premium tax credit.* The Exchange must calculate advance payments of the premium tax credit in accordance with 26 CFR 1.36B–3 and § 155.340(i) of this subpart.

* * * * *

■ 13. Amend § 155.320 by—

■ a. Revising paragraphs (d)(4) introductory text, (d)(4)(i) introductory text, and (d)(4)(i)(A);

■ b. Removing paragraph (d)(4)(i)(D).

■ c. Redesignating paragraph (d)(4)(i)(E) as paragraph (d)(4)(i)(D).

■ d. Removing paragraph (d)(4)(i)(F);

■ e. Redesignating paragraph (d)(4)(i)(G) as paragraph (d)(4)(i)(E) and revising newly redesignated paragraph (d)(4)(i)(E); and

■ f. Removing and reserving paragraph (d)(4)(ii).

The revisions read as follows:

§ 155.320 Verification process related to eligibility for insurance affordability programs.

* * * * *

(d) * * *

(4) *Alternate procedures.* For any benefit year for which it does not reasonably expect to obtain sufficient verification data as described in paragraphs (d)(2)(i) through (iii) of this section, the Exchange may follow the procedures specified in paragraph (d)(4)(i) of this section. For purposes of this paragraph (d)(4), the Exchange reasonably expects to obtain sufficient verification data for the benefit year when the Exchange is able to obtain data about enrollment in or eligibility for qualifying coverage in an eligible employer sponsored plan from at least one electronic data source that is available to the Exchange and that has been approved by HHS, based on evidence showing that the data source is sufficiently current, accurate, and minimizes administrative burden, as described under paragraphs (d)(2)(i) of this section.

(i) Based on the Exchange's assessment of risk for inappropriate payment of advance payments of the premium tax credit or cost-sharing reductions, implement a verification process that is reasonably designed to ensure the accuracy of the data and is based on the activities or methods used by an Exchange such as studies, research, and analysis of an Exchange's own enrollment data, for enrollment in or eligibility for qualifying coverage in an eligible employer sponsored plan, as appropriate.

(A) The Exchange must provide notice to the applicant if, as part of the verification process described under paragraph (d)(4)(i) of this section, the Exchange will be contacting any employer identified on the application for the applicant and the members of his or her family, as defined in 26 CFR 1.36B–1(d), to verify whether the applicant is enrolled in an eligible employer sponsored plan or is eligible for qualifying coverage in an eligible employer sponsored plan for the benefit year for which coverage is requested;

* * * * *

(E) To carry out the process described in paragraph (d)(4)(iii) of this section, the Exchange must only disclose an individual's information to an employer to the extent necessary for the employer to identify the employee.

* * * * *

■ 14. Amend § 155.340 by adding paragraph (i) to read as follows:

§ 155.340 Administration of advance payments of the premium tax credit and cost-sharing reductions.

* * * * *

(i) *Calculation of advance payments of the premium tax credit when policy coverage lasts less than the full coverage month.* (1) For plan years beginning with 2024 and beyond, when an Exchange determines that an individual is eligible for advance payments of the premium tax credit and the enrollee is enrolled in a policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month—

(i) In an Exchange using the Federal eligibility and enrollment platform, the amount of the advance payment of the premium tax credit paid to the issuer of the policy must equal the product of—

(A) The advance payments of the premium tax credit applied to the policy for one month of coverage divided by the number of days in the month; and

(B) The number of days for which coverage is being provided in the month under the policy described in paragraph (i)(1)(i) of this section.

(ii) [Reserved]

(2) For plan years beginning with 2024 and beyond, a State Exchange operating its own platform will be required to calculate advance payments of the premium tax credit in accordance with a methodology that does not cause the amount of advance payments of the premium tax credit applied to an enrollee's monthly premium to exceed their expected monthly premium assistance credit amount when the enrollee is enrolled in a policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month, and to prospectively report the methodology it intends to implement in the subsequent plan year to HHS under § 155.1200(b)(2).

■ 15. Amend § 155.420 by adding paragraph (g) to read as follows:

§ 155.420 Special enrollment periods.

* * * * *

(g) *Pre-enrollment special enrollment period verification.* At the option of the Exchange, an Exchange may verify prior to processing a qualified individual's plan selection that the qualified individual is eligible for a special enrollment period under this section. In circumstances where the Exchange determines that such pre-enrollment special enrollment period verification may cause undue burden on qualified individuals, the Exchange may provide an exception to the pre-enrollment special enrollment period verification process, provided it does so in a manner consistent with the non-discrimination requirements under § 155.120(c). Exchanges on the Federal platform will conduct pre-enrollment special enrollment verification of eligibility only for special enrollment periods under paragraph (d)(1) of this section.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 16. The authority citation for part 156 is revised to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

■ 17. Amend § 156.50 by:

■ a. Removing paragraph (c)(3); and

■ b. Revising paragraphs (d)(1) introductory text, (d)(2)(i)(A) and (B), (d)(2)(ii), (d)(2)(iii)(B), (d)(3) introductory text, (d)(4) and (6), and (d)(7) introductory text.

The revisions read as follows:

§ 156.50 Financial support.

* * * * *

(d) * * *

(1) A participating issuer offering a plan through a Federally-facilitated

Exchange or State Exchange on the Federal platform may qualify for an adjustment of the Federally-facilitated Exchange user fee specified in paragraph (c)(1) of this section or the State Exchange on the Federal platform user fee specified in paragraph (c)(2) of this section, to the extent that the participating issuer—

* * * * *

(2) * * *

(i) * * *

(A) Identifying information for the participating issuer and each third party administrator that received a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) or with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, whether or not the participating issuer was the entity that made the payments for contraceptive services;

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by a third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable; and

* * * * *

(ii) Each third party administrator that intends to seek an adjustment on behalf of a participating issuer of the Federally-facilitated Exchange user fee or the State-based Exchange on the Federal platform user fee based on payments for contraceptive services, must submit to HHS a notification of such intent, in a manner specified by HHS, by the 60th calendar day following the date on which the third party administrator receives the applicable copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4).

(iii) * * *

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by the third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable;

* * * * *

(3) If the requirements set forth in paragraph (d)(2) of this section are met, the participating issuer will be provided a reduction in its obligation to pay the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, equal in value to the sum of the following:

* * * * *

(4) If the amount of the adjustment under paragraph (d)(3) of this section is greater than the amount of the participating issuer's obligation to pay the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, in a particular month, the participating issuer will be provided a credit in succeeding months in the amount of the excess.

* * * * *

(6) A participating issuer that receives an adjustment in the user fee specified in paragraph (c)(1) or (2) of this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, documentation demonstrating that it timely paid each third party administrator with respect to which it received any such adjustment any amount required to be paid to the third party administrator under paragraph (d)(5) of this section.

(7) A third party administrator of a plan with respect to which an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section is received under this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, all of the following documentation:

* * * * *

■ 18. Amend § 156.111 by—

■ a. Revising the section heading;

■ b. Revising paragraph (d) and paragraph (e) introductory text; and

■ c. Removing paragraph (f).

The revisions read as follows:

§ 156.111 State selection of EHB-benchmark plan for plan years beginning on or after January 1, 2020.

* * * * *

(d) A State must notify HHS of the selection of a new EHB-benchmark plan by the first Wednesday in May of the year that is 2 years before the effective date of the new EHB-benchmark plan.

(1) If the State does not make a selection by the first Wednesday in May of the year that is 2 years before the effective date of the new EHB-benchmark plan, or its benchmark plan selection does not meet the requirements of this section and section 1302 of the ACA, the State's EHB-benchmark plan for the applicable plan year will be that State's EHB-benchmark plan applicable for the prior year.

(2) [Reserved]

(e) A State changing its EHB-benchmark plan under this section must submit documents in a format and manner specified by HHS by the first Wednesday in May of the year that is 2 years before the effective date of the new EHB-benchmark plan. These must include:

* * * * *

■ 19. Amend § 156.115 by revising paragraph (b)(2) to read as follows:

§ 156.115 Provision of EHB.

* * * * *

(b) * * *

(2) An issuer may substitute a benefit within the same EHB category, unless prohibited by applicable State requirements. Substitution of benefits between EHB categories is not permitted.

* * * * *

■ 20. Amend § 156.125 by revising paragraph (a) to read as follows:

§ 156.125 Prohibition on discrimination.

(a) An issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. Beginning on the earlier of January 1, 2023 (the start of the 2023 plan year) or upon renewal of any plan subject to this rule, a non-discriminatory benefit design that provides EHB is one that is clinically-based.

* * * * *

■ 21. Amend § 156.140 by revising paragraph (c) to read as follows:

§ 156.140 Levels of coverage.

* * * * *

(c) *De minimis variation.* (1) For plan years beginning on or after January 1, 2018 through December 31, 2022, the allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan is −4 percentage points and +2 percentage points, except if a health plan under paragraph (b)(1) of this section (a bronze health plan) either covers and pays for at least one major service, other than preventive services, before the deductible or meets the requirements to be a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code, in which case the allowable variation in AV for such plan is −4

percentage points and +5 percentage points.

(2) For plan years beginning on or after January 1, 2023, the allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan is −2 percentage points and +2 percentage points, except if a health plan under paragraph (b)(1) of this section (a bronze health plan) either covers and pays for at least one major service, other than preventive services, before the deductible or meets the requirements to be a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code, in which case the allowable variation in AV for such plan is −2 percentage points and +5 percentage points.

■ 22. Amend § 156.200 by revising paragraph (b)(3) to read as follows:

§ 156.200 QHP issuer participation standards.

* * * * *

(b) * * *

(3) Ensure that each QHP complies with benefit design standards, as defined in § 156.20, except that individual market silver QHPs must have an AV of 70 percent, with a *de minimis* allowable AV variation of −0 percentage points and +2 percentage points;

* * * * *

■ 23. Add § 156.201 to read as follows:

§ 156.201 Standardized plan options.

For the plan year 2023 and subsequent plan years, 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 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), but not for the zero and limited cost-sharing plan variations, as provided for at § 156.420(b).

■ 24. Amend § 156.230 by revising paragraph (a) to read as follows:

§ 156.230 Network adequacy standards.

(a) *General requirement.* (1) Each QHP issuer that uses a provider network must ensure that the provider network consisting of in-network providers, as available to all enrollees, meets the following standards:

(i) Includes essential community providers in accordance with § 156.235;

(ii) Maintains a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorder services, to ensure that all services will be accessible without unreasonable delay; and

(iii) Is consistent with the rules for network plans of section 2702(c) of the PHS Act.

(2)(i) *Standards.* A QHP issuer on a Federally-facilitated Exchange must comply with the requirement in paragraph (a)(1)(ii) of this section by:

(A) For plan years beginning on or after January 1, 2023, meeting time and distance standards established by the Federally-facilitated Exchange. Such time and distance standards will be developed for consistency with industry standards and published in guidance. Quantitative reviews of compliance with time and distance standards will be conducted using issuer-submitted data; and

(B) For plan years beginning on or after January 1, 2024, meeting appointment wait time standards established by the Federally-facilitated Exchange. Such appointment wait time standards will be developed for consistency with industry standards and published in guidance.

(ii) *Written justification.* If a plan applying for QHP certification to be offered through a Federally-facilitated Exchanges does not satisfy the network adequacy standards described in paragraphs (a)(2)(i)(A) and (B) of this section, the issuer must include it as part of its QHP application a justification describing how the plan's provider network provides an adequate level of service for enrollees and how the plan's provider network will be strengthened and brought closer to compliance with the network adequacy standards prior to the start of the plan year. The issuer must provide information as requested by the FFE to support this justification.

(3) The Federally-facilitated Exchange may grant an exception to the requirements in paragraphs (a)(2)(i)(A) and (B) of this section if the Exchange determines that making such health plan available through such Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates.

* * * * *

■ 25. Amend § 156.235 by revising paragraphs (a)(2)(i), (a)(2)(ii)(B), and (b)(2)(i) to read as follows:

§ 156.235 Essential community providers.

(a) * * *

(2) * * *

(i) The network includes as participating providers at least a minimum percentage, as specified by HHS, of available essential community providers in each plan's service area. Multiple providers at a single location will count as a single essential community provider toward both the available essential community providers in the plan's service area and the issuer's satisfaction of the essential community provider participation standard. For plans that use tiered networks, to count toward the issuer's satisfaction of the essential community provider 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 essential community provider standards; and

(ii) * * *

(B) At least one ECP in each of the six (6) 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, and Other ECP Providers. The Other ECP Providers category includes the following types of providers: 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.

* * * * *

(b) * * *

(2) * * *

(i) The number of its providers that are located in Health Professional Shortage Areas or five-digit zip codes in which 30 percent or more of the population falls below 200 percent of the Federal poverty level satisfies a minimum percentage, specified by HHS, of available essential community providers in the plan's service area. Multiple providers at a single location will count as a single essential community provider toward both the available essential community providers

in the plan's service area and the issuer's satisfaction of the essential community provider participation standard. For plans that use tiered networks, to count toward the issuer's satisfaction of the essential community provider 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 would be counted towards essential community provider standards; and

* * * * *

Subpart D—Standards for Qualified Health Plan Issuers for Specific Types of Exchanges

■ 26. Revise the subpart D heading to read as set forth above.

■ 27. Amend § 156.340 by revising paragraphs (a) and (b)(4) and (5) to read as follows:

§ 156.340 Standards for downstream and delegated entities.

(a) *General requirement.* Effective October 1, 2013, notwithstanding any relationship(s) that a QHP issuer may have with delegated and downstream entities, a QHP issuer maintains responsibility for its compliance and the compliance of any of its delegated or downstream entities with all applicable Federal standards related to Exchanges. The applicable standards depend on the Exchange model type in which the QHP is offered, as described in paragraphs (a)(1) and (2) of this section.

(1) QHP issuers participating in Exchange models that do not use the Federal platform, including State Exchanges and State Exchange SHOPs. QHP issuers maintain responsibility for ensuring their downstream and delegated entities comply with the Federal standards related to Exchanges, including the standards in subpart C of this part with respect to each of its QHPs on an ongoing basis, as well as the Exchange processes, procedures, and standards in accordance with subparts H and K of part 155 and, in the small group market, §§ 155.705 and 155.706 of this subchapter, unless the standard is specifically applicable to a Federally-facilitated Exchange or FF–SHOP;

(2) QHP issuers participating in Exchanges that use the Federal platform, including Federally-facilitated Exchanges, FF–SHOPs, SBE–FPs, and SBE–FP–SHOPs. QHP issuers maintain responsibility for ensuring their downstream and delegated entities comply with Federal standards related to Exchanges, including the standards in subpart C of part 156 with respect to each of its QHPs on an ongoing basis, as well as the Exchange processes, procedures, and standards in accordance with subparts H and K of part 155 of this subchapter and, in the small group market, §§ 155.705 and 155.706 of this subchapter if applicable to the Exchange type in which the QHP issuer is operating. QHP issuers are also responsible for their downstream and delegated entities' compliance with the standards of § 155.220 of this subchapter with respect to assisting with enrollment in QHPs, and the standards of §§ 156.705 and 156.715 of this subchapter for maintenance of records and compliance reviews if applicable to the Exchange type in which the QHP issuer is operating.

(b) * * *

(4) Specify that the delegated or downstream entity must permit access by the Secretary and the OIG or their designees in connection with their right to evaluate through an audit, inspection, or other means, to the delegated or downstream entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period;

(5) All agreements between issuers offering QHPs through an Exchange and delegated or downstream entities the issuers engage to support the issuer's activities on an Exchange must include language stating that the relevant Exchange authority may demand and receive the delegated or downstream entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period.

■ 28. Amend § 156.400 by revising the definition of ''*De minimis* variation for a silver plan variation'' to read as follows:

§ 156.400 Definitions.

* * * * *

De minimis variation for a silver plan variation means a −0 percentage point and +1 percentage point allowable AV variation.

* * * * *

■ 29. Amend § 156.430 by revising paragraphs (b)(1), (d) introductory text, (e) introductory text, and (e)(1) to read as follows:

§ 156.430 Payment for cost-sharing reductions.

* * * * *

(b) * * * (1) When there is an appropriation to make cost-sharing reduction payments to QHP issuers, a QHP issuer will receive periodic advance payments from HHS to the extent permitted by the appropriation and calculated in accordance with § 155.1030(b)(3) of this subchapter.

* * * * *

(d) *Cost-sharing reductions data submissions.* HHS will periodically provide a submission window for issuers to submit cost-sharing reduction data documenting cost-sharing reduction amounts issuers paid, as specified in paragraphs (d)(1) and (2) of this section, in a form and manner specified by HHS in guidance, calculated in accordance with paragraph (c) of this section. When HHS makes cost-sharing reduction payments to QHP issuers, HHS will notify QHP issuers that the submission of the cost-sharing data is mandatory for those issuers having received cost-sharing reduction payments for any part of the benefit year and voluntary for other issuers, and HHS will use the data to reconcile advance cost-sharing reduction payments to issuers against the actual amounts of cost-sharing reductions QHP issuers provided, as determined by HHS based on amounts specified in paragraphs (d)(1) and (2) of this section, as calculated in accordance with paragraph (c) of this section. In the absence of an appropriation to make cost-sharing reduction payments to issuers, HHS will notify QHP issuers that the submission of the cost-sharing data is voluntary. The cost-sharing data that must be submitted in either a voluntary or mandatory submission includes:

* * * * *

(e) *Cost-sharing reductions payments and charges.* If the actual amounts of cost-sharing reductions determined by HHS based on amounts described in paragraphs (d)(1) and (2) of this section are—

(1) More than the amount of advance payments HHS provided, and the QHP issuer has timely provided the data of actual amounts of cost-sharing reductions as required under paragraph (c) of this section, if an appropriation is available to make cost-sharing payments to QHP issuers, HHS will make a payment to the QHP issuer for the difference; or

* * * * *

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 30. The authority citation for part 158 continues to read as follows:

Authority: 42 U.S.C. 300gg–18.

■ 31. Amend § 158.140 by revising paragraph (b)(2)(iii) to read as follows:

§ 158.140 Reimbursement for clinical services provided to enrollees.

* * * * *

(b) * * *

(2) * * *

(iii) The amount of incentive and bonus payments made to providers that are tied to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers.

* * * * *

■ 32. Amend § 158.150 by revising paragraph (a) to read as follows:

§ 158.150 Activities that improve health care quality.

(a) *General requirements.* The report required in § 158.110 must include expenditures directly related to activities that improve health care quality, as such activities are described in this section.

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■ 33. Amend § 158.170 by revising paragraph (b) introductory text to read as follows:

§ 158.170 Allocation of expenses.

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(b) Description of the methods used to allocate expenses. The report required in § 158.110 must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, to each health insurance market in each State. A detailed description of each expense element must be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized, as well as the method by which it was aggregated.

* * * * *

Dated: April 28, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–09438 Filed 5–2–22; 4:15 pm]

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Part III

Department of Transportation

Federal Highway Administration

23 CFR Part 650

National Bridge Inspection Standards; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 650

[FHWA Docket No. FHWA–2017–0047]

RIN 2125–AF55

National Bridge Inspection Standards

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule updates the National Bridge Inspection Standards (NBIS) for highway bridges. The Moving Ahead for Progress in the 21st Century Act (MAP–21) required the Secretary of Transportation (Secretary) to update the NBIS. Through this final rule, FHWA updates the NBIS to address MAP–21 requirements, incorporate technological advancements including the use of unmanned aircraft systems, and addresses ambiguities identified since the last update to the regulation in 2009. FHWA also is repealing two outdated regulations: the Highway Bridge Replacement and Rehabilitation Program and the Discretionary Bridge Candidate Rating Factor.

DATES: This final rule is effective June 6, 2022. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of June 6, 2022.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Drda, P.E., Office of Bridges and Structures, HIBS–30, (919) 747–7011, or Mr. William Winne, Office of the Chief Counsel, HCC–30, (202) 366–1397, Federal Highway Administration, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document, the Notice of Proposed Rulemaking (NPRM), all comments received, and all background material may be viewed online at *http://www.regulations.gov* using the docket number listed above. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *https://www.federalregister.gov* and the Government Publishing Office's website at *www.GovInfo.gov.*

Executive Summary

I. Purpose of the Regulatory Action

This final rule updates the national standards for bridge inspections consistent with the provisions of MAP–21 (Pub. L. 112–141, 126 Stat. 405), which included new requirements for a highway bridge inspection program, maintaining a bridge inventory, and reporting to FHWA the inspection results and, in particular, critical findings, meaning any structural or safety-related deficiencies that require immediate follow-up inspection or action. The updated NBIS applies to all structures defined as highway bridges on all public roads, on and off Federal-aid highways, including tribally and federally owned bridges. In addition, NBIS applies to private bridges that are connected to a public road on each end.

Periodic and thorough inspections of our Nation's bridges are necessary to maintain safe bridge operation and prevent structural and functional failures. In addition, data on the condition and operation of our Nation's bridges is necessary for bridge owners to make informed investment decisions as part of an asset management program. Congress declared in MAP–21 that it is in the vital interest of the United States to inventory, inspect, and improve the condition of the Nation's highway bridges. As a result of this declaration and the authority established by MAP–21 in 23 U.S.C. 144, FHWA is updating the NBIS.

This regulatory action also eliminates two outdated regulations: the Highway Bridge Replacement and Rehabilitation Program (23 CFR part 650, subpart D) and the Discretionary Bridge Candidate Rating Factor (23 CFR part 650, subpart G).

II. Summary of the Major Provisions of the Regulatory Action in Question

This final rule revises the existing NBIS relative to the National Bridge Inventory (NBI), including the requirement to collect element level data for National Highway System (NHS) bridges. The regulations require inspections of bridges on all public roads, on and off Federal-aid highways, including tribally and federally owned bridges, and private bridges connected on each end by a public road. The regulations include several new terms to provide consistency and clarity in the implementation of the regulations. This revision includes renaming some existing terms in a more descriptive way, such as fracture critical member being renamed nonredundant steel tension member (NSTM).

The final rule requires the bridge inspection organizations to maintain a registry of nationally certified bridge inspectors to align with a similar provision in the National Tunnel Inspection Standards (NTIS) in 23 CFR part 650, subpart E. Training requirements for program managers and team leaders have been modified by defining a required amount of refresher training for both roles and defining training needed to be a team leader on a NSTM inspection.

The regulations prescribe the permissible inspection intervals for bridges, including options for more rigorous, risk-based intervals based on the consideration of certain factors. They provide options for establishing inspection intervals for each inspection type. An inspection interval tolerance of 3 months beyond the inspection date is included. Specific criteria have been established to allow for extended routine inspection intervals up to 48 months, and 72 months for underwater inspections. Similarly, requirements are described to enable the establishment of more rigorous, risk-based intervals in consideration of certain factors associated with bridges for routine, underwater, and nonredundant steel tension member inspections that would allow some inspection intervals to be up to 72 months.

The final rule requires written reports to FHWA of critical findings identified during inspections and they provide minimum criteria for what a critical finding is, for national consistency. The regulations also require that a bridge inspection organization provide information to FHWA for annual compliance reviews.

The updated regulations include new time frames for updating inventory data, and a process for tracking the updates of inventory data. In addition, they include a new document to identify data items for the NBI. This document, ''Specifications for the National Bridge Inventory (SNBI),'' replaces the ''Recording and Coding Guide for the Structure Inventory and Appraisal of the Nation's Bridges (Coding Guide).'' The final SNBI document is included in the docket.

III. Costs and Benefits

The total cost of the final rule is calculated over the 10-year analysis period (2022—2031) assuming that either 30 or 65 percent of eligible bridges will use the Method 1 risk-based 48-month inspection interval rather than the 24-month inspection interval. The total cost savings of the rule for the 10-year study period (2022—2031) is

between −$4.6 and −$195.4 million discounted at 7 percent.

The provisions required by MAP–21 (Sections 650.303, 650.309, and 650.313) have total cost of $7.1 million over the 10-year analysis period when discounted at 7 percent. The other discretionary provisions that impose costs have a 10-year discounted value of −$11.7 to −$202.5 million. The cost savings associated with the provision related to expanded inspection intervals has a plausible range for 10-year discounted costs of −$131.0 to −$321.7 million.

The FHWA believes the final rule will be net beneficial to society but is unable to monetize or quantify the benefits of this rulemaking. More detail on the costs and benefits of the rule can be found later in this document and in the Regulatory Impact Analysis posted to the docket for this rulemaking.

Background and Legal Authority

FHWA bridge inspection program regulations were developed as a result of the Federal-Aid Highway Act of 1968 (Pub. L. 90–495, 82 Stat. 815), which required the Secretary to establish the NBIS to ensure the safety of the traveling public on highway bridges, and directed the States to maintain an inventory of Federal-aid highway system bridges. The Federal-Aid Highway Act of 1970 (Pub. L. 91–605, 84 Stat. 1713) limited the NBIS to bridges on the Federal-aid highway system. The Surface Transportation Assistance Act of 1978 (Pub. L. 95–599, 92 Stat. 2689) extended the NBIS requirements to bridges on all public roads. The Surface Transportation and Uniform Relocation Assistance Act of 1987 (Pub. L. 100–17, 101 Stat. 132) expanded the scope of highway bridge inspection programs to include special inspection procedures for fracture critical members and underwater inspection. Section 1111 of MAP–21 modified 23 U.S.C. 144 by revising the NBIS and adding requirements for a parallel NTIS framework. FHWA adopted procedures for the NTIS via rulemaking on July 14, 2015, at 80 FR 41350. In order to update the NBIS regulations for MAP–21, and to align them with the successful procedures in place for NTIS, FHWA is making a number of changes to 23 CFR part 650.

The framework of this regulation is aligned with the current NBIS framework. Both start with sections discussing the purpose, applicability, and definitions. These are followed by sections on organization responsibilities, qualifications of select personnel, inspection intervals, and inspection procedures. The current and new regulation end with sections on inventorying bridges, submitting data, and incorporated references. Specific discussions on each section are detailed later.

FHWA is required by 23 U.S.C. 144(h), as amended by MAP–21, to update the NBIS to address the methodology, training, and qualifications for inspectors, as well as the frequency of bridge inspections. In carrying out the MAP–21 provisions, the Secretary is required to consider a risk-based approach to determining the frequency of bridge inspections.

The NBIS is required by 23 U.S.C. 144(h)(2), as amended by MAP–21, to specify the method by which the inspections shall be carried out by the States, Federal agencies, and Tribal governments, or their agents. The NBIS is also required to establish the maximum time period between inspections and the qualifications for those charged with carrying out the inspections. The NBIS requires each State, Federal agency, and Tribal government to maintain and make available to the Secretary, on request, written reports on the results of highway bridge inspections and notations of any action taken pursuant to the findings of the inspections and current inventory data for all highway bridges reflecting the findings of the most recent inspections conducted. The NBIS includes a procedure for national certification of highway bridge inspectors.

A requirement was introduced in 23 U.S.C. 144(d)(2), as amended by MAP–21, for each State and Federal agency to report element level bridge inspection data to the Secretary, as each bridge is inspected, for all highway bridges on the NHS.

The Secretary is required by 23 U.S.C. 144(h)(3)(B), as amended by MAP–21, to establish procedures for States in reporting critical findings relating to structural or safety-related deficiencies of highway bridges and reports on subsequent activities and corrective actions taken in response to a critical finding.

Under the authority delegated to FHWA in 49 CFR 1.85 and the above mentioned statutory authority, FHWA issued a Notice of Proposed Rulemaking (NPRM) on November 12, 2019, at 84 FR 61494. Based on the comments received on the NPRM, FHWA is issuing this final rule to update the NBIS for highway bridges.

Summary of Comments

FHWA received 265 submissions to the docket resulting in more than 3000 individual comments in response to the NPRM. FHWA received comments from the American Association of State Highway Transportation Officials (AASHTO), American Council of Engineering Companies, American Society of Civil Engineers, National Steel Bridge Alliance, American Association for Laboratory Accreditation, 41 State DOTs, the National Transportation Safety Board, 4 Federal agencies, city and county governmental agencies, consulting firms, and individual private citizens. FHWA has considered these comments in the development of the final rule. Docket comments and summaries of FHWA's analyses and determinations are discussed as follows.

Summary of Significant Changes Made in the Final Rule

The final rule was developed in response to comments received on the NPRM. The following paragraphs summarize the most significant of those changes. Editorial or slight changes in language are not addressed in this document.

Section 650.307(f) was revised to require that delegated roles and functions be documented. The proposed NPRM requirement for formal written agreements was removed.

Sections 650.311(a)(1)(ii) and 650.311(b)(1)(ii) were modified to allow a special inspection in lieu of routine or underwater inspection reduced interval inspections. This modification provides an option to monitor areas of concern, rather than requiring inspection of the entire bridge at reduced intervals.

Section 650.311(a)(1)(iii) was modified so that the extended routine inspection interval criteria more closely aligns with current FHWA approved extended inspection interval policies.

Section 650.313(q) was revised to change the critical finding condition rating threshold from serious (3) to critical (2) as defined in the 0–9 scale for superstructure and substructure condition ratings in the SNBI. FHWA has also included the Deck Condition and Culvert Condition ratings in these criteria.

Section 650.317(a)(1) was updated to incorporate only specific sections of the ''AASHTO Manual for Bridge Evaluation,'' Third Edition, (AASHTO Manual) and the 2019 and 2020 Interim Revisions.

Section-by-Section Discussion

The final rule was developed in response to comments received on the NPRM. The following paragraphs summarize major comments received and any substantive changes made to each section in the final rule. Editorial

or slight changes in language are not addressed in this document. For sections where no substantive changes are discussed, the substantive proposal from the NPRM has been adopted in the final rule.

Section 650.303 Applicability

Thirty-five commenters requested clarification of the definition for a private bridge for determining applicability of this regulation. Three commenters were in support of inspecting private bridges connected to a public road on both ends of the bridge.

FHWA Response: Because of the seamless nature of the transportation infrastructure across the Nation, FHWA believes that 23 U.S.C. 144 is intended to apply to all highway bridges carrying public roads. The inventory and inspection of all highway bridges open to public travel is essential to protect the safety of the traveling public and allow for the efficient movement of people and goods on which the economy of the United States relies. In certain cases, a public road is connected to a private highway bridge. The applicability of the NBIS to such private bridges is limited to where the public road directly carries the traveling public to the bridge, the public road continues on the other side, and the bridge is open to public travel.

Sixteen commenters indicated there may be State specific legislation restricting access to private property therefore preventing the ability of the State to perform inspections.

FHWA Response: The NBIS requires inspection of certain private bridges; however, it is not a requirement that the inspection be performed by State DOT inspectors. Rather, State DOTs, Federal agencies, and Tribal governments must cause inspections and evaluations of private bridges to be performed in accordance with the NBIS.

One commenter indicated support if the ''private bridge'' was referring to toll bridges.

FHWA Response: The vast majority of toll bridges identified in the National Bridge Inventory are publicly owned, often by a publicly chartered toll authority; therefore, they are subject to the NBIS. In the case of a privately owned toll bridge, the applicability of the NBIS is limited to where a public road directly carries the traveling public to the bridge, the public road continues on the other side, and the bridge is open to the public travel.

Three commenters requested clarification on the inspection requirements of pedestrian and bicycle bridges.

FHWA Response: The NBIS is only applicable to ''highway bridges'' located on ''public roads.'' Bridges that only carry pedestrian and bicycle traffic are not highway bridges and therefore are not subject to the NBIS. Similarly, the NBIS does not apply to railroad, pipeline, or other types of non-highway bridges, sign support structures, high mast lighting, retaining walls, noise barriers structures, and overhead traffic signs. Owners are strongly encouraged to inspect these non-highway bridges and other significant structures.

The FHWA adopts the private bridge portion of this section as proposed in the NPRM without further modification.

Section 650.305 Definitions

AASHTO Manual—The definition of the AASHTO Manual is updated in the final rule to include the sections incorporated by reference. This change reflects the effort that AASHTO has made to limit the provisions needed to implement the NBIS to specific sections. The intent of this effort was to avoid inadvertently creating unnecessary additional requirements on highway bridge owners by incorporating all of the AASHTO Manual as a reference.

Bridge inspection experience—Seven commenters suggested clarifying how much of an inspector's experience should be from performing bridge inspections. Two commenters recommended adding bridge load rating evaluations to the list of relevant bridge inspection experience.

FHWA Response: FHWA recognizes that there are many factors involved in evaluating an individual's bridge inspection experience and believes that the definition allows for some flexibility in this area. The individual's experience must include development of the necessary skills to properly perform NBIS bridge inspections. However, the predominate amount, or more than 50 percent, should come from NBIS bridge safety inspection experience. Other experience in bridge design, bridge load rating, bridge maintenance, or bridge construction may be used to provide the additional required experience. FHWA agrees that load rating experience is valuable and should be considered as acceptable in determining bridge inspection experience. FHWA suggests that a program manager evaluating an individual's experience for compliance with the requirements for a team leader could consider, among other things, the following factors:

1. The relevance of the individual's actual experience, *i.e.,* has the other experience enabled the individual to develop the skills needed to lead properly a bridge safety inspection.

2. Exposure to the problems or deficiencies common in the types of bridges being inspected by the individual.

3. Complexity of the structures being inspected in comparison to the knowledge and skills of the individual gained through their prior experience.

4. The individual's understanding of the specific data collection needs and requirements.

5. Demonstrated ability, through some type of a formal certification program, to lead bridge safety inspections.

6. The level of oversight and supervision demonstrated by the individual in prior experience.

Complex feature—Three commenters liked the definition change from complex bridge to complex feature since it placed the focus on portions of the bridge which are complex, while one commenter expressed concern the change will result in more complex inspections.

FHWA Response: FHWA agrees the change will place the focus of these types of inspections on the parts of bridges that warrant additional attention due to their inherent complexity, rather than an entire bridge that may have many other noncomplex elements and are addressed during routine inspections. FHWA does not anticipate an increase in complex inspections as a result of the change. Owners will have the ability, as they do now, to identify any complex feature beyond those in the regulation. The regulation is only clarifying that the focus of this inspection type is on the complex features, not the entire bridge.

Damage mode—Two commenters recommended clarifying the definition of damage mode by changing it to ''deterioration mode'' as deterioration is a more common defect than damage.

FHWA Response: FHWA agrees that use of deterioration mode would be a better description for use in determining risk-based inspection intervals. The definition has been changed in the final rule from damage mode to deterioration mode. Also, the definition was modified to include damage and deterioration.

Initial inspection—One commenter questioned how the initial inspection is a separate inspection as identified in § 650.313, but the proposed definition identifies the initial inspection as the first routine, underwater, or NSTM inspection.

FHWA Response: FHWA agrees that an initial inspection is a separate inspection type and the definition was modified to clarify this distinction in the final rule.

Inspection date—One commenter stated the NPRM specifies that the

inspection date is the date the inspection begins for a bridge, but that expectations for the timeframe in which to complete the inspection are unclear and need to be defined. The commenter noted that the proposed change may be reasonable for most bridges but is not reasonable for large, complex bridges that take several months to inspect.

FHWA Response: FHWA agrees that for large, complex bridges it would be better to define the inspection date as the date on which the field portion of the bridge inspection is completed. The definition has been updated to capture the inspection date as the last day of field inspection.

Inspection report—One commenter suggested that the inspection report identify the team leader. Two commenters suggested that the team leader signature should not be required.

FHWA Response: FHWA understands the need to clarify this definition, and that owners have many different methods, including electronic signature, to identify the team leader responsible for the inspection and report. FHWA is modifying the regulation to align with section 2.2 of the AASHTO Manual, which is incorporated by reference. The definition now includes the following language: ''identify the team leader responsible for the inspection and report.''

Legal load rating—In response to comments for inspection interval criteria in § 650.311(a)(1), FHWA added a new definition to the final rule for legal load rating, which is a term used in the Load and Resistance Factor Rating method.

Nonredundant member—Two commenters questioned why there was a definition in the NPRM for nonredundant member. Two commenters suggested adding a definition for NSTM. Two commenters suggested adding internal and system redundancy to the definition for nonredundant member in accordance with the AASHTO guide specification. Six commenters suggested the move away from the term fracture critical (FC) is unnecessary and will cause confusion. Two commenters stated replacing the FC terminology is beneficial because it avoids the mistaken assumption that a bridge under the FC or fracture critical member categories are dangerous and should not be used.

FHWA Response: The NPRM utilized the term ''nonredundant member'' in critical findings criteria and to support the definition of ''nonredundant steel tension member inspection.'' Based on comments received, the criteria for critical findings has been modified in the final rule and criteria related to the term ''nonredundant member'' has been removed, eliminating the need for this definition.

FHWA agrees with adding a new definition for NSTM in the final rule to provide clarity in implementation of the regulation and moving away from the term ''fracture critical'' as it is commonly misunderstood to those not familiar with the NBIS. As explained in the NPRM, replacing the general term of ''fracture critical member'' with a more descriptive term of NSTM is necessary to enable the risk-based approach to determining the frequency of inspection required by 23 U.S.C. 144(h)(7). Accordingly, a definition for NSTM has been added to the final rule that includes consideration of system and internal redundancy.

FHWA agrees that primary members without load path redundancy but with system or internal redundancy as demonstrated through a nationally recognized process do not require NSTM inspections. Nationally recognized means published in a peer-reviewed engineering journal; or developed, endorsed and disseminated by a national organization with affiliates based in two or more States; or currently adopted for use by one or more State governments or by the Federal Government; and is the most current version. Also, definitions for load path, system, and internal redundancy have been added to the regulation for clarity. The requirement for demonstration of system and internal redundancy has been added to § 650.313(f). Comments on this topic are addressed under that section.

Operating rating—Three commenters suggested the definition for operating rating should more closely align with the AASHTO Manual.

FHWA Response: FHWA agrees the definition should better align with the AASHTO Manual and has updated the definition accordingly.

Plan of action (POA)—Two commenters recommended changing name of ''plan of action'' to ''scour plan of action'' to make it clear that this term only applies to bridge scour.

FHWA Response: FHWA agrees with this recommendation and has changed the term to ''scour plan of action'' to clarify it is only related to scour.

Private bridge—35 commenters requested the addition of a definition for private bridge.

FHWA Response: A definition has been added to the final rule for private bridge.

Professional engineer (PE)—Four commenters requested that licensed structural engineers (SE) be considered qualified for program manager, team leader, and be responsible for load ratings in lieu of a PE.

FHWA Response: FHWA agrees that SEs who practice in the fields in which they are qualified would have acceptable credentials. The definition has been updated to acknowledge SE licensure.

Program manager—Two commenters supported the definition change to allow for multiple program managers. One commenter stated that their organization and other States are set up so that the program manager does not directly oversee load rating engineers. The commenter noted that since these two employees/positions are not interchangeable, and both have completely different skill sets and responsibilities, this would result in non-compliance. In addition, some commenters questioned whether a program manager would be required to be a PE if responsible for load ratings.

FHWA Response: Because of the issues identified by the commenters that some States do not have load rating engineers and the program manager under the same office, the responsibility for load rating was removed from the definition of program manager. FHWA clarifies in the final rule that the program manager has the overall responsibility to ensure conformity with the NBIS.

Rehabilitation—One commenter suggested adding a definition for rehabilitation, as it is used in multiple places in the regulation but is not defined, though the commenter did not suggest a particular definition.

FHWA Response: FHWA agrees that adding a definition to the final rule will provide clarity to what is considered rehabilitation for NBIS as use of the term varies by owners. This new definition is consistent with the SNBI. Rehabilitation typically includes deck or superstructure replacement, structure widening, or major modification to substantial portions of the bridge.

Routine inspection—One commenter suggested that the definition of routine inspection should not include the identification of critical findings because they can be identified in any type of inspection.

FHWA Response: FHWA agrees that critical findings can be identified in other inspection types. It was not the intent to require a routine inspection to determine a critical finding. The definition has been modified by removing the term critical finding and adding language from the existing regulation about ensuring that the structure continues to satisfy present safety requirements.

Routine permit load—One commenter questioned the need for this definition. Another commenter similarly asked about the intent of this definition and raised concern that it might interfere or restrict a State's ability to control permit movements.

FHWA Response: The NPRM proposed to use the same definition used in the existing NBIS regulation. The definition makes clear what is considered a routine permit in support of § 650.313(k). The requirement to load rate routine permit loads has not changed from the current NBIS to the final rule. This requirement ensures the safety of the travelling public by verifying that permit vehicles can safely cross the bridge, and is not intended to interfere or restrict States' use of routine permits.

Safe load capacity—One commenter stated safe load capacities are typically not being redone after each inspection and expressed concern that the definition implies that the load rating is only safe until the next inspection.

FHWA Response: The definition is the same definition used in the AASHTO Manual. Sections 2.2.7 and 4.2.5 of the AASHTO Manual indicate that load ratings are to be updated as needed to reflect changes in the condition, configuration, strength of members, or changes in loads. Owners should verify load ratings are still valid after each inspection to meet this requirement. It is not uncommon for bridge load rating to be valid for multiple inspection cycles.

Scour appraisal—One commenter requested FHWA define ''evaluation process'' and clarify whether the intent is for the analysis to be performed in accordance with Hydraulic Engineering Circulars, (HEC).

FHWA Response: FHWA has modified the definition of scour appraisal to clarify that a scour evaluation or scour assessment is to be used to complete the scour appraisal. Definitions for scour evaluation and scour assessment are added in the final rule to support the scour appraisal definition. The final rule clarifies that scour appraisals are to be consistent with the HEC documents.

Scour assessment—A definition has been added for scour assessment, which is a risk-based process that considers stream stability and scour potential.

Scour evaluation—A definition for scour evaluation has been added, which is the application of hydraulic analysis to estimate scour depths.

Service inspection—Six commenters stated that the definition is ambiguous which can lead to interpretations which do not meet the intent. These commenters requested that the qualifications and intent of service inspections be clarified.

FHWA Response: The definition has been updated to clarify the intent is to identify major deficiency and safety issues performed by bridge maintenance or inspection staff. This type of inspection does not require a team leader. The inspections are meant to be performed by bridge maintenance or inspection staff from the ground and are not intended to be as rigorous as routine inspections. Bridges that would require a service inspection are bridges with inspection intervals greater than 48 months, so the bridges would be classified as in good condition and classified in a lower risk category. FHWA utilized NCHRP Report 782—Proposed Guideline for Reliability-Based Bridge Inspection Practices [1] in the development of this definition.

Underwater Bridge Inspection Training—One commenter indicated that there is very little inspection material related to the underwater inspection of bridges.

FHWA Response: FHWA has amended the definition of underwater bridge inspection training to include reference to the publication Underwater Bridge Inspection (FHWA–NHI–10–027). The purpose of this manual is to provide guidelines for underwater bridge inspection; acquaint those responsible for bridge safety with underwater inspection techniques and equipment; and present commonly found defects. It should be of interest to bridge and maintenance engineers, divers, and inspectors.

Underwater bridge inspection diver—One commenter suggested a definition be added for underwater bridge inspector diver as it is not defined in the regulation.

FHWA Response: FHWA agrees with this comment and a definition has been added to clarify who is considered an underwater bridge inspection diver. This language also clarifies that a tender and safety diver are not considered underwater bridge inspection divers.

Unknown Foundations—After addressing comments related to scour plans of action, FHWA realized providing a definition for unknown foundations further clarifies the regulation and will lead to consistent implementation. The definition was developed based upon previous FHWA guidance, Frequently Asked Questions—Bridges over waterways with unknown foundations and Geotechnical Engineering Notebook GT–16, Determination of Unknown Subsurface Bridge Foundations.[2]

Section 650.307 Bridge Inspection Organization Responsibilities

General Comments

Two commenters were concerned that § 650.307(a), (b), and (c) contradict each other and, as written, would require inspection and reporting of a single bridge by multiple agencies.

FHWA Response: Section 650.307(a) states that a State DOT is only responsible for all highway bridges that are located within their State's boundaries, except for those that are owned by Federal agencies and Tribal governments. Section 650.307(b) and (c) identify the bridges that are under the responsibility or jurisdiction of Federal agencies or Tribal governments and aligns with the language in the current regulation. The bridge inspection and reporting responsibility of a bridge falls within one agency (State DOT, Federal, or Tribal).

One commenter stated that removing the term ''public roads'' from § 650.307(a) and (b) creates inconsistency with § 650.303, where the NBIS applies to all highway bridges located on all public roads.

FHWA Response: FHWA believes that both §§ 650.303 and 650.307 complement each other; accordingly, FHWA does not believe removing the term public roads from § 650.307 creates any inconsistencies with § 650.303. Section 650.307(a) and (b) outline the responsibilities of States and Federal agencies respectively, whereas § 650.303 outlines the applicability of the standards.

Section 650.307(d)

Twenty-two commenters expressed their support for written agreements for border bridges, but stated that only one agency should be responsible for submitting border bridge data to FHWA.

FHWA Response: The National Performance Management Measures, 23 CFR part 490, subpart D, requires all border bridges to be included with State NBI data submissions. Bordering States submit border bridge information because they are both responsible for that bridge in their performance measure statistics. In response to the comment, the SNBI has been modified to identify the Designated Lead State

[1] The NCHRP Report 782 may be found at the following URL: *http://www.trb.org/Publications/Blurbs/171448.aspx*

[2] The Frequently Asked Questions—Bridges Over Waterways with Unknown Foundations may be found at the following URL: *https://www.fhwa.dot.gov/unknownfoundations/090603.cfm,* and Determination of Unknown Subsurface Bridge Foundations can be found at the following URL: *https://www.fhwa.dot.gov/unknownfoundations/090603.cfm.*

that is responsible for submitting a full bridge record, and the Neighboring State will submit an abbreviated bridge record.

One commenter stated that they have two sister bridges that are owned and maintained by a local agency and cross a river with a bordering State. The commenter asked for clarification and whether these bridges fall into this category.

FHWA Response: In the scenario described, one written agreement between the three entities (the two State DOTs and the local owner) to delineate the responsibilities of each entity would be required. This agreement may also include the delegation requirements between the State DOT and local agencies in § 650.307(f).

One commenter asked whether the border bridge agreement should include both maintenance and inspection responsibilities rather than just ''inspection'' responsibilities.

FHWA Response: FHWA encourages that a border bridge agreement include not just NBIS inspection responsibilities, but all aspects involved with the bridge such as maintenance and financing. However, § 650.307(d) only pertains to determining NBIS inspection responsibilities.

One commenter questioned the need for a joint written agreement.

FHWA Response: FHWA's experience is that in some instances there has not been a clear delineation of the inspection responsibilities of border bridges. The lack of a clear delineation of inspection responsibilities can lead to undue delays in conducting and completing the required inspections, and in the overall management of the bridge. To align the NBIS process with that of the existing requirements in the NTIS, this language requires the affected agencies to have a written agreement in place to clarify the NBIS-related responsibilities of each entity for that particular bridge and help ensure that timely bridge inspections and follow-up actions are accomplished in accordance with these standards. Section 650.307(d) addresses the bridge inspection responsibilities of jointly owned bridges that involve bordering States or combinations of State DOTs, Federal agencies, or Tribal governments ownership, or different entities within a State, or Federal, or Tribal jurisdiction.

Section 650.307(e)

Twenty commenters expressed concern about the requirement for State DOTs to maintain a registry of nationally certified bridge inspectors and most suggested that FHWA assume the responsibility of maintaining such registry.

FHWA Response: FHWA believes it is important for each State DOT, Federal agency, or Tribal government to maintain their own specific registry of certified inspectors who perform or have performed inspections on their bridges. This requirement is consistent with the NTIS regulation. There are many reasons that each State should maintain its own registry. Recognizing that Federal regulations represent the minimum standards and that, in many instances, State DOT requirements exceed that of Federal regulations, maintaining a registry of qualified inspectors by State DOTs would be more appropriate. The registry can be used to communicate with inspectors who work in that State to announce such things as anticipated work, training requirements, and training opportunities. State specific requirements for inspectors can be incorporated, and data quality is more easily maintained at the State level. For clarity and consistency with the NTIS, the word ''central'' was removed in the final rule.

Several commenters asked if FHWA would assign a unique inspector identifier if each inspector would have their own number to be used in any State.

FHWA Response: FHWA will not assign a unique inspector identifier. The minimum requirements for the registry include a method to identify positively each inspector. The method is left to the State to determine. For example, a State may use a unique numbering system or naming convention as an element of identification method of qualified inspectors within their respective State.

Several commenters stated that they are currently maintaining or able to maintain a State based registry with State specific requirements. Some of these commenters indicated that they would not be aware of specific requirements in other States and would not be able to provide information on whether an inspector qualified in their State would also be qualified in an another. Other commenters indicated that individual States do not have governance for bridge inspectors in other States. Some of these commenters stated that there is a likelihood of significant redundant work in certifying consultant inspectors by multiple States.

FHWA Response: The NBIS does not require State DOTs, Federal agencies, or Tribal governments to share their registry of nationally certified bridge inspectors with other entities, nor does it require reciprocity between entities for these registries. The requirement of the registry is for each State DOT, Federal agency, and Tribal government to identify those inspectors that meet the minimum national qualification and perform bridge inspections work in their jurisdiction, as defined in § 650.307(a), (b), and (c). FHWA recognizes that in some instances, qualification for bridge inspectors may exceed the minimum standards, resulting in a qualified team leader in one entity not being qualified in another.

Nine commenters expressed concerns about the requirement to maintain information about adverse actions that may affect the good standing of bridge inspectors. Some asked for clarification and others recommended the removal of this requirement.

FHWA Response: FHWA believes adverse actions indicate an inability of a bridge inspection team leader to perform quality inspections in accordance with the NBIS. As such, including detailed information in the registry about adverse actions is intended to ensure that the ability to perform assigned inspection activities is not in question. Only adverse actions that occur within the State DOT, Federal agency, or Tribal government's jurisdiction are intended to be included in their own registry. The level of detail to be included in the registry is left to the judgment of the program manager.

One commenter requested clarification as to whether the documentation requirements for inspection intervals of less than 24 months are for individual bridges or on a general inventory level for all bridges.

FHWA Response: The requirement is to document the criteria for inspection intervals for the several inspection types identified in § 650.311. Section 650.307(e)(3) is clarified by adding the term ''criteria.''

Section 650.307(f)

Fifteen commenters expressed disagreement with formal written agreements citing additional undue burden placed on agencies. Some of the commenters indicated that States already delegate these responsibilities to local governments by State law or through their bridge inspection policies and further stated that requiring a formal written agreement would be a substantial burden.

FHWA Response: FHWA NBIS compliance reviews have shown that, in some situations, delegated agencies do not have a full understanding or commitment to performing the NBIS functions that are delegated to them. FHWA understands the concerns raised about the potential administrative

burden of formal written agreements. As such, § 650.307(f) has been revised to replace ''formal written agreement'' with the requirement that delegated roles and functions must be documented in State DOT, Federal agency, or Tribal government bridge inspection policies. It is essential that all parties involved have a clear understanding of what bridge inspection functions are being delegated. Ultimate responsibility for the inspection of highway bridges rests with the delegating State DOT, Federal agency, or Tribal government.

Several commenters expressed confusion regarding the concept of multiple agency program managers in §§ 650.305 and 650.307.

FHWA Response: FHWA has reconsidered its position on multiple program managers, reverting to requiring a single lead program manager as required in the current regulation. With this revision to the final rule, a State DOT, Federal agency, or Tribal government may have more than one individual with program manager responsibilities. But to alleviate confusion with the intent of the regulation, there must be one individual who has the overall responsibility for the program. The intent is that the program manager provides overall leadership and guidance for the inspection organization, and is available to inspection teams and load rating personnel to provide guidance.

Section 650.307(f) and (g)

The NPRM language made clear that a Tribal government may delegate its responsibilities under this subpart to Bureau of Indian Affairs (BIA), if BIA agrees, resulting in BIA acting as the program manager for the Tribes. However, FHWA's Federal Lands Highway (FLH) Office also can be delegated responsibilities to act as program manager for Tribes under the Tribal Transportation Program Agreement. FHWA has been carrying out these responsibilities for FHWA Agreement Tribes since 2019. Language has been added to clarify that these delegations to FHWA continue to be permissible under these regulations and to correct this oversight in the NPRM language. A Tribal government that does not delegate its responsibilities to BIA or FHWA continues to need to maintain a bridge inspection organization.

Section 650.309 Qualifications of Personnel

Section 650.309(a)

Two commenters stated that program managers should be a licensed PE because they are responsible for load ratings. One commenter stated their organization and other States are set up so that the program manager does not directly oversee load rating engineers. The commenter noted that since these two employees/positions are not interchangeable, and both have completely different skill sets and responsibilities, this would result in the State being non-compliant.

FHWA Response: FHWA maintains its position on the longstanding success the NBIS has had using program managers qualified by experience in lieu of a PE. Because of the issues identified by the commenter that some States do not have load rating and the program manager in the same office and the positions have different skill sets, the responsibility for load rating was removed from the definition of program manager.

Five commenters suggested that the qualifications for a program manager with PE should also have a minimum of 6 months bridge inspection experience. Two commenters highlighted that a team leader with a PE requires more bridge inspection experience than a program manager.

FHWA Response: FHWA has included the bridge inspection experience requirement for PE team leaders to ensure that all team leaders have some experience and are familiar with the collection and recording of bridge inspection information as well as the process and procedures associated with bridge inspection activities. FHWA encourages program managers to have bridge inspection experience, however the NBIS has had longstanding success with PE program managers. It is not the intent of FHWA to require a program manager also to be a certified bridge inspection team leader. The NBIS provides minimum national standards and organizations can make their standards more stringent than the NBIS.

Four commenters suggested the option for a licensed SE to qualify in lieu of a PE where applicable in § 650.309 for a program manager, team leader, and for load ratings.

FHWA Response: FHWA agrees that licensed SEs who practice in the fields in which they are qualified would have acceptable credentials. The definition of PE in § 650.305 has been updated to acknowledge SE.

Six commenters asked for clarification regarding grandfathering of the training under prior regulations. Twelve commenters raised concern regarding the 24-month timeframe for program managers and team leaders to satisfy qualification requirements for comprehensive bridge inspection and refresher training for individuals serving in those positions under prior regulations. Three commenters expressed that the 60-month interval for obtaining 18 hours of refresher training was too stringent.

FHWA Response: FHWA believes that the minimum criteria established in § 650.309 for program managers and team leaders with respect to comprehensive and refresher training are necessary to ensure that bridge inspectors are qualified to inspect bridges. The 60-month timeframe for refresher training is also consistent with the NTIS. FHWA believes the requirement to complete the training within 24 months of the effective date of the final rule is reasonable.

Several commenters noted that the effective date of the final rule will increase demand for National Highway Institute (NHI) courses.

FHWA Response: Training for bridge inspection is a critical part of the NBIS program and NHI is actively working to revise training to conform with the final rule. Required training will be available shortly after the final rule is published, which should provide sufficient time for all deadlines to be met.

One commenter questioned how the 24-month timeframe to satisfy the training requirements would be enforced.

FHWA Response: The program manager of each State DOT, Federal agency, or Tribal government has the duty and responsibility to ensure the inspection organization is serviced by qualified individuals per § 650.309. FHWA additionally assesses compliance with the NBIS on the national level via the NBIS oversight process per § 650.313(r).

Section 650.309(b)

Eighteen commenters touched on the bridge inspection experience required for team leaders. Most of these comments were on the requirement for team leaders who qualify based on PE licensure also to have 6 months bridge inspection experience. Of the 18 commenters, 6 supported the revision requiring team leaders who qualify based on a PE also to have 6 months bridge inspection experience, and 1 commenter proposed increasing the required experience. Five other commenters were opposed to the experience requirement for PE.

FHWA Response: FHWA believes experience is a very important factor in being a successful team leader. The revision to include the bridge inspection experience requirement will ensure that all team leaders have some experience and are familiar with the collection and recording of bridge inspection

information as well as the process and procedures associated with bridge inspection activities. FHWA believes that minimum experience requirements for all team leaders will bring increased national consistency to bridge inspections, evaluations, data collection, and data submission.

Section 650.309(c)

Eight commenters supported the requirement for team leaders of NSTM inspections to successfully complete training on NSTM inspections. Four commenters felt the new requirement was not necessary for various reasons such as the additional cost to get personnel trained, the difficulty in getting in-State NHI training, or that the training might be valuable for more complex or larger NSTM bridges but was not needed for simpler NSTM bridges such as short span truss bridges. Three commenters pointed out that the proposed rule made no allowance for grandfathering NSTM (Fracture Critical Member) training which was completed under prior regulations.

FHWA Response: FHWA believes the variability and complexity of structures with NSTMs requires training that will bring national consistency to NSTM bridge inspections, evaluations, and data collection/submission. It is important to ensure that team leaders of NSTM inspections possess the higher level of training commensurate with the importance of these members. FHWA acknowledges that some organizations will have some additional burden related to training, but many team leaders have already completed the training even though it was not required. The final rule has been updated to clarify that completion of FHWA-approved NSTM training (ex. FHWA–NHI–130078) under prior regulations satisfies this new requirement, which will reduce the burden.

Section 650.309(e)

Three commenters asked if divers who completed the underwater bridge inspection diver training under prior regulations would be deemed to have satisfied the requirement to complete the diver training proposed in the NPRM. Two commenters suggested a timeframe of 24 months to satisfy the qualification requirement if serving as an underwater bridge inspection diver under prior regulations.

FHWA Response: The changes proposed in the NPRM were not intended to require underwater bridge inspection divers who qualified under prior regulations to requalify. FHWA has clarified in the final rule that completion of FHWA-approved comprehensive bridge inspection training or FHWA-approved underwater bridge inspection training under prior regulations satisfies the requirement in § 650.309(e). Given this clarification, there is no need to set a timeframe to satisfy requirements for individuals who qualified as underwater bridge inspection divers under prior regulations.

One commenter highlighted the need for a definition of an underwater bridge inspection diver.

FHWA Response: FHWA agrees that adding a new definition for underwater bridge inspection diver in the final rule will clarify who is required to have the training. The regulation clarifies the required training for an underwater bridge inspection diver applies to personnel performing the physical inspection of the underwater portion of the bridge. Non-inspection personnel supporting the underwater bridge inspection diver, such as the tender or safety diver, are not required to meet the requirement of § 650.309(e).

Two commenters pointed to the potential challenge to complete the underwater bridge inspection training because the course is not offered very often and generally there are not enough people to meet NHI's 20-person minimum class size.

FHWA Response: Because of the new requirement, FHWA anticipates more demand for this course. FHWA encourages States that do not have enough demand to partner with other agencies, States, or entities to meet the minimum class size.

Section 650.309(f)

Three commenters indicated they use team leaders for all inspections and questioned the need to establish separate qualifications for the Damage, Special, and Service Inspection types. One commenter recommended FHWA clarify the minimum expectations for personnel performing these inspections.

FHWA Response: FHWA is intentionally not establishing minimum qualifications for personnel performing Damage, Special, or Service Inspection types. Inspection protocols and qualifications for these inspection types can vary widely between States, Federal agencies, and Tribal governments. FHWA is providing flexibility to bridge inspection organizations for determining the personnel to be used. FHWA believes bridge inspection organizations are in a better position to determine qualifications based on the way they conduct work related to these inspection types. This section provides agencies and governments the flexibility to establish personnel qualifications with a focus on ensuring safety of the traveling public under their jurisdiction. An inspection organization should have an appropriate process in place to be able to verify and ensure that individuals performing these types of inspections are qualified per organizational requirements.

Section 650.309(g)

Three commenters questioned the need for adding the new ''Service Inspection'' type.

FHWA Response: Written personnel qualifications for the Service Inspection type are only required for agencies that establish inspection intervals exceeding 48 months for routine inspections per §§ 650.311 and 650.309(g). FHWA utilized NCHRP Report 782 [3]—Proposed Guideline for Reliability-Based Bridge Inspection Practices in the development of this inspection type. The service inspection type is defined in § 650.305. These provisions provide flexibility to bridge inspection organizations for determining the personnel to be used.

One commenter noted that there is no consideration for performance-based qualifications for inspectors using unmanned aircraft systems (UAS). The commenter recommended performance requirements to ensure there is sufficient training and testing for accuracy, visual acutance, image quality, and documentation involving the use of UAS for inspections.

FHWA Response: UAS are a tool to access visually hard to reach areas of a bridge. UAS operators in both the public and private sectors must adhere to statutory and regulatory requirements. Public aircraft operations (including UAS operations) are governed under the statutory requirements for public aircraft established in 49 U.S.C. 40102 and 40125. A bridge inspection team leader is required to be on site for the duration of the bridge inspection and is subject to the requirements as outlined in this final rule. The requirements for a routine inspection that includes a UAS-assisted visual inspection are the same as a standard visual inspection. FHWA has been researching opportunities for the appropriate use of UAS in the bridge inspection program and monitoring the research of others. FHWA will continue to look for opportunities and integrate these tools when it is believed they will contribute to the continued success of the bridge inspection program.

[3] The NCHRP Report 782 may be found at the following URL: *http://www.trb.org/Publications/Blurbs/171448.aspx.*

Section 650.309(h)

Five commenters raised concern for the proposed requirement that instructors of alternate training courses meet program manager or team leader qualifications, because valuable supplemental instruction may come from hydraulic engineers, structural engineers, load raters, software personnel, construction staff and others.

FHWA Response: FHWA has reconsidered its position for instructors of alternate training and has removed this requirement from the final rule. The intent of the qualifications requirement was to ensure knowledgeable personnel teach the course. FHWA agrees valuable supplemental instruction may come from hydraulic engineers, geotechnical engineers, structural engineers, load raters, software personnel, construction staff, and others. Removing instructor qualification requirements from the final rule is also consistent with the NTIS.

Fourteen commenters stated that further clarification is needed on the FHWA approval process of alternate training and how NHI materials will be made available. Several commenters requested clarification regarding grandfathering of NHI and FHWA-approved training per prior regulations.

FHWA Response: The regulation provides two options for acceptable bridge inspection training. The purpose of the options is to provide flexibility and consistency in the delivery of training. The first option is the approved NHI training courses identified in the NBIS, and the second option allows for State, federally-, and tribally-developed training courses. For the second option, FHWA outlines that alternate training materials and end-of-course assessments must include all the topics from the NHI courses and be submitted to FHWA for approval. FHWA intends to make NHI bridge inspection course materials available to State DOTs, Federal agencies, and Tribal governments through a formal written agreement in accordance with applicable requirements. The written agreement will establish controls on use of the material and the qualifications of those who deliver the training.

For agencies that have existing FHWA-approved alternate training, the NBIS requires that agencies review and update the prior approved training materials and resubmit for FHWA approval to ensure the training satisfies the requirements as defined in §§ 650.305 and 650.309. FHWA has revised § 650.309(h)(3) from the proposed regulation to clarify the requirements. Agencies may have the need to train personnel during the 24-month transition period and before they are able to revise fully prior approved materials and obtain FHWA approval. During the 24-month transition period, existing FHWA-approved training (*i.e.,* approved by FHWA prior to the effective date of the final rule) can still be used to train inspection personnel. Bridge inspection organizations will also have available to them the opportunity to schedule NHI training to meet the training requirements.

One commenter suggested that FHWA maintain a registry of all acceptable FHWA-approved (non-NHI) bridge inspection training that fulfill the requirements as outlined in the new regulation, to include various State, federally-, and tribally-developed training courses; the commenter noted this might streamline approval of inspector training qualifications when individuals seek employment in different States.

FHWA Response: FHWA agrees that maintaining a list of approved non-NHI courses could be beneficial for owners and individuals who need training. FHWA will continue to consider this suggestion, but does not believe it to be appropriate to include in the final rule as training is just one component of the qualifications requirements. State DOTs, Federal agencies, and Tribal governments are responsible to ensure all qualifications are met.

Section 650.311 Inspection Interval

General Comment

There were numerous comments on risked-based inspection intervals in § 650.311 of the NPRM. As background and support of FHWA responses to NPRM comments, the following is an overview of the basis and approach FHWA used in the NPRM and this final rule.

In accordance with 23 U.S.C. 144(h)(7), FHWA has outlined a risk-based processes for determining the frequency of bridge inspections. There are two different options for State DOTs, Federal agencies, and Tribal governments to determine the inspection interval. Method 1 offers a simplified assessment approach, while Method 2 offers a more rigorous assessment methodology to determine inspection intervals. The methods for establishing risk-based intervals are based on the NCHRP Report 782 Proposed Guideline for Reliability Based Bridge Inspection Practices [4] and FHWA's current practice for establishing 48-month inspection intervals.

Bridges typically exhibit structural deterioration in a controlled and stable manner over time; therefore, risk is considered an effective measure upon which to base the interval of inspections. When risk grows, bridges should be inspected more often, and when risk is reduced, bridges may be inspected less often. The process for identifying risk-based intervals involves the identification and use of an interval that is commensurate with the risk of safety or service loss in a given bridge. It provides additional flexibility to bridge inspection organizations by applying their experience and engineering knowledge to determine the use of limited resources in a more optimal way across their inventory. The general framework and process for assessment of risk provides bridge inspection organizations the latitude to exercise their interpretations to determine probability, consequence, and risk for bridges in their inventory. The intent of the rule is not to mandate the application of the rigorous risk-based approach to an entire inventory, although it is an option. Rather, the final rule allows State DOTs, Federal agencies, and Tribal governments to use Method 1 or Method 2 to determine the inspection interval for each type of inspection and for each bridge.

Section 650.311(a)

Sixteen commenters stated that a complete routine inspection for serious but localized conditions is unnecessary and would result in excessive costs, a waste of public resources, and unnecessary impacts to traffic. They stated that special inspections are typically used to monitor areas of concern between routine inspections and suggested that the regulation be revised to allow the use of special inspections.

FHWA Response: FHWA agrees that special inspections are appropriate in certain situations. Sections 650.311(a)(1)(ii) and 650.311(b)(1)(ii) of the final rule are revised to allow a special inspection limited to monitoring localized deficiencies and, in accordance with § 650.313(h), in lieu of a full routine inspection or full underwater inspection when one or more condition ratings are coded three (3) or less due to those localized deficiencies.

One commenter requested that FHWA explicitly state that either the simplified (Method 1) or the rigorous (Method 2) assessments of risk may be used, or that a mix of both methods may be used to determine inspection intervals. Another

[4] The NCHRP Report 782 may be found at the following URL: *http://www.trb.org/Publications/Blurbs/171448.aspx.*

commenter stated that the flexibility would be beneficial, particularly since it will take States time to determine the best approach to determining inspection intervals.

FHWA Response: The final rule allows the State DOT, Federal agency, or Tribal government to use Method 1 or Method 2 to determine the inspection interval for each type of inspection and for each bridge. This flexibility allows for the better allocation of inspection resources in consideration of risk. The SNBI has an item for recording which method is being used for each type of inspection for each bridge.

Fifteen commenters criticized the Method 2 approach of determining risk-based intervals for routine, underwater, and NSTM inspections as ''complicated,'' ''cumbersome,'' ''difficult,'' ''confusing,'' ''subjective,'' ''resource intensive,'' and ''unable to implement.'' One commenter expressed concerns that Method 2 would result in more frequent inspections and added cost burden. Five commenters expressed support and one commenter expressed strong support for Method 2.

FHWA Response: State DOTs, Federal agencies, and Tribal governments may utilize Method 1 or Method 2 to establish inspection intervals. FHWA utilized NCHRP Report 782—Proposed Guideline for Reliability-Based Bridge Inspection Practices [5] as a nationally recognized approach in the development of the optional Method 2. The FHWA believes the level of consideration and rigor identified in the underlying research are appropriate to maintain adequate highway bridge safety for intervals of inspection determined using this method. Several State DOTs have explored how to incorporate this approach in the current regulation and FHWA disagrees that it cannot be implemented. The Method 2 approach is intended to allow for better allocation of limited program resources; it is not intended as only a means for cost savings or reduced inspections. FHWA believes that the cost of development and management of the Method 2 approach will provide improvements in resource allocations and safety as described in the RIA.

Two commenters stated that requiring a bridge with a deck condition of three (3) or less to be inspected every 12 months is excessive for little gain.

FHWA Response: FHWA believes bridge decks rated in serious condition, as with other major bridge components, necessitate more frequent monitoring to protect public safety until corrective actions are taken.

Two commenters suggested that the 12-month interval criteria should be a condition rating of a four (4) or less for deck, superstructure, substructure, or culvert. One of the commenters, an inspector, stated that 24-months between routine inspections on bridges in poor condition is too long. The other commenter stated that a case can be made for a condition of four (4) or less on high traffic roads such as State highways.

FHWA Response: FHWA agrees that there may be other cases that could suggest shorter intervals between inspection. The rule defines the minimum cases for which FHWA requires 12-month interval; additional criteria to determine intervals, considering factors including condition ratings and known deficiencies, must also be developed and documented.

One commenter stated that the 12-month interval criteria condition code of 3 is too conservative for all bridges and suggested that the determination of inspection intervals should be left to the judgement of the agency and program manager. Another commenter stated that they have an objective method to determine when inspection frequencies less than 12 months are required and do not need further constraints on their inspection cycles.

FHWA Response: FHWA disagrees and has established minimum criteria to maintain a uniform level of safety.

Eight commenters expressed confusion or requested clarification regarding the new SNBI Scour Condition Rating item and how it would be used in setting routine and underwater intervals. One of the commenters had concerns about bridges with unknown foundations requiring 12-month inspection intervals. Another of the commenters suggested a scour critical bridge POA alone should dictate the inspection interval. Another commenter was concerned about requiring a 12-month interval because a bridge is coded as scour critical.

FHWA Response: Both § 650.311(a)(1)(ii) and (b)(1)(ii) use the new SNBI Scour Condition Rating item as criteria for determining reduced routine and underwater inspection intervals. This is a new item that is only based on observed scour; it is not equivalent to the Coding Guide's Item 113. Therefore, whether a bridge has been appraised as scour critical or the foundation is unknown has no effect on the inspection intervals required. The criteria for reduced intervals in both sections is for a condition rating of three (3) or less. The SNBI defines a rating of three (3) as serious or worse condition, meaning that major scour exists and the strength and/or stability of the bridge is seriously affected, typically necessitating more frequent monitoring, load restrictions, and/or corrective actions.

Seven commenters stated that the criteria in § 650.311(a)(1)(ii)(C), ''Details, loading, conditions, or inspection findings that are known to affect the performance of the bridge or its elements within the next 24 months,'' is vague and unknowable. Two commenters suggested adding the word ''safe'' before ''performance,'' and one suggested replacing the word ''known'' with ''expected.''

FHWA Response: FHWA agrees that the phrase is vague and it has been removed from the criteria.

One commenter was concerned that the Method 1 routine criteria has too many constraints, making the method too conservative and not worthwhile.

FHWA Response: FHWA believes minimum constraints are necessary to maintain consistency in the levels of inspection. The Method 1 criteria has been revised to be simpler, to align better with current extended frequency policy, and to relate more directly to SNBI items.

Twenty-nine commenters stated that the proposed Method 1 NBI routine inspection condition code of seven (7) or greater for extended intervals is too restrictive. Many of these commenters explained that this threshold is more restrictive than the current criteria approved by FHWA for extended frequencies, resulting in significantly fewer bridges being eligible for extended intervals than currently approved.

FHWA Response: The extended inspection interval condition criteria has been revised to be based on NBI condition ratings greater than or equal to 6. This change, along with the change to base the load rating factor criteria on the NBI inventory rating with a rating factor value greater than or equal to 1.0 for HS–20 or HL–93, reverts to the criteria currently used for FHWA approval of extended intervals. We anticipate these changes will result in a similar number of bridges being eligible for extended intervals as under the existing regulation. However, the actual number of bridges with extended inspection intervals is expected to increase as FHWA approval is no longer required.

Fifteen commenters suggested that the operating rating or legal load rating factor of 1.1 criteria for eligibility for extended inspection intervals be revised to be based on a rating factor greater than or equal to 1.0. Common reasoning

[5] The NCHRP Report 782 may be found at the following URL: *http://www.trb.org/Publications/Blurbs/171448.aspx*

offered is that an operating rating factor of 1.0 indicates that a bridge is already able to carry those loads with a built-in safety factor, that the Load and Resistance Factor operating rating was calibrated to a rating factor of 1.0 at an inspection interval of 5 years, and that requiring a more conservative operating rating provides no added benefit.

FHWA Response: The extended inspection interval load rating factor criteria has been revised to be based on an NBI inventory rating factor of greater than or equal to 1.0. This change, along with the change to the NBI condition rating criteria of greater than or equal to 6, reverts to the criteria currently used for FHWA approval of extended intervals, which we expect to result in a similar number of bridges being eligible for extended intervals as under the existing regulation. However, the actual number of bridges on extended inspection intervals is expected to increase, as FHWA approval is no longer required.

One commenter proposed that the routine 48-month interval load rating criteria in § 650.311(a)(1)(iii)(C) be tied to the SNBI Routine Permit Loads item.

FHWA Response: FHWA agrees with the comment, as the tie to the SNBI Routine Permit Loads item was intended. The § 650.311(a)(1)(iii)(C) criteria has been revised to require that SNBI Routine Permit Loads, item B.LR.08, be coded either an A for load capacity is adequate for all routine permit loads, no routine permit loads are restricted, or N for bridge does not carry routine permit loads, agency does not issue routine permits.

One commenter stated that there are steel bridges with AASHTO category E and E' fatigue details that have performed safely for more than 50 years and that restricting inspection intervals based on those details alone does not reflect a realistic consideration of risk. Another commenter suggested that the steel bridge detail criteria should eliminate bridges with non-redundant steel tension members.

FHWA Response: The steel bridge fatigue detail criteria for Method 1 extended inspection intervals is intended to be simple and conservative; additional criteria would greatly complicate the determination of the proper inspection interval. For bridges with NSTMs, criteria for determining inspection intervals for those specific NSTM members are provided in § 650.311(c). FHWA realizes this could result in different routine and NTSM inspection intervals for the same bridge, with a 48-month routine interval and a 24-month NSTM interval being common.

Twelve commenters were concerned with the vertical clearance criteria for extended inspection intervals. Some were concerned with not allowing extended intervals for bridges with a history of over height vehicular damage and recommended that this provision be removed, while others were concerned with excluding bridges with vertical clearances of less than 16'-0'' over interstates, freeways, and other arterials, stating that this is more restrictive than currently approved criteria.

FHWA Response: FHWA agrees. The criteria for extended inspection intervals has been revised to remove the criterion that bridges have no history of over height vehicular impact damage and to change the minimum vertical clearance requirement to 14'-0'' over all roadways.

Fourteen commenters recommended removal of the substructure material and environment extended inspection intervals criteria, stating that the substructure condition rating is sufficient in determining the inspection interval and that no data exist for the criteria and would be difficult to obtain.

FHWA Response: The substructure material and environment extended inspection intervals criteria has been removed. However, § 650.311(a)(1)(iii)(B) is modified and requires State DOTs, Federal agencies, or Tribal governments that implement extended intervals to develop and document a policy for determining the inspection interval, considering factors including materials and environments.

Four commenters stated that they thought the scour condition code criteria of 6 or greater for extended inspection intervals is too conservative and recommended changing to 5 or greater, with the reasoning that a code of 5 says the strength and stability of the bridge are not affected.

FHWA Response: A scour condition code of 5 is fair, moderate scour. Though the strength and stability of the bridge are not yet affected, FHWA believes an extended interval should not be allowed in such a condition, which is one code away from being severe enough potentially to affect the strength or stability of the bridge, and declines to make the suggested change in the final rule.

Seven commenters stated that the criteria in § 650.311(a)(1)(iii)(I) ''Details, loading, conditions, and inspection findings that are not expected to affect the performance of the bridge or its elements within the next 48 months'' is vague or ambiguous and suggested it be removed.

FHWA Response: FHWA agrees that the phrase is vague and inclusion of this criteria did not add essential information contributing to the requirements of this section, so the language has been removed from the final rule.

Two commenters noted that in the definition of risk assessment panel (RAP), the term ''expert'' is undefined, and the level of collective experience is unspecified. One commenter thought that some clarification would be useful, including education, licensing, and professional work experience in requisite fields in order to rely justifiably on the panels' judgments on risk assessments and inspection intervals. Another commenter suggested removing the word expert from the definition and replacing it with ''well experienced.''

FHWA Response: FHWA agrees with the commenters and has modified the language in the definition of risk assessment panel to use the term ''well experienced'' in lieu of ''expert.'' The requirement previously contained in the NPRM definition to require two PEs be part of the panel, has been relocated to § 650.311(a)(2) to better consolidate all requirements of the RAP to one location. Requiring PEs to be part of the panel establishes the professional expectation while providing flexibility for well experienced individuals who may not be PEs. Laws governing PE licensure within each State ensure that PEs only practice engineering in the fields in which they are qualified and experienced.

One commenter stated that the Method 2 process needs to have a timeframe for approval or disapproval.

FHWA Response: FHWA expects to review Method 2 submissions and provide approval in a timely manner. A specific timeframe is not provided, as the complexity of submissions will likely vary quite broadly.

One commenter stated that the regulation language should include ''deterioration'' modes.

FHWA Response: FHWA agrees and ''deterioration mode'' has been added to the final regulation.

One commenter stated that the Method 2 approach is resource intensive, difficult to implement, more stringent, and may result in more bridge inspections as compared to current regulations. However, other commenters expressed support.

FHWA Response: This regulation is intended to provide better allocation of limited bridge inspection resources. The Method 2 approach for determining intervals is an option that provides the ability to decide if the cost of development of the risk-based approach is worthwhile in comparison to return

in improvements in resource allocations and safety.

One commenter stated that the Method 2 approach does not explain if the interval is set by the highest risk element, and does not explain if different intervals are allowed for different elements.

FHWA Response: It would not be practical or manageable to have different intervals for different members of the bridge, so FHWA will continue to require one interval for the bridge which is governed by the members with the highest risk, as proposed.

One commenter questioned whether 72 months is too long an inspection interval under the risk-based approach outlined in Method 2 of the proposed rule.

FHWA Response: FHWA believes that the regulation in total, including the requirement for FHWA review and approval of the process used to justify a 72 month interval, will provide adequate safeguards for the safety of the Nation's network of bridges.

One commenter questioned whether timber structures could be included in the Method 2 approach.

FHWA Response: The regulations do not preclude timber structures from Method 2. Common deterioration modes in timber structures should be considered.

One commenter suggested that for deterioration modes in concrete elements, post-tensioning steel should also be included.

FHWA Response: FHWA agrees and has added ''prestressing'' steel in the final regulation, which is the steel used in both pre-tensioning and post-tensioning methods of fabrication or construction.

Sixteen commenters expressed concerns about the service inspection requirement. Comments were critical of the frequency of the inspection (24 months) and the undefined scope and data collection, and suggested that it defeats the purpose of the Method 2 risk-based approach when going beyond 48 months. One commenter expressed particular concern for service inspection of culverts because this inspection may take just as much effort as a routine inspection.

FHWA Response: The service inspection is needed to identify critical safety issues and can be performed by personnel with general knowledge of bridge maintenance or bridge inspection. It is intended to be much less rigorous and costly as compared to routine inspection. The service inspection has been revised to clarify that only ''inspection date and any follow up actions'' are required to be documented in the bridge file. Also, the interval has been changed to half of the routine inspection interval when that interval is greater than 48 months.

Section 650.311(b)

Six commenters expressed concern with automatically requiring underwater inspections at reduced intervals for a substructure condition rating of 3 or less, stating that the rating includes above water portions of the substructure. One of the commenters suggested that the requirement be modified to specify conditions that would be evaluated during an underwater inspection. Another commenter added that the number of bridges impacted would be minimal, but the requirement would cause the additional burden of having to have off-cycle contracts.

FHWA Response: The proposed substructure condition criteria for underwater inspections has been replaced in the final rule with criteria based on the underwater condition. With this change, the reduced underwater inspection interval criteria will only apply to those portions of the bridge evaluated during an underwater inspection. An item has been added to the SNBI to record the underwater condition rating.

Two commenters suggested that underwater components in poor or worse condition should have 12-month inspection intervals, since the likelihood of failure should be identical regardless of whether located above or below water.

FHWA Response: The underwater inspection interval for bridges with underwater components in serious or worse condition has been revised from the proposed rule to not exceed 24-months. This interval is a maximum for those bridges meeting the criteria of § 650.311(b)(1)(ii)(B). State DOTs, Federal agencies, and Tribal governments are additionally required to develop and document supplemental criteria for reduced underwater inspection intervals. FHWA anticipates that the supplemental criteria will often result in this subset of bridges having an interval of 12-months or less.

Two commenters requested that benign environment needed to be defined with more objective language.

FHWA Response: The proposed benign freshwater environment criteria has been removed from § 650.311(b)(1)(iii) in the final rule. However, State DOTs, Federal agencies, and Tribal governments that implement revised § 650.311(b)(1)(iii)(A) are required to develop and document an underwater extended interval policy, which should consider factors including the benign or aggressive nature of the environment.

Section 650.311(c)

Two commenters stated that the proposed regulation is too conservative and restrictive for NSTM Inspections, and suggested that intervals of 72 and 96 months should be allowed. The commenters cited research findings by Purdue University.[6]

FHWA Response: FHWA is aware of the cited research, that suggests that greater intervals for NSTMs are possible in low risk cases. This rule provides a step from the currently required 24-month interval toward those greater intervals. This risk-based approach for NSTM intervals will allow for many bridges to move to a 48-month interval, which is substantial relief as compared to current requirements. FHWA will continue to evaluate research in this area and the performance of this step and may consider longer intervals in future regulation.

Two commenters stated that bridges with NSTMs should not be eligible for intervals beyond 24 months.

FHWA Response: FHWA is basing NSTM interval requirements on published research[7] that suggests that greater intervals for NSTMs are acceptable for low risk cases. Risk is the combination of likelihood and consequence. While the consequence of failure of an NSTM is high, the risk can be mitigated in cases when the likelihood is very low.

One commenter asked about how the new AASHTO Guide Specifications for Internal Redundancy of Mechanically-Fastened Built-Up Steel Members[8] will be implemented with the new regulations.

FHWA Response: Section 650.313(f) allows for a State DOT, Federal agency, or Tribal government to demonstrate to FHWA that a member has system or internal redundancy through the use of nationally recognized methods. The AASHTO Guide Specifications for Internal Redundancy of Mechanically-Fastened Built-Up Steel Members[7] and AASHTO Guide Specifications for Analysis and Identification of Fracture

[6] Michael J. Parr; Robert J. Connor; and Mark Bowman, M.ASCE, Proposed Method for Determining the Interval for Hands-on Inspection of Steel Bridges with Fracture Critical Members, may be found at the following URL: *https://ascelibrary.org/doi/10.1061/%28ASCE%29BE.1943-5592.0000057.*

[7] *Ibid.*

[8] The AASHTO Guide Specifications for Internal Redundancy of Mechanically-Fastened Built-Up Steel Members, 1st Edition may be found at the following URL: *https://store.transportation.org/Item/PublicationDetail?ID=4149.*

Critical Members and System Redundant Members [9] are considered acceptable nationally recognized methods for determining system or internal redundancy.

Ten commenters questioned the meaning of ''significant corrosion'' as it relates to the NSTM inspection interval requirements.

FHWA Response: FHWA agrees that this terminology was vague; the criteria is revised to be based on the NSTM Inspection Condition, a new SNBI item.

One commenter suggested that ''fracture prone details'' should be considered for reduced NSTM intervals.

FHWA Response: FHWA did not include fracture prone details in the criteria as many of the bridges identified with these details have been, and continue to be, evaluated and, if necessary, retrofitted in accordance with the FHWA July 10, 2001, memorandum [10] on the subject of the Hoan Bridge Investigation. Therefore, FHWA does not believe it is necessary to include in the final rule. State DOTs, Federal agencies, or Tribal governments that are aware of bridges with these details should include such details as a risk factor in the documented reduced interval criteria.

One commenter suggested that ''in accordance with the fracture control plan'' should be defined.

FHWA Response: FHWA disagrees that fracture control plan needs to be defined in the regulation as it is a commonly recognized term, which was implemented by AASHTO in 1978, and is well defined.[11] The term is used in bridge fabrication and construction to describe elevated material and fabrication requirements applied to NSTMs to reduce the likelihood of fracture.

Two commenters suggested that ''details, loading, conditions, or inspection findings that are known to affect the expected performance'' is vague.

FHWA Response: FHWA agrees that the phrase is vague. The language is revised in the final rule with the intent that knowledge about unique aspects of the inventory known to affect performance is considered in the development of interval policies. The language has been incorporated in the § 650.311(c)(1)(ii) and (iii) narratives.

Two commenters stated that they prefer the NTIS tolerance—a window for performing inspections—and that the proposed tolerance will result in inspection date creep.

FHWA Response: During the development of the NPRM, FHWA considered using the NTIS tolerance method, which requires a fixed target inspection date to be set and allows a plus or minus 2-month tolerance. However, the NTIS method, unlike the NBIS final rule, does not allow for inspections to be conducted early; this is undesirable for the significantly larger bridge inventory. Therefore, FHWA declines the commenters' suggestion to use the NTIS tolerance method for the NBIS.

Section 650.311(e)

One commenter indicated the 3 month tolerance should not apply to bridges on an interval less than or equal to 12 months.

FHWA Response: FHWA agrees; § 650.311(e) has been revised to reduce the tolerance to 2 months for inspection intervals of less than 24 months.

Two commenters were concerned that it is not usually possible to know of rare and unusual circumstances in advance of the inspection due date and suggest allowing an extension request up to the tolerance date. Another commenter requested clarification as to when a request would need to be made.

FHWA Response: The exceptions to the inspection interval tolerance due to rare and unusual circumstances, such as a hurricane, which impact the ability of the owner to perform bridge inspections, have been revised to require that a request must be approved in advance of the inspection due date plus the tolerance. For example, for an inspection due on June 17, 2021, an exception request must be provided to FHWA with adequate time for review and approval before the end of the 3-month tolerance on September 30, 2021; accordingly, exception requests should be made as soon as a delay is known to be a possibility.

Section 650.313 Inspection Procedures

Section 650.313(a)

Seven commenters stated that the references in § 650.313 identify a version of the AASHTO Manual that is no longer current.

FHWA Response: FHWA agrees. New editions of the AASHTO Manual have been released since the development of the NPRM. This final rule adopts specific sections of the current version of the AASHTO Manual as stated in § 650.317. References to specific sections of the AASHTO Manual throughout § 650.313 have been updated accordingly. The NBIS specifically references Section 1.4, Section 2.2, Section 4.2, Section 6, and Section 8.

Fifteen commenters had questions and concerns about inspection requirements for portions of a bridge that are not visible. Several commenters stated that in some situations, non-visual methods to inspect these portions are unnecessary, costly, or not proven to be reliable.

FHWA Response: FHWA acknowledges that portions of bridges are not visible during inspections; for example, buried foundations and reinforcing bars in concrete elements. It was not FHWA's intent in the NPRM to require the inspection of such elements as part of a routine inspection. The statement requiring non-visible portions to be assessed via another method has been removed from the final rule. The intent of this requirement is to ensure all areas of the bridge to be inspected are properly accessed as identified in the AASHTO Manual. The Bridge Inspector's Reference Manual (BIRM) and NHI training courses identify methods for accessing portions of the bridge to be inspected.

Eleven commenters did not support documenting equipment needs in an inspection plan for all bridges. The commenters questioned if a written inspection plan was required for all inspection types, especially routine inspections of common bridge types, *e.g.* reinforced concrete culvert.

FHWA Response: FHWA agrees that documenting equipment, while a good practice, does not need to be written in a plan or a procedure for all inspection types and has removed that statement from this section of the final rule. Inspection plans are not required for all types; however § 650.313(g), which addresses NSTM, underwater, in-depth, and complex feature inspection types does require documented inspection procedures for these inspection types.

Seven commenters sought clarification on whether advanced technologies such as UAS or structural monitoring, could be used in bridge inspection. One commenter suggested FHWA continue to monitor technological advancements, evaluate their use in bridge inspection, and update policies which allow their use accordingly.

FHWA Response: FHWA encourages bridge owners to evaluate use of advanced technologies in bridge inspection. FHWA, through research and other programs, also evaluates advanced technologies and encourages their use where proven to be effective tools and methods for assessing bridge

[9] *Ibid.*

[10] FHWA July 10, 2001, memorandum on the subject of the Hoan Bridge Investigation may be found at the following URL: *https://www.fhwa.dot.gov/bridge/steel/010710.cfm.*

[11] Clause 12 of the AASHTO/AWS D1.5M/D1.5, *Bridge Welding Code,* 6th Edition.

safety and condition. FHWA's position is that proven advanced technologies may be used to supplement but not supplant bridge inspection personnel and inspection methods. These technologies are not a replacement for personnel performing inspections nor are they intended to replace visual and physical methods. Advanced technologies may be useful when their use enables an inspection to be done more efficiently without compromising the thoroughness and effectiveness of the inspection or when visual and physical methods are not able to assess fully a bridge component.

UAS may be used by qualified personnel to supplement portions of a bridge inspection, but it cannot address all aspects of an inspection (*i.e.* live load response, auditory cues, sounding of members). For example, UAS cannot currently perform physical (tactile) examination such as sounding or hammering on the surface of a bridge member. This type of examination is needed because it establishes the soundness of the material and if present, the dimensions of the defect for tracking deterioration over time and for determining strength or capacity when calculating a load rating. Use of UAS may also be subject to practical considerations such as lighting, the need for cleaning the portion inspected, and the potential for driver distraction.

When used effectively to supplement a bridge inspection, the use of UAS has the potential to provide efficiencies for some inspections such as limiting the amount of time access equipment is used and reducing the time working adjacent to live traffic. UAS may be used to supplement a bridge inspection when its capabilities are able to meet the requirements of a specific task in the bridge inspection. For example, a UAS may be an efficient tool for taking birds-eye view photography of a bridge site so that qualified personnel can observe and document changes in the channel since the last inspection. But even where UAS are used, if the photography shows concerning changes, the inspector must utilize physical (tactile) techniques to investigate further.

Technologies will continue to be developed that will change the way inspectors perform bridge inspection. FHWA will continue to evaluate these new tools in partnership with our stakeholders and update its bridge inspection guidance document, the BIRM, to allow these technological advancements to make their way into the National Bridge Inspection Program (NBIP).

Section 650.313(b)

Two commenters asked for clarification on what type of construction work constitutes ''rehabilitation'' as this triggers the need to perform an initial inspection.

FHWA Response: FHWA added the term ''rehabilitation'' and defines the term in § 650.305 of the final rule. Performing maintenance, repairs, or preservation work would not trigger a need to perform an initial inspection.

Two commenters questioned the need to perform an initial inspection on a rehabilitated bridge because the construction work was designed by a licensed engineer and overseen by qualified construction personnel.

FHWA Response: While many bridge construction projects are designed in accordance with State standards by licensed engineers and overseen by qualified construction personnel, not all work on bridges is designed to standards or administered by personnel meeting these professional qualifications. Further, the focus of design and construction personnel is different from that of personnel performing an NBIS safety inspection. Design and construction personnel strive to build a quality and durable bridge. The focus of personnel performing an initial inspection is to assure safety, update inventory data, establish baseline conditions of the bridge, and to establish the timeline for all other types of inspections.

Thirty-three commenters had concern with completing an initial inspection prior to opening a bridge to traffic. These commenters cited several reasons including difficulty coordinating with construction contractors, a pressing need to open a bridge to alleviate traffic congestion, rigorous oversight during construction, minimal benefit, and costs associated with delaying an opening. One commenter supported completing an initial inspection prior to opening a bridge to traffic.

FHWA Response: FHWA acknowledges the concerns raised by many commenters that timing an inspection with the completion of a construction project can be challenging, could unnecessarily delay use of a new bridge by the public, and that many bridge construction projects are overseen by construction engineers and inspectors to ensure a quality bridge is properly built. For these reasons, FHWA has revised the requirement so that owners have 3 months from the date the bridge is opened to traffic to complete the initial inspection. However, FHWA continues to encourage owners to complete the initial inspection before the structure is open to traffic when possible, which allows for an inspection under more convenient circumstances for both the inspector and the travelling public.

Fourteen commenters had questions about the statement ''[s]ubmit NBI data after the initial inspection of the entire bridge being open to traffic,'' and whether this would require an additional submission above and beyond the annual data submission to the NBI that is required in other parts of the NBIS.

FHWA Response: FHWA does not require an additional data submission to the NBI for an initial inspection of a bridge. This statement has been removed from the final rule. FHWA requires that the data from the initial inspection be recorded in the State DOT, Federal agency, or Tribal government's inventory as specified in § 650.315, and to be submitted to the NBI in the next annual data submission.

Twenty-eight commenters had concerns with performing initial and routine inspections on phased and temporary bridges. The commenters cited several reasons including difficulty coordinating with construction contractors, concerns with inspecting contractor owned temporary bridges, monitoring performed during construction by on-site personnel, and costs associated with performing these inspections, particularly if the project is accelerated and has many phases.

FHWA Response: Inspection of temporary bridges and bridges in phased construction that are open to public traffic is not a new requirement. See FHWA's Q&A 303–7 listed in 2011, at *https://www.fhwa.dot.gov/bridge/nbis/index.cfm* for clarification of the existing regulation. FHWA continues to require inspection of these types of bridges. The statements in the NPRM were to clarify this requirement as FHWA has received many questions about these types of bridges over the years. Questions have been asked about how specific sections of the NBIS would apply to various situations. Given the seamless nature of the Nation's highway system and the public's expectation for a uniform level of safety and reliability, it is FHWA's position that when these bridges are open to public traffic, they are to follow the requirements of the NBIS to ensure public safety.

Regarding inspection of contractor-owned bridges and monitoring during construction, many factors influence the in-service performance of contractor-owned bridges and the thoroughness of monitoring that occurs during a construction project. To ensure a uniform level of safety and reliability

when they are carrying public traffic, these bridges must be inspected to the requirements of the NBIS.

In the final rule, FHWA removed the specific language for these types of bridges in the initial and routine inspection types in § 650.313 and added language in § 650.303 'Applicability' to clarify that these types of bridges are subject to all requirements of the NBIS. The first requirement is to complete the initial inspection, which is due within 3 months of being opened to public traffic. The timeline for all other applicable inspection types are established from this inspection.

If a temporary bridge is opened to traffic, then subsequently removed or permanently closed to public traffic less than 3 months later, it would not be subject to the NBIS. If a bridge is being built in phases, the initial inspection is required within 3 months of the first phase that opens all or a portion of the bridge to traffic. On projects with many phases or rapid progression through phases (*e.g.* nightly or weekend closures), it is possible for up to 3 months of construction work to occur and multiple phases to have elapsed before the initial inspection is due. FHWA understands the possible challenges with performing initial and routine inspections on phased and temporary bridges; however, inspection of these bridges that are open to public traffic is not a new requirement and FHWA retains this requirement in the final rule.

Six commenters had questions about what constitutes a phase of construction.

FHWA Response: Phased construction is intended to address bridges which are partially built in stages with portions opened to traffic until the final full cross section is completed and all lanes are opened to traffic.

Section 650.313(c)

Eighteen commenters had questions about the scope of a routine inspection. These commenters also had questions about two statements in this section, specifically ''any portion[s] of the bridge not visible using standard access methods . . .'' and ''an area of the structure requires a closer, more detailed inspection . . .''. Commenters demonstrated wide interpretation of inspection requirements that could result from these statements.

FHWA Response: FHWA has removed these statements from the final rule. A routine inspection is defined in § 650.305, and a specific reference to AASHTO Manual Section 4.2 has replaced the removed statements to point the reader to specific material that explains what is required to perform a routine inspection. Additional information is available in the BIRM and NHI training courses to explain access techniques and inspection methods utilized on a routine inspection that when utilized, satisfy the requirements of this regulation.

Three commenters had questions about submitting NBI data for temporary bridges and whether this would require an additional submission above and beyond the annual data submission to the NBI that is required in other parts of the NBIS. The commenters also raised concerns with creating and removing records in the inventory for bridges that are only in service for a short period of time.

FHWA Response: FHWA does not require additional data submissions to the NBI for a temporary bridge. This statement has been removed from the final rule. In response to concerns with adding and removing data for temporary bridges in a State DOT, Federal agency, or Tribal government's inventory, FHWA has added in § 650.315 a provision which gives these entities the option not to submit inspection data for a temporary bridge as part of the annual data submission to the NBI until it has been open to traffic for 24 months. This is to provide some relief to owners in adding and removing bridges from their inventory, and preparing and submitting data to the NBI for those bridges which are truly temporary and only in service for a short period of time.

Section 650.313(e)

Twenty-five commenters had concern with completing an underwater inspection within 6 months of opening a bridge to traffic. Commenters cited several reasons including climatic factors such as winter weather, timing of seasonal high-water, rigorous oversight during construction, and availability of specialized inspectors, *e.g.* divers. Two commenters expressed support for completing an inspection within 6 months of opening a bridge to traffic.

FHWA Response: FHWA acknowledges owners need some discretion in scheduling this type of inspection due to the timing of when a bridge opens to traffic, use of specialized personnel and equipment, and climactic or environmental restrictions. However, it is the position of FHWA that an underwater inspection occur soon after the bridge is open to traffic to ensure the safety of the travelling public and establish a baseline for future inspections. FHWA has modified the proposed requirement in the NPRM for completing the first underwater inspection within 6 months, to completing it within 12 months after a bridge is opened to traffic. This allows a bridge owner a full seasonal cycle to perform the first underwater inspection because of the issues identified.

Eight commenters questioned the need to perform an underwater inspection on a rehabilitated bridge when the scope of rehabilitation work did not affect the underwater portions of the bridge.

FHWA Response: FHWA agrees with the commenters and has modified the NBIS to clarify that a rehabilitated bridge only needs an underwater inspection within 12 months if work was performed on portions of the bridge that are underwater. Any underwater portions that were not rehabilitated do not need an underwater inspection within 12 months and can remain on their current underwater inspection interval. For bridges being rehabilitated in phases, those portions must receive an underwater inspection within 12 months of the phase opening to traffic or the phase being completed if the bridge was never closed to traffic during the rehabilitation work.

Two commenters requested FHWA approval to use underwater imaging technology such as sonar on underwater inspections.

FHWA Response: The use of underwater imaging technology for performing an underwater inspection is not excluded in the current NBIS or this final rule. Also, the AASHTO Manual Section 4.2, which is incorporated by reference, requires diving or 'other appropriate techniques' to complete an underwater inspection. FHWA recognizes there may be instances in which an underwater inspection cannot be safely performed using traditional diving methods. The program manager must identify and document all requirements for performing underwater imaging for underwater inspection.

Section 650.313(f)

Nine commenters had concern with completing an NSTM inspection within 6 months of opening a bridge to traffic. Commenters cited several reasons including climatic factors such as winter weather, rigorous oversight during construction, and availability of specialized NSTM inspectors. Two commenters expressed support for completing an inspection within 6 months of opening a bridge to traffic.

FHWA Response: Similar to requirements for an underwater inspection, FHWA acknowledges owners need some discretion in scheduling this type of inspection due to the timing of when a bridge opens to traffic, use of specialized personnel and

equipment, seasonal constraints, and other restrictions. However, FHWA believes it is important for the safety of the travelling public that an NSTM inspection occur relatively soon after it is opened to traffic to understand the overall condition of the bridge and to develop a baseline for the future inspections. Therefore, FHWA has modified the proposed requirement in the NPRM for completing the first NSTM inspection within 6 months, to completing it within 12 months after a bridge is opened to traffic. This allows a bridge owner a full seasonal cycle to optimize the timing of the first NSTM inspection.

Four commenters questioned the need to perform an NSTM inspection on a rehabilitated bridge when the scope of rehabilitation work did not affect NSTM members on the bridge.

FHWA Response: Similar to the requirements for an underwater inspection, FHWA agrees with the commenters and has modified the NBIS to clarify that a rehabilitated bridge only needs an NSTM inspection within 12 months if the work was performed on a NSTM. Any NSTMs that were not rehabilitated do not need an NSTM inspection within 12 months and can remain on their current NSTM inspection interval. For bridges with NSTMs being rehabilitated in phases, the rehabilitated NSTMs must receive an NSTM inspection within 12 months of the phase opening to traffic or the phase being completed if the bridge was never closed to traffic during the rehabilitation work.

Eight commenters listed several types of redundancy and questioned which ones required demonstration of redundancy through an FHWA approved process. Three commenters asked for information explaining what is required for an FHWA approved process.

FHWA Response: A provision has been added in § 650.313(f) of the final rule which allows for a State DOT, Federal agency, or Tribal government to demonstrate to FHWA that a member has system or internal redundancy through the use of nationally recognized methods. The AASHTO Guide Specifications for Internal Redundancy of Mechanically-Fastened Built-Up Steel Members [12] and AASHTO Guide Specifications for Analysis and Identification of Fracture Critical Members and System Redundant Members [13] are examples of nationally recognized methods. FHWA has added criteria to the regulation on what should be submitted by a State DOT, Federal agency, or Tribal government, such as design and construction details, and we will review the policies and procedures for approval based upon conformance with the nationally recognized methods. If the owner demonstrates either system or internal redundancy, a hands-on, NSTM inspection of the member is not required. The bridge would still be subject to all other inspection types as applicable.

Section 650.313(g)

Four commenters requested clarification for what traditional inspection methods are, and how FHWA would grant approval of exceptions.

FHWA Response: Inspection methods are explained in the AASHTO Manual, the BIRM, and training courses. FHWA does not intend to approve exceptions to traditional inspection methods and has removed this statement in the final rule. If an owner proposes to use methods that are not described in these sources, such as an emerging technology, the owner should perform the inspection with proven methods and may also utilize the emerging technology to supplement the inspection or to compare results.

Section 650.313(h)

Twelve commenters requested that a special inspection of a bridge be allowed which focuses on the areas of deterioration or damage in lieu of routine and underwater inspections when the routine and underwater inspection intervals as described in § 650.311 are reduced below 24 months and 60 months, respectively.

FHWA Response: The intent of reducing an inspection interval is to increase monitoring and scrutiny in areas that are deteriorating, damaged, or otherwise of concern. When the routine and underwater inspection intervals are reduced below 24 and 60 months respectively, FHWA agrees a special inspection may be performed in lieu of a routine or underwater inspection of the full bridge. Provisions were added to §§ 650.311 and 650.313 allowing this option for bridge owners. When this option is invoked, routine and underwater inspections of the full bridge are still required at least every 24 and 60 months, respectively. For this type of inspection, the NBIS requires a qualified team leader and documented inspection procedures which identify the area(s) to be inspected, methods to be used, and other pertinent information necessary to ensure an adequate special inspection is performed. Special inspections are to be focused in the area(s) of concern on the bridge that are causing the inspection interval(s) to be reduced.

Section 650.313(i)

Six commenters stated the requirements of a service inspection are unclear and requested that service inspection requirements be clarified.

FHWA Response: FHWA has clarified the purpose of a service inspection and personnel that would perform these inspections in the discussion for § 650.305, Definitions. FHWA utilized NCHRP Report 782—Proposed Guideline for Reliability-Based Bridge Inspection Practices [14] in the development of this inspection type. FHWA has added a paragraph to § 650.313 to explain that all bridges with a routine inspection interval greater than 48 months require a service inspection and that inspection results, including the date of inspection and any required follow-up actions, are to be documented in the bridge file when this inspection type is performed.

Section 650.313(j)

One commenter suggested a team leader be required to perform special inspections.

FHWA Response: The purpose of a special inspection is to monitor a known or suspected deficiency, or to monitor special details or unusual characteristics of bridges that do not necessarily have defects. As a result, the scope of special inspections can vary widely between owners and bridges. Many of the parameters for performing a special inspection are to be defined by the owner and documented in special inspection procedures. The NBIS only requires a qualified team leader for a special inspection as described in § 650.313(h) and (j). Since there are a number of reasons why special inspections are performed, FHWA is not requiring that a Team Leader perform all special inspections. There may be situations where it is not necessary for a Team Leader to lead the inspection, but this must be documented in the special inspection procedures.

[12] The AASHTO Guide Specifications for Internal Redundancy of Mechanically-Fastened Built-Up Steel Members, 1st Edition may be found at the following URL: *https://store.transportation.org/Item/PublicationDetail?ID=4149.*

[13] AASHTO Guide Specifications for Analysis and Identification of Fracture Critical Members and System Redundant Members, 1st Edition may be found at the following URL: *https://store.transportation.org/Item/PublicationDetail?ID=41491.*

[14] The NCHRP Report 782 may be found at the following URL: *http://www.trb.org/Publications/Blurbs/171448.aspx.*

Section 650.313(k)

Twenty-one commenters stated 3 months is not enough time to load rate some bridges or address changes which affect large portions of a bridge inventory. Two commenters expressed support for a 3-month timeframe to load rate bridges.

FHWA Response: Timely completion of load ratings is important to understand the live load carrying limits of a bridge and maintain the safety of the traveling public. Therefore, FHWA maintains the requirement to complete load ratings within 3 months from the time the need for a load rating is identified. This requirement is aligned with the NTIS. In the rare and unusual circumstance that certain bridges, such as those with especially complex features, may require more than 3 months to complete a load rating, bridge owners should contact FHWA staff promptly.

When a large portion of the inventory requires load rating because of changes in Federal law or regulation, FHWA will continue to work with the States to address these situations through appropriate methods. We note that FHWA and States faced a similar challenge with respect to accommodating load ratings for emergency vehicles after those vehicles were made legal loads in the Fixing America's Surface Transportation Act.

When a large portion of a State's inventory requires load rating because of changes in State law or regulation, FHWA will work with the State to develop a plan to address this issue.

Six commenters had questions about when a bridge needs to be re-rated for loads. Commenters also requested that owners have discretion to set criteria for when a bridge needs to be re-rated and the priority for completing the load rating.

FHWA Response: FHWA agrees and has clarified in the final rule when a bridge should be re-rated. Change in condition of a structural element, change in dead load, change in live load, or completion of construction, reconstruction, or rehabilitation are the most common reasons a bridge needs to be re-rated. These are typically found during an inspection, and as a result, the need to re-rate a bridge is often in response to an inspection finding. However, there are other reasons a bridge may need to be re-rated, such as new legal vehicles introduced or damage resulting from an unexpected event. The AASHTO Manual and the BIRM provide additional information. Bridge owners have discretion to set criteria and priorities for re-rating bridges which are more stringent than the NBIS.

Ten commenters questioned why a bridge needs to be load rated for a permit load. Commenters also stated they have tools and processes developed that enable them to efficiently process permit requests they routinely receive.

FHWA Response: Because permit loads utilize public roads, verification that bridges can carry the load is required to ensure the safety of the travelling public and hauler; as such, FHWA has retained the requirement to analyze permit loads in the final rule. FHWA recognizes some owners have developed screening tools and other processes for analyzing permit loads for which they routinely receive permit requests. These tools and processes are acceptable methods of analyzing permit loads, provided they are founded upon actual modeling and analysis of bridge responses under permit vehicles and loads that envelope the hauling vehicle and load that is requesting a load permit.

Section 650.313(l)

Fifteen commenters expressed concerns about posting for routine permit loads. Commenters cited driver confusion, costs, and infeasibility of installing posting signs at bridges for a potentially infinite number of permit vehicles. Commenters stated their permitting processes address whether a permit load can cross a bridge.

FHWA Response: For unrestricted legal loads, load posting is a public safety issue. Bridges must be posted informing the travelling public of the maximum load that bridges can safely carry. However, for routine permitted vehicles that do not fall within the general posted weight limit, and where load posting for these vehicles is not feasible, the FHWA has historically said that the permit process is an acceptable means for bridge owners to verify that bridges on designated routes can safely carry the permitted vehicles. Permit vehicles are restricted from travelling off of designated routes. Because of this, FHWA agrees that load posting of bridges for routine permit vehicles is not required. The final rule has been revised to clarify that restriction is acceptable in lieu of posting bridges for permit vehicles. This is consistent with previous NBIS regulations.

Thirty-six commenters expressed concerns about the feasibility of load posting bridges in 30 days or less. Commenters cited several reasons including the time needed to fabricate signs, lengthy processes required in some State or local laws, postings of varying urgency, and weather and site restrictions.

FHWA Response: Load posting informs the travelling public of the maximum load that bridges can safely carry. As discussed above, for unrestricted legal loads, lack of load posting signs is a public safety issue, which some bridge owners consider to be a critical finding requiring immediate follow-up action. Due to the safety issue and other factors, owners must establish procedures that prioritize installation of load posting signs based upon the associated risks and need. In some situations, the urgency to implement a load posting is much less than 30 days. FHWA acknowledges that posting within 30 days or less in very urgent situations may require some bridge owners to change their business practices. The NBIS establishes requirements for timely installation of load posting signs that align with the load posting requirements in the NTIS.

Section 650.313(m)

Six commenters expressed concerns with developing criteria for closing a bridge. Commenters stated that closing a bridge is often dependent upon parameters that are specific and unique to a specific bridge and therefore it is difficult to develop standard criteria.

FHWA Response: Similar to the general procedures described in § 650.313(g), FHWA is requiring general procedures for closing bridges be documented. General procedures are applicable to many bridges and describe criteria for when a bridge must be closed and the process which describes the steps and timelines for closing a bridge. FHWA acknowledges that all factors requiring bridge closure cannot be anticipated; therefore, these procedures are expected to be general in nature and should be applicable to many bridges.

Two commenters expressed concern that a 3-ton gross live load is too low for bridge closure. Commenters stated that many vehicles in the general non-commercial vehicle fleet are heavier than 3 tons and preferred a closure weight of 4–5 tons.

FHWA Response: FHWA acknowledges there are some vehicles in the general passenger vehicle fleet, and many commercial trucks, that have an empty vehicle weight of more than 3 tons. FHWA has set 3 tons as the absolute minimum gross live load capacity as this is consistent with the AASHTO Manual. FHWA encourages owners to adopt more stringent closure criteria. This may include requiring closure at higher gross live load weights than 3 tons.

Section 650.313(n)

Based on seven comments previously discussed in § 650.313(a) which desired incorporation of a more current version of AASHTO Manual into the NBIS, FHWA has revised the section reference for bridge files to AASHTO Manual Section 2.2.

FHWA has only adopted Section 2.2 of Chapter 2 of the AASHTO Manual to describe components of a bridge file. This more exact reference points the reader to the specific components listed in Chapter 2 of the AASHTO Manual that are required to be in a bridge file. Other portions of Chapter 2 describe other excellent components that may be useful to an owner and could be contained in a bridge file. FHWA encourages maintaining these in the bridge files as well; however, those outside of Section 2.2 are not required as part of the NBIS.

Section 650.313(o)

Three commenters requested FHWA explain the ''scour appraisal'' process. One commenter requested FHWA explain the ''scour evaluation'' process. One commenter requested FHWA explain the ''scour assessment'' process. Five commenters asked if these processes are to be performed in accordance with HECs.

FHWA Response: Based on the comments in this section and § 650.305, the definitions related to the identified scour processes and this section have been revised to provide clarity of the requirements of the NBIS. FHWA recognizes that HECs 18, 20, and 23 are the state of practice for the appraisal, design, and inspection of bridge scour, stream stability, and scour countermeasures. As stated in the final rule, the scour appraisal and scour evaluation processes should be consistent with HEC 18 and 20. The scour assessment process should be consistent with HEC 20. The development of a scour POA for a bridge should be consistent with HEC 18 and 23.

Five commenters requested clarification for how scour appraisal, scour evaluation, and the scour assessment processes work together.

FHWA Response: This section and the scour related definitions have been updated to clarify scour appraisal is the overarching process that includes three methods for determining the worst case scour at a bridge; observed scour, scour evaluations, or scour assessments. The bridge owner must perform a scour appraisal for each bridge over water to determine if the bridge is scour-critical and whether it requires a scour POA. The scour appraisal determination for a bridge is to be based upon the least stable of observed scour, evaluated scour, or assessed scour.

Eight commenters requested clarification for when scour POAs are needed for bridges over water. Several commenters specifically questioned whether a bridge with an unknown foundation requires a scour POA.

FHWA Response: All bridges that are scour critical or have unknown foundations require a scour POA. The existing NBIS regulations state that owners must develop a scour POA for each bridge that is scour critical. There are several guidance documents and reference manuals available on FHWA's Hydraulic Engineering web page that address these requirements and provides guidance for developing a scour POA.

If a bridge has unknown foundations, no scour appraisal can fully determine vulnerability to scour; therefore, such a bridge requires a scour POA to manage scour risks associated with that bridge. The FHWA memo, ''Additional Guidance for Assessment of Bridges Over Waterways with Unknown Foundations,'' dated October 29, 2009,[15] as well as other guidance documents and reference manuals, provide information for developing a scour POA specifically for a bridge with an unknown foundation type.

Ten commenters requested FHWA clarify that a scour POA can be based solely upon monitoring and does not need to describe installation of physical or hydraulic countermeasures.

FHWA Response: FHWA agrees that for certain bridges, a scour POA may be based on a monitoring program to manage the risks associated with scour. As HEC 18 and 23 and other guidance documents explain, bridges with the greatest risk from scour-induced failure should have a scour POA that describes installation of physical or hydraulic countermeasures, or even replacement, and also include a monitoring program that allows time to implement these physical or hydraulic countermeasures. Bridges that present a lesser risk may be considered candidates for a scour POA based solely on a monitoring program as an acceptable countermeasure.

Two commenters asked if existing scour evaluations completed prior to this regulation need to be redone.

FHWA Response: The final rule only requires existing scour evaluations or scour assessments to be updated when the assumptions, bridge conditions, channel conditions, or other pertinent factors used in the existing scour evaluation or scour assessment are no longer representative of current conditions or are determined to be invalid.

Section 650.313(p)

Two commenters had questions about whether quality control (QC) and quality assurance (QA) must be performed by independent personnel. Commenters were concerned that additional qualified personnel would be required to observe inspection teams at a bridge site, effectively doubling personnel needs.

FHWA Response: As described in AASHTO Manual Section 1.4, which is incorporated by reference in § 650.317 of this final rule, QC and QA reviews are to be performed by a person other than the originating person(s). However, the specific parameters of a QC and QA program, including the extent and interval for observing inspection teams to ensure quality are defined by the program manager. The NBIS language has been updated to emphasize this. While this has been clarified, the basic requirements are in the existing regulation, so there should be no additional personnel needs.

Section 650.313(q)

General

The critical findings section received over 125 comments and FHWA has incorporated many of the suggested changes made by commenters. Specific changes are described in greater detail below following an overview of the general changes to this section.

The definition for ''critical finding'' does not substantially change from the existing regulation; however, State DOTs, Federal agencies, and Tribal governments are required to identify what they consider a critical finding based upon the minimum requirements in § 650.313(q) of the final rule. Paragraph (q) contains only the minimum requirements; FHWA encourages bridge owners to adopt more stringent criteria as appropriate that align with the characteristics of their organization and the issues they experience in their bridge inventory.

The reporting process for notifying FHWA of critical findings and corrective actions taken in response to critical findings is updated in the final rule. State DOTs are to report critical findings information to their respective FHWA Division office. Similarly, Federal agencies and Tribal governments are to report required

[15] Additional Guidance for Assessment of Bridges Over Waterways with Unknown Foundations may be found at the following URL: *https://www.fhwa.dot.gov/unknownfoundations/091029.cfm.*

information to the FHWA FLH office. FHWA's goal is safety and national consistency. Federal agencies and Tribal governments are to follow the same procedures as those required for State DOTs.

Section 650.313(q)(1)(i) lists several deficiencies that result in a critical finding. This section also identifies that any condition posing an imminent threat to public safety is a critical finding. Owners are required to develop procedures that identify critical findings based upon their inventory. Critical findings procedures have two main objectives: First, the procedures must clearly establish criteria for those deficiencies which are critical findings and require immediate action to preserve public safety; and second, the procedures must describe a process to resolve immediately the critical finding.

Four commenters expressed concern with the duplication of ''full or partial closure of a bridge'' and a ''recommendation for a full or partial closure of a bridge by the program manager'' as critical findings.

FHWA Response: FHWA agrees and has removed the duplicative criteria of a program manager recommending closure.

Twenty-one commenters expressed concern with the minimum critical finding criteria for Superstructure Condition and Substructure Condition ratings of serious (3) as too conservative. The commenters also felt that over time, such conservative criteria could desensitize staff to the significance and urgency of critical findings. The commenters stated this would significantly increase the number of critical findings and would require significant additional resources to follow-up on issues that, while serious, may not be critical.

FHWA Response: FHWA agrees with the commenters. The threshold has been revised from serious (3) to critical (2) as defined in the 0–9 scale for condition ratings in the SNBI. FHWA has added Channel Condition and Scour Condition ratings of critical (2) or worse as defined in the SNBI to the minimum criteria defining critical findings. This is consistent with other deficiencies described in the general description of critical findings. FHWA has also included the Deck Condition and Culvert Condition ratings, as it is our position that critical findings on these components pose a threat to public safety.

Twenty-seven commenters expressed concern with the minimum criteria for a nonredundant member with any quantity in Condition State 4 (CS4). Commenters cited several reasons why implementing this criteria could be problematic, including that element level data is not required and therefore not available on all bridges (non-NHS bridges); element data is typically used for bridge management purposes, not safety inspection; the sometimes temporary nature of an element being in CS4; the inclusion of non-critical conditions included in the CS4 definition; and questions concerning how a nonredundant member is defined.

FHWA Response: FHWA has changed this criteria in the final rule by removing the nonredundant term and adding the NSTM to the critical findings section. This change requires owners to consider redundancy or lack of redundancy in steel tension members as part of the general criteria for a critical finding.

Twenty-seven commenters expressed concern with missing load posting signage as critical findings criteria. The primary concern was with the amount of resources that would be needed to report on these issues as they work to resolve them.

FHWA Response: Missing or illegible signs are a public safety issue, and must be replaced according to the owner's posting procedure. FHWA acknowledges that owners have a wide range of processes for addressing missing or damaged load posting signage. We have moved this criteria from the critical findings process to load posting in § 650.313(l)(3) of the final rule. Consistent with our 2019 policy memorandum and to align with the NTIS, a 30-day maximum timeframe, from when the need is identified, to replace missing or damaged load posting signs is in the final rule.

Thirteen commenters asked whether a critical finding occurs if immediate restrictions, postings, repairs, or other follow-up actions are performed and the deficiency is immediately resolved.

FHWA Response: Whenever there is an imminent threat to public safety that demands an immediate response, the deficiency is considered a critical finding regardless of whether it was resolved immediately upon discovery or not. These deficiencies are to be reported as required in the NBIS.

Two commenters asked whether planned versus unplanned closures and restrictions result in a critical finding.

FHWA Response: The final rule requires that when deficiencies are found that result in a full or partial closure, this is to be identified as a Critical Finding. It is not possible to address every possible situation; however, generally planned closures and restrictions are not critical findings and unplanned closures and restrictions are critical findings. For example, a planned bridge closing because of a construction project starting is usually not a critical finding. However, if that same bridge was open to traffic during a construction project and was unexpectedly closed or restricted because of a newly discovered deficiency, that would be a critical finding and should be reported as such.

Eighteen commenters expressed concern with reporting critical findings to FHWA within 24 hours of discovery. They stressed that during the first 24 hours, an owner is urgently focused on resolving the critical finding and that reporting is not the highest priority.

FHWA Response: A similar requirement for notifying FHWA within 24 hours is in the NTIS. Consistent with the NTIS, the regulation does not require a formal report or a developed resolution, but only simple notification of the local FHWA Division Office. FHWA believes this can easily be accomplished through a telephone conversation or an email message. Due to the critical nature of these conditions, FHWA does not believe that these requirements are excessive. The intent of these requirements is to create a reporting mechanism to FHWA of the critical items that could be a threat to the traveling public's safety. Further, this specific portion of the final rule seeks to ensure that severe conditions are addressed in a timely and appropriate manner through oversight and partnership with FHWA, which was specifically required in MAP–21.

Twenty-one commenters asked for clarification on what is meant by reporting until the critical finding is ''permanently resolved.''

FHWA Response: FHWA revised the final rule to require reporting until ''resolved'' to align with the NTIS. Similar to the NTIS, FHWA expects bridge owners to report and provide updates on each critical finding until it is resolved. Resolved means an action has been taken and completed to mitigate the deficiencies and protect public safety. This could involve lane or load restriction, shoring, repair, closure, or replacement of the bridge. Increased inspection frequency alone does not fully resolve a critical finding if the underlying safety issue is not rectified. A critical finding is to be reported monthly until the threat to public safety is no longer present.

Four commenters requested clarification on whether all critical findings are to be reported monthly, or if reporting is only intended for new critical findings that have occurred since the previous report.

FHWA Response: FHWA requires all critical findings be reported monthly, or as requested, until each critical finding is resolved. It is expected that critical findings be resolved as soon as possible, typically in less than 30 days, which would mean most critical findings are reported on for only the initial month and possibly a second month, depending upon the dates when the critical finding occurs and is resolved within a monthly reporting interval.

Section 650.315 Inventory

Ten commenters indicated the reduction from 180 days to 3 months for local bridge data submission of revised data is too constrictive and local agencies may not be able to meet the time constraint. One local agency commenter indicated they already submit data within 3 months.

FHWA Response: FHWA believes that with current technological capabilities, the requirement of 3 months for reporting bridge inspection data to be recorded in the State, Federal agency, or Tribal government database is reasonable. FHWA only collects this data once a year and any delay in the data being properly inventoried would not provide FHWA the most current data available. Up-to-date information is vital to program oversight, management, and stewardship for the State and FHWA. It is also important that FHWA have current data because this data is used to: (1) Track bridge performance measures, (2) provide reports to Congress, and (3) make critical decisions regarding the bridge program. This necessitates adherence to a firm 3-month collection period and is also consistent with the NTIS.

Three commenters indicated opposition to collecting element level data for non-NHS bridges. One commenter supported the collection of element level data to provide bridge owners improved planning and decisionmaking data. One commenter wanted clarification of when element level data is required to be collected.

FHWA Response: As required by Congress in 23 U.S.C. 144(d)(2), each State and Federal agency shall report element level data for all highway bridges on the NHS. Section 650.315(a) of this final rule supports this requirement. The NBIS does not require States to submit element level data for bridges off the NHS. However, FHWA and its NBI will accept element level data for bridges off the NHS if a State DOT chooses to submit it. As identified in § 650.315(c), element level data is to be updated for all inspection types if there is a change in condition.

Section 650.317 Incorporation by Reference

The AASHTO recommended the contact information for AASHTO publications be updated.

FHWA Response: The contact information has been updated.

The AASHTO commented that they understand FHWA must reference a specific edition of the Manual for Bridge Evaluation and Manual for Bridge Element Inspection and that the regulation cannot simply say ''most current edition.'' Since both publications are updated more frequently than the NBIS, it forces States to use outdated guidance. Since 23 CFR 625.4 contains a list of other standards, policies, and specifications and is subject to more frequent updates, AASHTO recommends adding these two publications to the next update of 23 CFR 625.4, and including in this section language referencing these specific editions or the most current ones as shown in 23 CFR 625.4.

FHWA Response: FHWA acknowledges the procedural challenges with updating material incorporated by reference. FHWA follows the regulations and procedures of the Office of the Federal Register for this process. The documents incorporated by reference represent the minimum standards required for compliance with the NBIS. As in the past, when a new edition of an incorporated by reference document is available, FHWA has recognized through policy memo where changes in the new edition exceed the minimum standards and can be used while maintaining compliance with NBIS.

Four commenters commented that the 3rd edition of the AASHTO Manual be incorporated into the NBIS. Fourteen commenters suggested referencing the latest edition, and not stating a specific edition.

FHWA Response: FHWA agrees and has adopted specific sections of the current 3rd edition version of the AASHTO Manual available at the time the final rule is published. References to specific sections of the AASHTO Manual throughout NBIS have been updated accordingly. The NBIS specifically references Section 1.4, Section 2.2, Section 4.2, Section 6, and Section 8, excluding the 3rd paragraph in Article 6B.7.1. This paragraph was excluded because FHWA is not aware of any research that served as the basis for the practice described in this paragraph and as such does not align with the requirements of the NBIS. Office of the Federal Register regulations at 1 CFR 51.1(f) provide that incorporation by reference of a publication is limited to the edition of the publication that is approved and that future amendments or revisions of the publication are not included. A specific edition of the manual must be referenced in the regulation. This provides certainty to the users of the regulation which standards apply, in addition to insuring for notice and comment as required by the Administrative Procedure Act. Where differences exist, the NBIS takes precedence over the AASHTO Manual. The FHWA will continue to update, as necessary, the materials incorporated by reference in its regulations on a regular basis.

Specifications for the National Bridge Inventory

With the publication of the final rule, the SNBI will supersede the FHWA Recording and Coding Guide for the Structure Inventory and Appraisal of the Nation's Bridges (Coding Guide), 1995. The final SNBI document in portable document format (PDF) is available for download on the docket for this rulemaking and as noted in § 650.317.

Bridge inventory information collected by each State DOT, Federal agency and Tribal government is reported to FHWA, as requested, in accordance with the NBIS reporting requirements. The resulting information is maintained in the National Bridge Inventory (NBI) database. The reporting of inventory data for all highway bridges subject to the NBIS, and their related features, are based on the definitions, explanations, and data items supplied in the SNBI. State DOTs, Federal agencies, and Tribal governments use the data items and instructions in the SNBI when reporting NBI data to FHWA.

General

One commenter proposed that the SNBI document provide for scheduled revisions, similar to the AASHTO manuals.

FHWA Response: The processes that FHWA must follow for updating a document incorporated by reference are discussed above and are different from AASHTO's. FHWA will continue to work through established processes when updates are needed. Updates are completed through the rulemaking process.

Many commenters indicated concerns with the number of added items in the proposed SNBI, and questioned their purpose and value.

FHWA Response: The items in the SNBI serve the following practical purposes and benefits: Ensuring highway bridge safety; enabling

oversight of the NBIP; reporting to Congress; emergency response; administering a risk-based, data driven, performance management program in accordance with MAP–21, the FAST Act, and 23 CFR part 490; and providing quality data through clarity and ease of use.

Element level data for NHS bridges, as required by 23 U.S.C. 144, have been reported to FHWA since April 2015 and are not considered new data for this rule; the 2014 Specification for the National Bridge Inventory—Bridge Elements (SNBIBE) has been merged with the SNBI. Fifty-seven of the 154 data items in the SNBI are considered new with respect to the Coding Guide and SNBIBE; 4 of these are calculated by FHWA and States are not required to be collected or reported to FHWA. Thirty-five of the 57 items are collected at a frequency indicated as ''I'' (Initial), where data is recorded initially and updated when necessary, but will not typically change from inspection to inspection. Only fifteen of the 57 new items are collected at a frequency indicated as ''EI'' (Each Inspection), where data is verified and/or updated by the inspector during each inspection. Items that are no longer used by FHWA have been removed.

Sixteen commenters indicated concerns with the number of item code changes proposed for those data items that have been brought forward from the Coding Guide into the SNBI. Three State DOTs suggested that there might be confusion when comparing data items between the two specifications, and expressed concern over the resources that will be required to populate and submit the SNBI data. One commenter requested that when the final rule is published, FHWA at that time also publish the new data submission format and details, as well as the updated processing logic for agencies. Agencies will need this information to update their software to support the SNBI data. Six commenters indicated a need for a migration process.

FHWA Response: FHWA recognizes that the transition from the Coding Guide to the SNBI will be a significant effort, and aims to reduce the burden on bridge owners. Many SNBI data items are identical to those in the Coding Guide, and coding options have been revised where practical to align more closely with codes in the Coding Guide, thereby facilitating the transition to the SNBI. FHWA will provide a crosswalk in the coming months that defines the relationship between the Coding Guide and the SNBI. The anticipated data submission format and data checking protocols will also be provided. In addition, FHWA will develop a computer-based tool to transition data from the Coding Guide format to the SNBI format, where the data can be accurately transitioned; this tool should be available at FHWA's website for use within 12 months of the effective date of the final rule.

Twenty commenters were concerned about the timeframe for implementation of the SNBI due to the need for updating databases, migrating existing data, training personnel, and collecting and reporting the required data. These commenters recommended implementation timeframes between 24 to 48 months before the first data submission, with full implementation taking up to 10 years, given extended inspection frequencies.

FHWA Response: An implementation timeline is under development with an expectation of collecting initial SNBI data in the March 2026 data submittal. Based on analysis, this will allow sufficient time for FHWA and State DOTs to develop, test, install, and set up new data collection and management systems. The initial dataset will largely consist of transitioned data (data that can be accurately converted from the Coding Guide format to the SNBI format), as well as those limited data items that do not transition accurately, but are required for administering FHWA programs. The remaining items that do not transition accurately may be populated, and the transitioned items may be verified, during the following inspection cycle, with the expectation that all data for all bridges be populated and verified by the March 2028 data submittal. FHWA considers this timeline to be fair and achievable based on FHWA developing and providing tools for data transition, training, and data reporting format, and the need to collect specific data required by the final rule for extended inspection intervals.

One State DOT requested a data dictionary for the SNBI.

FHWA Response: The SNBI document provides information for a data dictionary, specifically Figure 1 and the tables in Appendix B.

Several commenters questioned whether event-related data items (*i.e.* Work Performed) will require reporting of events that occurred prior to implementation of the SNBI.

FHWA Response: FHWA will not require the reporting of event-related data that occurred prior to implementation of the SNBI.

Some commenters requested the inclusion of additional illustrations to communicate how item values are to be determined.

FHWA Response: Multiple illustrations were added or revised where clarification was needed based on comments received and FHWA internal reviews. Language was also revised to address situations where the intent may not be conveyed sufficiently by the included language or illustrations.

Cost

In response to the request by FHWA, eleven State DOTs provided data for costs associated with the proposed change from the Coding Guide to the SNBI. The reported costs ranged from approximately $200,000 to $18,000,000.

FHWA Response: FHWA recognized that bridge owners would incur a one-time cost associated with changing from the Coding Guide to the SNBI. However, as many of the data items are the same or similar, and there is a wide variety of data management and reporting systems being used, FHWA was unable to estimate these costs. The cost information received from the commenters was used to update the Regulatory Impact Analysis (RIA), available in the docket for this rulemaking.

Discontinued Items

One commenter indicated that the discontinued *Parallel Structure Designation* item (Item 101) in the Coding Guide was useful for designating twin bridges.

FHWA Response: The *Parallel Structure Designation* item has been discontinued, as it is no longer needed by FHWA. Bridge owners can continue to collect the data for their use, but will not report the data to FHWA.

New Items Proposed

One commenter proposed an *Approach Roadway Surface* item that distinguishes between roadway surface types that impact bridge management or bridge design. For example, preservation actions for a bridge can be completely different due to the deicing treatments that are used on paved roads, but not gravel. Concrete roads require consideration for roadway expansion effects on bridge approaches.

FHWA Response: FHWA appreciates this suggestion but does not require these data to fulfill its stewardship and oversight roles and responsibilities.

SNBI Analysis

Table of Contents

Four commenters suggested adding the Item ID to the Expanded Table of Contents (TOC) as a cross reference to the item name, to make the TOC more useful and easy to use.

FHWA Response: FHWA agrees that this change would assist in navigating the SNBI and has added Item IDs to the Expanded TOC. Item IDs have also been provided in the index tables of appendix B for useful cross references between the item names, IDs, format, and document sections. The condensed and expanded TOCs are hyperlinked throughout the document for ease of navigation; as are the item names in the index tables of appendix B.

Introduction

One commenter referenced the data relationship diagram (Figure 1). This commenter indicated that the element level data should be tied to each inspection event, rather than to each submission, thereby allowing the tracking of element condition over time, similar to the current practice for component condition ratings.

FHWA Response: Element level condition data and component condition rating data are considered inclusive of the results of all inspections performed since the last data submission to FHWA. All condition data can be tracked historically, as both element level and component condition data are collected during each data submission.

Definitions

As a result of changes made to the definitions for these terms in the final rule definitions were modified in the SNBI for *Bridge, Inspection Date, Operating Rating, Routine Inspection,* and *Safe Load Capacity,* and a definition was added for *Unknown Foundations.* Due to the addition of the *NSTM Inspection Required* and *Inspection Due Date* items, definitions were added for *Nonredundant Steel Tension Member Inspection* and *Inspection Due Date.* Because of changes made to the handling of border bridges, definitions were added for *Designated Lead State* and *Neighboring State.* To provide clarity for several items in the Highways subsection, a definition was added for *Divided Highway.* To provide clarity for the *Legal Load Rating Factor* item, the definition for *Legal Load* was expanded, and a definition was added for *Legal Load Rating.* The definition of *Initial Inspection* was simplified for clarity.

Two commenters expressed concern over the definition of *Nonredundant Member* causing confusion with *Nonredundant Steel Tension Member.*

FHWA Response: As the term *Nonredundant Member* is not used in the SNBI, it has been deleted from the Definitions section.

One commenter requested an additional definition for *Nonredundant Steel Tension Member* since only *Nonredundant Steel Tension Member Inspection* was originally included.

FHWA Response: For completeness, a definition from the final rule was added for *Nonredundant Steel Tension Member.*

One commenter requested clarification of the intent of the *Plan of Action* definition, asking that Scour be added to the term.

FHWA Response: FHWA agrees and the entry was changed to *Scour Plan of Action* and is consistent with the final rule.

One commenter requested clarification of the definition for *Rehabilitation.*

FHWA Response: After further consideration, definitions were developed for *Major Rehabilitation* and *Minor Rehabilitation* in place of the original *Rehabilitation* definition to coincide better with the codes for major and minor rehabilitation in the *Work Performed* item.

Two commenters requested clarification on the requirements for evaluated scour.

FHWA Response: Definitions for *Scour Appraisal, Scour Assessment,* and *Scour Evaluation* were added to provide more clarity and are consistent with the final rule definitions.

Three commenters requested clarification on the requirements of a service inspection.

FHWA Response: The definition for *Service Inspection* was updated with the definition used in the NBIS.

One commenter requested clarification on the requirements of a scour monitoring inspection.

FHWA Response: The NBIS requires a scour plan of action (POA) for all bridges that are determined to be scour critical. An important part of a scour POA is the monitoring program as indicated in Hydraulic Engineering Circular No. 23 (HEC–23)—Bridge Scour and Stream Instability Countermeasures: Experience, Selection, and Design Guidance, Third Edition. The monitoring program portion of the scour POA addresses the type and frequency of monitoring (*i.e.,* inspection) required by the bridge owner. To ensure that the monitoring program within the scour POA is implemented, a *Scour Monitoring Inspection* type was created. Therefore, a definition for *Scour Monitoring Inspection* was created by FHWA and added to provide clarity.

One commenter suggested adding a definition for *Culvert.*

FHWA Response: Since Culverts were reinstated into the SNBI, a definition for *Culvert* was added. The *Culvert* definition was created by FHWA using the culvert definition from the 1995 NBI Coding Guide and modifying that definition to improve culvert bridge type reporting consistency.

Specification Format

Five commenters advocated for the use of a date format consistent with ISO 8601. ISO 8601 is the standard pertaining to date formats established by the International Organization for Standardization and can be located at *https://www.iso.org/iso-8601-date-and-time-format.html.*

FHWA Response: FHWA concurs with this recommendation and has adjusted the date format accordingly.

Five commenters expressed concern over the items that should not be reported where they do not apply, fearing that items might be forgotten rather than deliberately omitted, thereby affecting data quality.

FHWA Response: FHWA shares this concern, and allows omission of only those items where a null value can be verified by another means; a code of N is required for all inapplicable condition rating items and for all items where applicability cannot be verified via other data items. This approach will help to minimize file sizes and reduce data processing times. FHWA has standardized data reporting requirements throughout the SNBI to the extent possible, as follows: 0 represents ''none,'' X represents ''other,'' and N or not reported represents ''no'' (N only), or ''not applicable.'' FHWA specifies only how the data should be reported to FHWA, not how data items should be recorded or stored in a bridge owner's database.

Section 1: Bridge Identification

Subsection 1.1: Identification

The specification for the *Bridge Number* item was revised to emphasize that a bridge spans from abutment to abutment per the NBIS, and therefore multiple spans between abutments are to be reported as one bridge. This change was made primarily to address an ongoing issue where a limited number of State DOTs have been reporting a subset of spans as bridges, causing issues with other data items and resulting in inconsistent national reporting of bridge numbers.

Subsection 1.2: Location

Thirty-one commenters suggested that one State DOT should submit border bridge information for both States.

FHWA Response: To reduce the burden on States without inspection

responsibility, a change was made to have the Designated Lead State submit a full bridge record and the Neighboring State submit an abbreviated bridge record. The Designated Lead State is determined through agreement between the two bordering States.

Twenty-three commenters remarked on the location where the measurements are taken for the *Latitude* and *Longitude* items. Some preferred the center of the bridge, others requested that the State be allowed to select the location, and some preferred the proposed location of the beginning of the bridge on the edge of the right traveled way in the direction of the route mileage.

FHWA Response: In an effort to minimize burden, the specification for these items has been changed to indicate that the measurement should be taken at a location in accordance with agency procedures.

Five commenters were in favor of the decimals degrees format for the *Latitude* and *Longitude* items. Two requested the allowance of negative values.

FHWA Response: The examples for the *Longitude* item were updated to clarify that negative values are permitted.

Four commenters recommended eliminating the *Bridge Location* item.

FHWA Response: This item was retained, as it is the same as an item in the Coding Guide, and is easily transferred.

Five commenters recommended deleting the *Metropolitan Planning Organization* item. One commenter felt it was a positive addition.

FHWA Response: This item was retained because it can be used to assist in calculating Metropolitan Planning Organization performance measures and targets required by 23 CFR part 490.

One commenter asked whether the *Metropolitan Planning Organization* item included Regional Planning Organizations (RPOs).

FHWA Response: A note was added to the commentary to clarify that this item need not include the names of RPOs or single county planning organizations.

Subsection 1.3: Classification

One commenter requested an additional code for Bureau of Reclamation be added to the *Federal or Tribal Land Access* item.

FHWA Response: The additional code was added.

Five commenters asked that the *Toll* item codes be revised to line up with the *Toll* item (Item 20) in the Coding Guide.

FHWA Response: The codes were reorganized to line up with the Coding Guide. A code for ''Bridge does not carry a toll road and is not a toll bridge'' was also added, making the codes more easily transferable.

Thirteen commenters remarked on the *Emergency Evacuation Designation* item. Though most of the commenters indicated that there will be little value for this item from a State's perspective, some do see the value for some other States to use this coding. Others felt it was a planning code, or there does not appear to be a significant/clear benefit to the addition of the code.

FHWA Response: The Emergency Evacuation Designation item is retained since this information will be beneficial in identifying potential impacts to emergency evacuation routes, and to regional and national freight and passenger mobility, if the serviceability of the bridge is restricted or diminished.

Section 2: Bridge Material and Type

Seventeen commenters noted the additional data requirements in the Bridge Materials and Type section and questioned the value in collecting the additional information required by the SNBI.

FHWA Response: NBI data are used by State DOTs, FHWA, and other Federal agencies to monitor and evaluate bridge performance, enhance bridge safety, and support risk management. Many of these users rely on identifying and classifying bridges by structural type. The Coding Guide only allows for the identification of superstructure type in the main and approach spans. The utility of inventory data for identification and classification purposes will be enhanced with more granular information on all superstructure and substructure materials and types present in a bridge.

Fifteen State DOTs and AASHTO objected to the removal of the culvert structure type by incorporating culverts into superstructure and substructure types and condition ratings.

FHWA Response: FHWA reconsidered the proposed approach and due to the comments, the SNBI is modified so bridge owners can uniquely identify a culvert bridge type using the *Span Configuration Designation* item, and a separate *Culvert Condition Rating* item is reinstated. However, FHWA emphasizes that the term ''culvert'' has a particular meaning for the SNBI and therefore *Culvert* is defined in the Definitions section of the SNBI. FHWA understands that bridge owner agencies may define this term differently as a program management tool, but for data submissions the FHWA definition must be used.

Subsection 2.1: Superstructure/Deck Material and Type (Now Span Material and Type)

Ten commenters requested clarification on how to partition structural type data sets when complex groupings of main, approach, and widened superstructures and substructures may be present in a bridge.

FHWA Response: The intent of the specification is to classify and identify the different configurations of material, type, and design present on the bridge, regardless of where those configurations are located. Configurations need not be in contiguous spans or used to widen the same type of main or approach span to be considered part of the same span or substructure data set. The specifications and commentary were updated, and numerous examples were created, to clarify this intent.

Twelve commenters requested clarification on FHWA's intended use of the *Number of Beam Lines* item.

FHWA response: This item will enhance FHWA's oversight of the NBIP by identifying bridges that lack load path redundancy which, combined with other data items, can identify bridges with NSTMs.

Subsection 2.2: Substructure Material and Type

Three commenters requested clarification on the proper assignment of substructure type when a bridge has been widened and it may difficult to determine which substructure configuration is predominant.

FHWA response: To clarify intent, a third configuration designation for widening has been added to the *Substructure Configuration Designation* item.

Subsection 2.3: Roadside Hardware

Eighteen State DOTs and 1 Federal agency expressed concern with the addition of the *Bridge Railing* and *Transitions* items, and many of these commenters questioned the need for them. Most had concerns regarding the level of effort to collect detailed crash test data for a wide variety of existing bridge railings and transitions on a large number of bridges. Other concerns included the lack of data for railings on older bridges, the lack of familiarity that bridge inspectors have regarding standards for bridge railings and transitions, and the potential for error. Some suggested reverting to the *Traffic Safety Features* item (Item 36) in the Coding Guide, either in its current form or a modified version. Some recommended removing one or both of

these items entirely, simplifying them significantly, or making them optional. One State DOT indicated that they collect data on rail types installed on all bridges and intend to migrate the data to meet this requirement. In addition, their State finds value in categorizing crash test level for the bridge railings.

FHWA Response: Bridge railings and transitions are very important traffic safety features that serve to redirect smoothly errant vehicles and reduce crash severity. These data items provide for more objective information to evaluate safety risks, whereas ''meet currently acceptable standards'' in the Coding Guide is neither clear nor well understood; FHWA believes that these data are very valuable for risk assessment. The information needed to determine the appropriate codes should be available in bridge records, as it is also needed to report appropriately the applicable code for the *Bridge Railings* and *Transitions* items (Items 36A and 36B) in the Coding Guide. In addition, the AASHTO Manual, which has been incorporated by reference in the NBIS since January 2010, serves as a standard and provides uniformity in the procedures and policies for determining the physical condition, maintenance needs, and load capacity of the Nation's highway bridges. Article 2.3.1, regarding railings and parapets, indicates that the type and material of the railing/parapet, along with its dimensions, should be recorded. Article 4.8.4.6.1, regarding railings, indicates that they should be evaluated as to condition and as to adequacy of geometry and structural capacity, and that the inspector should be familiar with the railing requirements of the bridge owner. Article 4.3.5.11.4 in the AASHTO MBE, Third Edition, 2018, regarding approach guide rails and their transition to the bridge railing or parapet, indicates that agencies should ensure that inspectors are familiar with current agency standards for approach guide rail types, installation heights, and any minimum clearances, and check each approach guide rail assembly as to its conformance to current standards. Therefore, the information should also be available for agencies that follow the AASHTO MBE. In addition, bridge inspection related courses available through NHI contain course material on bridge railings. Finally, the inspector is not intended to be the only individual involved in identifying the appropriate code, similar to the coding of load rating items. These items may best be coded by the agency's safety engineer or other individual with appropriate expertise, and the inspector would field verify the installed configuration.

Five commenters recommended a code for ''unknown'' be added to the crash testing codes table to indicate that no information is known about the crash test level or an agency approved standard.

FHWA Response: The commentary for the *Bridge Railings* and *Transitions* items address the code to be reported when no information is known about the crash test level or an agency approved standard.

One State DOT recommended that code ''0'' (zero) in the crash testing codes table should be modified to read ''required and none provided,'' to help clarify the difference between codes ''N'' and ''0.'' Another indicated that examples were needed to clarify the difference between these two codes.

FHWA Response: The code 0 description was modified as suggested to make the code descriptions for ''N'' and ''0'' more self-explanatory without the need for further examples.

Two commenters requested clarification for reporting more than one code when there is a mixture of bridge railings or transitions on a bridge.

FHWA Response: The commentary for both items in this section was updated to clarify reporting of one applicable code when there is more than one type of bridge railing or transition.

One State DOT suggested that the nature of the *Bridge Railing* and *Transitions* items is more indicative of an appraisal item and should be moved to the Appraisal subsection. The commenter also suggested that the Bridge Railings item be integrated with National Bridge Element (NBE) items in the Element Conditions subsection.

FHWA Response: These items remain in the Bridge Material and Type section to be contained together with other related items that will likely be inventoried from plans. These items are considered a classification or categorization of the bridge railings and transitions, and not an appraisal. Bridge railing element data, in the element subsections, address condition and not crashworthiness. There is no NBE defined in AASHTO's ''Manual for Bridge Element Inspection'' (MBEI), Second Edition, 2019 or the SNBI for bridge railing transitions.

Section 3: Bridge Geometry

Multiple commenters questioned the need for several items in this section. The more substantial comments pertained to the *NBIS Bridge Length, Minimum Span Length, Curved Bridge, Curved Bridge Radius, Maximum Bridge Height,* and *Irregular Deck Area* items.

Five commenters questioned the need for the proposed *NBIS Bridge Length* item.

FHWA Response: This item describes the dimension that is used to distinguish a bridge, as defined in the NBIS, from a structure that is shorter than a bridge. The referenced definition is used to identify bridges that are subject to the NBIS and must be reported to the NBI. The *NBIS Bridge Length* item (Item 112) in the Coding Guide had only a yes or no value, and has not sufficiently served its purpose of identifying NBIS bridges. To reduce the burden associated with this item, the value may be estimated when the *Total Bridge Length* item is 30 feet or greater.

Nine commenters questioned the need for the proposed *Minimum Span Length* item, and one acknowledged the need for the item.

FHWA Response: To date, only the maximum span length has been reported. It has been found that both maximum and minimum span length are needed for preliminary screening of bridges to identify impacts from changes in national load rating vehicles, or changes to truck sizes and weights (either proposed or mandated). Article C6A.4.4.2.1b of the AASHTO MBE, Third Edition, 2018 (with 2019 and 2020 interim revisions), recognizes this point, as it communicates that bridges with a rating factor greater than 1.35 for the AASHTO legal trucks will have adequate load capacity for special hauling vehicles only when the span lengths exceed the values specified therein.

Three commenters questioned the need for the proposed *Curved Bridge* item.

FHWA Response: This item indicates whether a bridge is comprised of girders that are curved or aligned to approximate a horizontal curvature. Curved bridges can require different procedures and specifications for structural analysis and design, and for load rating analysis for legal and permit vehicles, including permit vehicle size restrictions. Curvature is also an attribute that can raise the importance of inspection, maintenance, and repair of certain members as compared to straight bridges. This in turn may impact risk-based inspection interval selection, inspection scope, and repair prioritization. Curvature can also affect the assessment of vulnerability to seismic events using system-level procedures. The *Curved Bridge* item has been retained, but has been revised to address comments asking for clarification about the difference between a curved bridge comprised of curved versus chorded girders.

Nine commenters questioned the need for the proposed *Curved Bridge Radius* item.

FHWA Response: FHWA acknowledges that the radius of curvature alone is often insufficient for decision-making, and procedures will frequently require obtaining this information from drawings or files in conjunction with other details. This item has been removed.

Fourteen commenters questioned the need for the proposed *Maximum Bridge Height* item. Multiple commenters also questioned the need to update the reported value for this item when maximum height occurs over water that has a fluctuating bed elevation.

FHWA Response: Bridge height is an attribute that can inform multiple procedures, including inspection planning to identify access equipment needs, seismic vulnerability assessments, and cost estimation associated with work types or needs. To reduce the burden associated with this item, and to facilitate identification of bridges with limited clearance over water, the specification for this item has been revised so that measurement is from the top of deck to the ground line or water surface, whichever yields a higher value.

Two commenters questioned the need for the proposed *Irregular Deck Area* item.

FHWA Response: This item allows an agency to report the deck area of a bridge when using the values reported for *Total Bridge Length* and *Bridge Width Out-to-Out* does not provide an accurate representation. Deck area is used to support multiple procedures including the calculation of performance measures and the implementation of 23 CFR part 490.

Section 4: Features

Subsection 4.1: Feature Identification

The *Feature Type* item was revised to add a numeric sequential field for each feature, for ease of State and FHWA tracking of multiple features of the same type, and to address confusion expressed by several commenters.

Several commenters asked how many features below a bridge are to be identified for the *Feature Type* item, and if at least one is required.

FHWA response: The commentary for this item was updated to indicate that at least one feature is to be identified both on and below the bridge, and that many bridges will have more than one. However, a code of ''D'' (dry terrain) or ''B'' (urban feature) need be reported only once, if applicable.

A few commenters stated that reporting multiple features for bridges would be excessive burden for questionable benefit.

FHWA response: FHWA believes that for most bridges, the majority of features will already be known by inspection teams and will need to be input but not collected. For some bridges, it is acknowledged that some data will need to be collected, but only one time over the life of the bridge except in rare cases where another feature is built above, on, or under the bridge. Highway features under structures that are not bridges per the NBIS will no longer be reported to FHWA, providing a decrease in burden.

Subsection 4.2: Routes (Now Subsection 4.2 Routes and Subsection 4.3 Highways)

Several commenters expressed concern with the perceived increase in the amount of route data to be reported. A few noted that many of the items in the Routes section are actually associated with the highway, which can carry multiple routes, and therefore should be collected and reported only once for each highway.

FHWA Response: FHWA agrees with the commenters, and this subsection has been divided accordingly. Highway-related items were removed from the Routes subsection and placed in a separate Highways subsection, where each item will be reported once for each highway feature associated with the bridge. For a highway feature crossing above a bridge, only the *Crossing Bridge Number* item need be reported, because the highway feature above will always be a bridge. Therefore, the remaining highway and route information can be accessed via the data associated with the crossing bridge record. This also applies when the highway feature directly below an inventory bridge is a crossing bridge. The Routes subsection now contains only five route-related items, which will be reported for each route associated with the highway feature.

Subsection 4.3: Railroads (Now Subsection 4.4)

Six commenters questioned the need for the proposed *Railroad Service Type* item.

FHWA Response: This item distinguishes between passenger and freight services and between electrified and non-electrified rail lines. It is useful for inspection planning to identify access and coordination needs.

Two commenters suggested that the data for the items in this section should be obtained by FHWA from national databases maintained by the Federal Railroad Administration, for example.

FHWA Response: Agencies can use available resources to assist in coding the *Railroad Service Type* item. However, national databases do not necessarily include sufficient data to report all bridge related railroad items, or include information for all categories of railroads.

Subsection 4.4: Navigable Waterways (Now Subsection 4.5)

Four commenters questioned the need for the *Navigation Channel Width* and *Navigation Channel Minimum Horizontal Clearance* items, as these items are not currently reported to the NBI.

FHWA Response: The data items in this section are used to identify bridges that cross navigable waterways and are at risk of vessel collision, which will assist FHWA in identifying risks to highway bridge safety. The *Navigation Channel Width* item and *Navigation Channel Minimum Horizontal Clearance* item clarify the requirements for data currently reported for the *Navigation Horizontal Clearance* item (Item 40) in the Coding Guide. These data should be available from the navigation permit drawings required for all bridges over navigable waterways.

Section 5: Loads, Load Rating, and Posting

Subsection 5.1: Loads and Load Rating

Four commenters requested clarification on how to assign codes for the *Design Method* item when no plans exist for a bridge.

FHWA Response: The commentary for this item addresses this situation, allowing for bridge owners to infer which design method was in use at the time the bridge was built based on the characteristics of the bridge and design policy in effect at the time of construction.

Six commenters disagreed with the requirement to truncate load rating factors to the nearest hundredth rather than allowing values to be rounded.

FHWA Response: The load rating factor is calculated as a ratio of other values that have their own accuracy and precision. Truncating such a value to the hundredth will assign precision in a conservative fashion that will vary from the calculated rating factor by, at most, 1 percent.

Seven commenters requested clarification on FHWA's intended use for the *Controlling Legal Load Rating Factor* item.

FHWA Response: Many States and local agencies have their own legal load combinations that they must consider in addition to the nationally recognized

AASHTO Legal Loads when load rating bridges. There is wide variety in the axle weights and spacings of these legal loads, making it impractical to define every combination in the SNBI. However, the rating factor is a universal value representing a ratio of capacity to demand, with 1.0 being the minimum value indicating a bridge's ability to carry safely a given legal load configuration. By identifying the minimum calculated rating factor of all legal loads considered in the load rating, the *Controlling Legal Load Rating Factor* item serves the purpose of improving NBIP oversight by identifying bridges that require posting, based on their ability to carry State legal loads that may vary from those established by AASHTO.

Ten commenters requested clarification on FHWA's intended use of the *Routine Permit Loads* item.

FHWA Response: The NBIS requires States to post or restrict bridges that cannot safely carry routine permit loads as demonstrated through a valid load rating. This item identifies bridges that carry routine permit loads, to differentiate between bridges that do and do not require that the posting analysis consider those loads.

Subsection 5.2: Load Posting Status

Eight commenters recommended corrections and changes to the table of load posting status codes in the *Load Posting Status* item.

FHWA Response: The table has been updated to incorporate many of the recommendations to remove similar codes, and to differentiate between bridges that are currently open with no restrictions and require posting, and those that are currently posted but require a posting reduction.

One State DOT requested clarification on the definition of temporary and supported structures and when those conditions will result in a change in the *Load Posting Status* item that will be reported to FHWA.

FHWA Response: The specification for this item was updated to include more detailed descriptions of temporary and supported conditions, and expectations for the length of time those conditions are expected to be in place to be considered in the reporting of this item.

Subsection 5.3: Load Evaluation and Posting

Ten commenters requested clarification on whether State-specific legal loads need to be reported for the items in this subsection.

FHWA Response: Given the large number of State-specific legal load configurations, it is not feasible to include non-AASHTO-defined legal loads for the items in this subsection. However, the load rating evaluation must consider all legal loads operating in the State and if a State-specific legal load configuration results in the lowest rating factor from the evaluation, that value will be reported in the *Controlling Legal Load Rating Factor* item.

Five commenters requested clarification on whether AASHTO legal loads that are not evaluated because their force effects are enveloped by another AASHTO load (for instance, the Notional Rating Load (NRL)) need to be reported for the items in this subsection.

FHWA Response: The introduction to the Load Evaluation and Posting subsection states that ''Data items in this subsection are reported for each AASHTO legal load configuration evaluated, only when the bridge has undergone a posting analysis.'' If the posting analysis uses the NRL to screen out the need to evaluate individually other loads, there is no need to rate and report data for those vehicles.

Section 6: Inspections

Subsection 6.1: Inspection Requirements

Eight commenters were concerned with the level of effort to collect the information for the *Fatigue Prone Details* item.

FHWA Response: This item has been renamed to *Fatigue Details.* Category D details were removed from the data collection requirement, thereby reducing the burden.

Subsection 6.2: Inspection Events

Three commenters recommended deletion of Service (Code 8) for the *Inspection Type* item, as they did not consider that it was needed.

FHWA Response: Service inspection type is needed for risk based extended intervals as part of the NBIS.

Four State DOTs requested definitions clarifying the intent of the inspection types.

FHWA Response: Definitions for each of the inspection types are included in the Definitions section.

Fourteen commenters requested clarification on the *Nationally Certified Bridge Inspector* item, as to how the unique identifier certifications will be assigned and who is responsible for assigning them. Many questioned the need for this item or suggested that it should be the responsibility of FHWA to certify inspectors.

FHWA Response: The commentary was updated to indicate that the unique identifier code is assigned by the State DOT, Federal agency, or Tribal government. FHWA does not certify bridge inspectors.

Four commenters questioned the need for the *Inspection Interval Type* item, as it can easily be determined from the *Inspection Interval* item.

FHWA Response: FHWA agrees, and the *Inspection Interval Type* item has been removed.

Two commenters requested the addition of a calculated *Inspection Due Date* item.

FHWA Response: This item has been added to identify the next inspection due date.

Eleven commenters requested clarification as to the need for the *Inspection Quality Control Date* and *Inspection Quality Assurance Date* items. Several of these commenters also requested that the commentary language be adjusted to allow an independent QC or QA review from outside the agency.

FHWA Response: These items will ensure that information on QC and QA procedures is available to FHWA for oversight of the NBIP. FHWA agrees that an independent review from outside the agency can also be part of a QC or QA program; the commentary language for both items has been adjusted as requested.

The name of the *Inventory Update Date* item has been changed to *Inspection Data Update Date,* as that better aligns with the intent of the item and may help alleviate confusion expressed by some commenters.

Ten State DOTs questioned the need for the *Inspection Equipment* item.

FHWA Response: FHWA requires this information to verify that a quality inspection is performed.

Three commenters questioned the need for the *Inspection Note* item.

FHWA Response: This item is used to explain what portions of the bridge were inspected when a partial inspection is performed and not a full bridge inspection.

Section 7: Bridge Condition

Subsection 7.1: Component Condition Ratings

Fifteen State DOTs and AASHTO objected to the incorporation of culverts into superstructure and substructure types and condition ratings.

FHWA Response: These comments were addressed in the Section 2 (Bridge Material and Type) comment responses.

Ten State DOTs and AASHTO felt that the changes to the component condition rating code descriptions made them too complex or prescriptive and too similar to the AASHTO element level descriptions; most felt that the

meaning of the component condition rating codes had changed significantly from the Coding Guide. Another State DOT suggested eliminating component condition ratings entirely based on the similarity of the descriptions to the element data descriptions. Two commenters appreciated the detailed guidance, and three appreciated the clarity of the Specifications and Commentary.

FHWA Response: FHWA agrees that these codes became overly complex in the draft document. The intent was to clarify the component condition language from the Coding Guide without significantly changing the meaning. To that end, the optional detailed guidance tables have been moved to the Appendix and the condition language has been simplified.

Seven commenters suggested that the guidance provided in the guidance tables precluded improvement of a concrete bridge component from fair to good condition if effective repairs were completed; they did not feel that a sound patch should be considered a defect.

FHWA Response: A patched area that is sound is in fair condition per the AASHTO MBEI; the guidance provided in the tables for evaluating the condition of concrete components is consistent with that determination.

Ten commenters had some difficulty locating descriptions of terms and other specific guidance within the section, or requested clarification of certain requirements.

FHWA Response: Key terms are defined in the introduction to the section and in the Definitions section, requirements have been clarified as needed, and the optional detailed guidance tables have been moved to the Appendix.

Thirteen State DOTs and one association questioned the need for the *Bridge Railing Condition Rating, Bridge Railing Transitions Condition Rating, Bridge Bearings Condition Rating,* and *Bridge Joints Condition Rating* items, particularly since they are collected with the element data. Three commenters expressed support for these items.

FHWA Response: Element level condition data, in accordance with MAP–21, are required to be reported only for bridges on the NHS. Therefore, these data do not exist for a large percentage of the NBI. These new items in the SNBI will serve to ensure the safety of all highway bridges.

Four State DOTs objected to the addition of the *Scour Condition Rating* item, not appearing to understand its relationship with the *Scour Vulnerability* item. Three commenters expressed support for the change.

FHWA Response: These comments are addressed below in the Subsection 7.3 (Appraisal) comment responses.

Two commenters objected to the separation of the *Channel Condition Rating* and *Channel Protection Condition Rating* into two items; one embraced the change.

FHWA Response: FHWA believes that the separation will improve clarity regarding channel condition. No change has been made.

Ten commenters objected to the inclusion of the *Bridge Condition Classification* and *Lowest Condition Rating Code* items.

FHWA Response: These items are calculated by FHWA and are not required be collected or reported by the bridge owner. These items are related to national bridge performance measures and are provided in the SNBI for transparency.

Six State DOTs expressed concern over the assumption that a structural or hydraulic review, or both, must have been completed for a condition rating of 4 of less, and what that review might entail.

FHWA Response: FHWA has clarified the requirement and added definitions for ''structural review'' and ''hydraulic review'' in the Definitions section.

Two commenters objected to the language for a condition rating of 4 or less that states that the strength or performance of the component is affected.

FHWA Response: A rating of 4 or below indicates Poor condition, which is defined as affecting the strength or performance of a bridge. No change was made to this language.

One State DOT requested guidance on insignificant defects.

FHWA Response: As insignificant defects do not affect the rating of a bridge component, no guidance is offered. An insignificant defect is one that is less than minor.

Four State DOTs objected to the statement that the wearing surface should not be considered in determining the *Deck Condition Rating* code. One of these State DOTs also requested clarification of situations with integral wearing surfaces and decks where the underside cannot be seen.

FHWA Response: The commentary has been updated to address these situations and add clarity regarding wearing surfaces.

Subsection 7.2: Element Conditions (Now Subsection 7.2 Element Identification and Subsection 7.3 Element Conditions)

Three commenters indicated support for the inclusion of element level bridge data items, seven requested clarification regarding reporting of these data for bridges not on the NHS, two were not in favor if this resulted in duplicative reporting, and two were opposed.

FHWA Response: As required by 23 U.S.C. 144, State and Federal agencies have been reporting element level data to FHWA for bridges on the NHS since April 2015 using guidance provided in the SNBIBE. The guidance in the SNBIBE is now included in the SNBI and will not cause duplicative reporting of element data, as the SNBIBE will be discontinued when the SNBI becomes effective. The introductions to the Element Identification and Element Condition subsections have been updated to clarify further that element level data are only required to be reported to FHWA for bridges that carry NHS routes, while reporting is optional for bridges that carry non-NHS routes.

Two State DOTs recommended deletion of the culvert elements, since the *Culvert Condition Rating* item (Item 62) in the Coding Guide was proposed to be discontinued in the SNBI. One State DOT requested clarification on the intent of these elements, given the discontinuance.

FHWA Response: The culvert elements have been retained in the SNBI, as FHWA has reinstated the *Culvert Condition Rating* item, and has made provisions in the Bridge Material and Type section to accommodate bridge-sized culverts.

Two commenters proposed revisions to the bridge elements table.

FHWA Response: The proposed changes were not accepted since FHWA agreed with AASHTO to adopt the AASHTO MBEI for element descriptions, quantity calculations, and condition state definitions. The bridge elements table title was revised to ''Bridge elements reported to the FHWA'' since there are some elements described in the AASHTO MBEI that are not reported to FHWA.

One commenter requested clarification for reporting elements that are typically not exposed for inspection (*e.g.,* piles, pile cap footings), but become exposed for an inspection, and are subsequently not exposed for the next inspection.

FHWA Response: Text has been added to clarify reporting expectations for this situation, and provides for agency flexibility in reporting the element data.

One commenter proposed that element level data be reported separately, as the file size may become an issue if all data in the SNBI is reported together in one file.

FHWA Response: FHWA will consider and evaluate potential solutions to provide options for reporting large data files.

One commenter proposed that changes be made to FHWA's proposed expectations, in the introduction to the Element Conditions subsection, that quantities reported to FHWA in condition state four indicate that a structural review has been completed.

FHWA Response: FHWA did not intend to change the condition state description in the AASHTO MBEI for condition state four, that indicates the following: ''The condition warrants a structural review to determine the effect on strength or serviceability of the element or bridge; OR a structural review has been completed and the defects impact strength or serviceability of the element or bridge.'' Since it may not be practical in all cases for a structural review to be completed prior to reporting data to FHWA, based on the timing of the inspection and the completion of a structural review, the paragraph of concern to the commenter has been removed.

One commenter proposed that the SNBI include the FHWA relationship checks between element numbers and element parent numbers.

FHWA Response: The relationship checks by FHWA are not included in the SNBI, but can be found on the internet through FHWA's Policy and Guidance Center at *www.fhwa.dot.gov/pgc.*

One commenter proposed that it would be easier to understand if the Item ID for *Element Quantity Condition State* items ended in 1, 2, 3, and 4 respectively.

FHWA Response: The Element Conditions section has been separated into two subsections, Element Identification and Element Conditions. As a result, Item IDs for *Element Quantity Condition State* items have changed to B.CS.01, B.CS.02, B.CS.03, and B.CS.04.

Subsection 7.3: Appraisal (Now 7.4)

One State DOT noted that the Coding Guide appraisal rating items are all rated on a scale of 0–9 and expressed concern that the proposed changes to the codes would affect the historic continuity of these items. It was further suggested that the proposed alphanumeric codes provide no obvious meaning without referring back to the guidance, and would incur substantial cost with questionable value. One State DOT appreciated the proposed changes to the *Approach Roadway Alignment* and *Overtopping Occurrence* (now *Overtopping Likelihood*) items; indicating that the items are much simpler. One commenter indicated that the addition of the *Scour Plan of Action* item will clear up confusion and help to alert inspectors and others that the bridge has a POA.

FHWA Response: The SNBI includes two new data items in the Appraisal subsection, which provide additional information about potential bridge vulnerabilities: *Scour Plan of Action* and *Seismic Vulnerability.* The *Approach Roadway Alignment, Overtopping Likelihood* (formerly *Waterway Adequacy*), and *Scour Vulnerability* (formerly part of *Scour Critical Bridges*) items have been carried over from the Coding Guide, but with new codes that are simpler, clearer, and easier to understand. Since these items typically do not change from inspection to inspection, and the crosswalk of data is well aligned, the historical continuity can be maintained, and the cost will not be substantial. The following calculated appraisal items from the Coding Guide have been discontinued: *Structural Evaluation* (Item 67), *Deck Geometry* (Item 68), and *Underclearances, Vertical and Horizontal* (Item 69).

Four commenters recommended removal of the *Overtopping Occurrence* item, largely due to concerns about potential inaccuracy of the data. One commenter proposed a two-character field indicating the number (01 to 99) of overtopping occurrences, presumably since construction.

FHWA Response: The name of this item has been changed to *Overtopping Likelihood* and the codes and descriptions changed accordingly. This information is valuable for evaluating risk-based inspection intervals, evaluating risks for traffic disruptions, identifying actions to mitigate risks, and as an indicator of changes to the waterway hydraulics that could impact the safety and performance of the bridge. The information for reporting the applicable code should be readily available, as similar information was needed to report the appropriate code for the *Waterway Adequacy* item (Item 71) in the Coding Guide.

One commenter requested clarifying commentary for the *Overtopping Occurrence* item to address more clearly bridges where the superstructure has been washed off the abutments and repairs are made without betterments, thereby leaving the bridge at the same elevation and the same likelihood for overtopping. Three commenters proposed the addition of a code for ''unknown.''

FHWA Response: Additional commentary has been provided to address considerations for determining the appropriate code for existing and newer bridges. Recognizing that an ''unknown'' code was not provided in the Coding Guide, and that the relevant information should be available in the agency's bridge file, a code for ''unknown'' has not been added.

Four State DOTs objected to the addition of the *Scour Condition Rating* item, not appearing to understand its relationship with the *Scour Vulnerability* item. Three commenters expressed support for the separation of the *Scour Critical Bridges* item (Item 113) in the Coding Guide into these two distinct items. Several requested clarification regarding the relationship between the code descriptions in the Coding Guide and those in the *Scour Vulnerability* item. Some commenters requested additional codes or clarification regarding coding for specific situations; one requested clarification as to what will be considered ''scour critical.'' One State DOT expressed concern that the changes would require a large number of bridges to be reassessed, and one indicated concern regarding the resources that would be required to perform rigorous scour studies on locally owned bridges.

FHWA Response: The *Scour Vulnerability* and *Scour Condition Rating* items are intended to separate potential for scour from field observed scour (severity and extent). The *Scour Vulnerability* item addresses the scour critical status and vulnerability determination from scour appraisals required by the NBIS, while the *Scour Condition Rating* item captures the actual scour condition as observed during the inspection. Though the items and codes have been changed, there is significant correlation with the code descriptions for the *Scour Critical Bridges* item (Item 113) in the Coding Guide (Errata 12/01/2003). The codes and descriptions have been revised for clarity and for consistency with the NBIS definition of a scour critical bridge, and additional commentary has been provided to improve further correlation between the SNBI codes and those in the Coding Guide. It is not expected that these changes will require any bridges to be reassessed or reevaluated for scour, unless there are conditions that trigger a need for adjustments to the original scour appraisal. Alignment of the codes will be addressed in the crosswalk, which will be made available in the coming months.

Two commenters recommended a separate code indicating that a scour POA has been developed but not implemented.

FHWA Response: The code descriptions for the *Scour Plan of Action* item have been revised to accommodate this situation.

Three State DOTs questioned the need for the *Seismic Vulnerability* item. One of these commenters indicated that coding the item would require significant resources for low value, and another suggested simplifying the item.

FHWA Response: This item provides available information resulting from seismic evaluation and retrofit programs that an agency may have performed of its own volition. This item, along with other supporting items, can aid in risk assessment and potential needs assessment for bridge preservation funding from a national perspective. The codes for the item allow for broad interpretation based on the reporting agency's methods and evaluation criteria. Seismic evaluation studies should already be part of an agency's bridge record/file per Article 2.2.13 of the AASHTO MBE, First Edition, 2008, incorporated by reference in the NBIS since January 2010. Bridges with seismic retrofit should not require a significant amount of time to identify from bridge files if the agency is following Article 4.3.5.7.1 of the AASHTO MBE, Third Edition, 2018, which outlines procedures for inspection of seismic restraint devices. The SNBI provides a code that can be used if an agency has bridges that do not require seismic evaluation due to low anticipated ground motion or agency prioritization.

Subsection 7.4: Work Events

Twelve commenters questioned the need for the proposed *Construction Cost* item. Multiple commenters also said the data would be difficult to obtain or implied that the data would also need to be reported for replacement and rehabilitation projects that occurred prior to implementation of the SNBI.

FHWA Response: The item has been removed based on these comments.

Subpart D—Highway Bridge Replacement and Rehabilitation Program

One commenter requested that subpart D not be removed and that FHWA keep the sufficiency rating used in previous NBIS regulation as it provides a process for prioritizing bridge rehabilitation and replacement projects. By making the change the State will need to undertake significant effort to revise the Federal funding prioritization process for bridges.

FHWA response: It is not the intent of FHWA to revise a prioritization process with the removal of subpart D. This subpart was removed as the Highway Bridge Program was not reauthorized by MAP–21. The MAP–21 restructured core highway formula programs. Activities that were carried out under the Highway Bridge Program were incorporated into the National Highway Performance Program and the Surface Transportation Program (now Surface Transportation Block Grant Program). Sufficiency rating is not used by FHWA for funding or prioritization of projects. States have the ability to establish their own process for prioritizing projects or to continue using the sufficiency rating method if so desired.

Discussion Under 1 CFR Part 51

FHWA is incorporating by reference the more current versions of the manuals listed herein.

AASHTO's 2008 ''Manual for Bridge Evaluations,'' would be replaced with a more current edition of the ''AASHTO Manual for Bridge Evaluation.'' Specifically, FHWA is incorporating by reference Sections 1.4, 2.2, 4.2, 6, and 8, excluding the 3rd paragraph in Article 6B.7.1 of the 2018 Third Edition, together with the 2019 and 2020 Interim Revisions of these sections. This document was developed by AASHTO to assist bridge owners by establishing inspection procedures and evaluation practices that meet FHWA's National Bridge Inspection Standards regulatory requirements. The manual is been divided into eight sections, with each section representing a distinct phase of an overall bridge inspection and evaluation program.

In addition, FHWA adds the AASHTO MBEI. This document is a reference for standardized element definitions, element quantity calculations, condition state definitions, element feasible actions, and inspection conventions. Its goal is to capture the condition of bridges in a simple, effective way that can be standardized nationwide, while providing enough flexibility to be adapted by both large and small agencies. AASHTO designed the document for use by State departments of transportation and other agencies that perform element-level bridge inspections. This reference supports the Section 1111(a) of MAP–21 for element level data to be reported to FHWA for bridges on the NHS. The AASHTO MBEI is referenced in FHWA's ''Specification for the National Bridge Inventory Bridge Elements,'' and would establish a uniform understanding of the inventory data to be reported in order to satisfy the statutory requirement.

Finally, FHWA incorporates by reference FHWA's ''Specifications for the National Bridge Inventory'', 2022. The SNBI details how to code and submit data gathered on highway bridges for the NBI, including items on location, structure type, condition ratings, and inspection dates. This document replaces the current Coding Guide and defines the required inventory data that is submitted to FHWA to fulfill the requirements of § 650.315.

The documents that FHWA is incorporating by reference are reasonably available to interested parties, primarily State DOTs, local agencies, and Tribal governments carrying out Federal-aid highway projects. These documents represent the most recent refinements that professional organizations have formally accepted and are currently in use by the transportation industry. The documents incorporated by reference are available on the docket of this rulemaking and at the sources identified in the regulatory text below. The specific standards are discussed in greater detail elsewhere in this preamble.

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

The final rule is a significant regulatory action within the meaning of Executive Order (E.O.) 12866 and DOT Rulemaking and Guidance Procedures in DOT Order 2100.6A (June 7, 2021). This action complies with E.O. 12866 and E.O. 13563 to improve regulation. This action is considered significant because of widespread public interest in the safety of highway bridges, though not economically significant within the meaning of E.O. 12866. FHWA has filed into the docket a Regulatory Impact Analysis (regulatory analysis or RIA) in support of the final rule on NBIS. The RIA estimates the economic impact, in terms of costs and benefits, on Federal, State, and local governments, as well as private entities regulated under this action, as required by E.O. 12866 and E.O. 13563.

This section identifies the estimated costs and benefits resulting from the rule in order to inform policy makers and the public of the relative value of this action. The complete RIA may be accessed from the rulemaking's docket (FHWA–2017–0047).

The docket for the rulemaking included an RIA analyzing the economic impacts of the proposed rule.

The NPRM received 256 comments in relation to the NBIS and the SNBI, some of which pertained to the RIA.

This RIA has been updated to reflect public comments provided in response to the NPRM RIA. The RIA comments came exclusively from State agencies and related to absence of cost estimation for the changes to the SNBI. In particular, States estimated that they will incur costs due to the SNBI changes, including the following issues:

- The increased costs associated with updating software and software systems to accommodate additional data or recoding of existing variables.
- The increased costs associated with inspections due to the additional inspection categories in the updated SNBI compared to the existing coding guide.
- The increased cost associated with updating inspection manuals and inspector trainings to be consistent with the updated SNBI.

In response to those concerns, this RIA has been updated to include estimates of the additional cost associated with the SNBI changes. The specific adjustments are detailed in Section 4.3 of the RIA found on the docket for this rulemaking.

Additionally, States were concerned that the NPRM RIA did not address the benefits of the proposed rule. The RIA has also been updated to include a qualitative discussion of those benefits.

In addition to the changes made in response to the public comment, a number of input values to the economic analysis have been updated in this final rule RIA compared to the NPRM RIA. The updates include:

- The effective date of the rule has been changed to 2022 rather than 2020. This changes the period of analysis from 2020–2029 to 2022–2031.
- The wage rates have been updated to the 2019 values from the 2016 values used in the NPRM RIA.
- Rather than analyzing the cost savings from assuming 1 percent of eligible bridges use the expanded inspection interval as was used in the NPRM, this economic assessment uses uncertainty analysis in relation to the share of bridges that are expected to use the Method 1 extended interval of 48 months which requires a simplified risk inspection and the Method 2 extended interval of up to 72 months under Method 2 which requires a detailed risk inspection (compared to the currently required 24-month interval). The FHWA anticipates that agencies will infrequently use the Method 2 for intervals greater than 48 months and that a plausible range for the share of bridges inspected under Method 1 is 30 to 65 percent. That range is based on data on the number of States that currently use the 48-month exception for any bridges/culverts,[16] public comment from the NPRM, and other information about State agencies practices (*e.g.,* State law and Transportation Asset Management Plans (TAMPs)). The justification for this range is described more fully under Section 3 of the RIA under Section 650.311: Inspection Interval.
- The share of bridges that currently use a 24-month interval that are expected to use a 12-month interval is 100 percent, reflective of the requirement of the rulemaking. This provision is new to the final rulemaking and was not included in the original NPRM RIA.
- The cost of inspections has been updated. The NPRM RIA assumed that on average a regular inspection required 4 hours of engineer time to complete at a total cost of $257.[17] Based on public comment,[18] available inspection cost data, interviews with Federal and State agencies, and FHWA program office input, the final rule RIA updates the average cost per bridge inspection to be $2,000. The justification of this average inspection costs is detailed in Section 4.2 of the RIA.

Estimated Cost of the Final Rule

To estimate costs for the final rule, FHWA assessed the level of effort, expressed in labor hours and the labor categories, and capital investments needed to comply with each component of the rule. Level of effort by labor category is monetized with loaded wage rates to estimate total costs.

The rulemaking will impose some additional costs on agencies but will also create opportunities for cost savings. The cost savings are due to the risk-based inspection interval approach that allows for a potentially large number of bridges that currently use a 24-month inspection interval to use Method 1 48-month inspection interval instead. The actual number of bridges for which this expanded inspection interval will be adopted is unclear; therefore, this assessment uses an uncertainty analysis on this key parameter. FHWA judges a plausible range to be that 30 to 65 percent of eligible bridges will use the Method 1 48-month risk-based inspection interval rather than a 24-month inspection interval. The informational basis for this range is described in RIA Section 3 under Section 650.311: Inspection Interval.

While the rulemaking provides cost saving on net, there are several components of the rule that increase costs. The largest cost increases come from the impacts of the updated SNBI (§ 650.315), which will require States to upgrade software systems, update inspection manuals, train inspectors, and will increase the hours required for inspection for all bridges for the first inspection after the compliance date of the provision. The other important source of cost increases come from the risk-based approach requirement that some bridges will be inspected at 12-month intervals rather than the current 24-month intervals, which will increase the frequency of inspections and therefore increase costs.

Table 1 displays the total cost of the final rule (2019$) for the 10-year analysis period (2022–2031) assuming that either 30 or 65 percent of eligible bridges will use the Method 1 risk-based 48-month inspection interval rather than the 24-month inspection interval. The total cost savings of the rule for the 10-year study period (2022–2031) is between −$4.6 and −$195.4 million discounted at 7 percent.

The provisions required by MAP–21 (§§ 650.303, 650.309, and 650.313) have total cost of $7.1 million over the 10-year analysis period when discounted at 7 percent. The other discretionary provisions that impose costs have a 10-year discounted value of −$11.7 to −$202.5 million. The cost savings associated with the provision related to expanded inspection intervals has a plausible range for 10-year discounted costs of −$131.0 to −$321.7 million.

Estimated Benefits of the Rule

The FHWA believes the rule will be net beneficial to society but is unable to monetize or quantify the benefits of this rulemaking. These benefits are centered around bridge safety, which was the original premise for developing this regulation when it was initiated in 1971.

[16] Under existing NBIS policies, an agency may request that a bridge may be inspected under a 48-month inspection interval based on relatively stringent requirements which excludes bridges: With any condition rating of 5 or less; (b) that have inventory ratings less than the State's legal load; (c) with spans greater than 100′ in length; (d) without load path redundancy; (e) that are very susceptible to vehicular damage, *e.g.,* structures with vertical over or underclearances less than 14′-0″, narrow thru or pony trusses. The requirements for a 48-month inspection frequency policy are described in the FHWA Technical Advisory T 5140.21 dated September 16, 1988. This document is available on-line at: *https://www.fhwa.dot.gov/reports/techadvs.cfm.*

[17] The total cost of inspection used in the NPRM RIA was estimated using the average loaded wage rage for civil engineers in 2016 from BLS ($64.19) and an assumption of 4 hours per inspection (4 hours × $64.19 = $257.76 in 2016 dollars).

[18] Comments from NYSDOT. FHWA–2017–0047–0138. Accessible from: *https://www.regulations.gov/document?D=FHWA-2017-0047-0138.*

This regulation will result in more consistent inspections and output from bridge inspections, better-qualified inspection personnel, and more robust reporting on structural and safety related deficiencies found during bridge inspections.

The benefits are separated into two categories: The benefits due to the NBIS changes and the benefits due to the SNBI changes. The FHWA believes that the benefits of each provision outweigh its costs. The NBIS changes will reduce the risk of negative safety impacts from sudden bridge deterioration of bridges at lower condition ratings, produce more consistent outputs from bridge inspections, enable better qualified inspection personnel, and result in more consistent reporting on structural or safety-related deficiencies. At the same time, FHWA does not expect that the rule will result in any safety disbenefits due to increased inspection intervals for some bridges. The SNBI changes are necessary for FHWA's required reports to Congress and will provide FHWA with additional data by including additional data elements in their ongoing bridge safety analysis practices which support various bridge safety programs including oversight of the NBIS and supporting the development of emergency response plans.

The safety benefits of the rule primarily come from the requirement for increased inspections for safety critical bridges, which are required to be inspected at a 12-month interval rather than the current 24-month interval. These increased inspections are expected to result in agencies identifying deteriorating conditions on bridges sooner than under the current rule. By identifying those conditions sooner, agencies can take safety mitigation measure more quickly. Those mitigation activities could include: Repairs, reducing allowed load weights, reducing traffic volumes on the bridge through lane closures, or bridge closures. By taking those actions sooner, the agencies will better protect the asset and the traveling public. However, those benefits are difficult to quantify.

The FHWA does not believe there will be safety disbenefits due to any provision of the rule. While the final rule allows agencies to increase the inspection interval from 24 months to 48 months for bridges that have condition ratings of 6 or above under method 1, it does not require them to do so. The expectation is that States would choose to use the Method 1 48-month interval in low-risk situations. Similarly, Method 2, which allows inspection intervals up to 72 months if the bridge passes a detailed risk analysis, is not required. The expectation is that agencies will rarely choose the Method 2 72-month interval, *e.g.,* maybe on pre-stressed single-span concrete bridges with low vehicle volume over low-risk streams. Agencies would not use Method 2 simply because a bridge has a high condition rating, *e.g.,* new bridges. If a specific bridge experienced an event that might cause its condition to change suddenly such as an adverse weather event, a strike, or construction activity, the agency will still be required to conduct initial and special inspections under § 650.311(d) of the regulations. The rulemaking follows the recommendations of the NCHRP Report 782, Proposed Guideline for Reliability-Based Bridge Inspection Practices which demonstrated and verified that inspection intervals of 72 months (24 months longer than the proposed rulemaking) will be suitable for certain bridges based on their risk profiles.[19]

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[19] National Academies of Sciences, Engineering, and Medicine 2014. Proposed Guideline for Reliability-Based Bridge Inspection Practices. Washington, DC: The National Academies Press. *https://doi.org/10.17226/22277.*

Table 1: Total Benefits and Cost of the Rule (2019$, base year=2018), Based on 30 to 65 Percent of Eligible Bridges using the Method 1 Risk-based 48-month Inspection Interval

Components	10-year Total Amount		Annualized Amount	
Discount Rate	0.07	0.03	0.07	0.03
COSTS				
Section 650.303, 650.307 -Applicability	$2,987,067	$4,067,105	$425,291	$476,789
Inspection of Bridges on/off Federal highways	$2,987,067	$4,067,105	$425,291	$476,789
Section 605.305 – Definitions	$0	$0	$0	$0
Section 650.307 - Bridge Inspection Organization Responsibilities	$7,144,641	$9,455,259	$1,017,236	$1,108,445
Establish Agreements for Border Bridges	$1,384,539	$1,612,469	$197,127	$189,031
Maintain Registry of Certified Inspectors	$208,292	$283,604	$29,656	$33,247
Establish Inspection Organizations	$5,551,810	$7,559,186	$790,453	$886,167
Section 650.309 - Qualifications of Personnel	$2,252,075	$2,731,751	$320,645	$320,245
Refresher Training for Program Managers and Team Leaders	$901,390	$1,141,477	$128,338	$133,816
Training on NSTM Inspections for Team Leaders	$1,181,278	$1,375,746	$168,187	$161,279
Proprietary Training Review	$169,407	$214,528	$24,120	$25,149
Section 650.311 - Inspection Intervals	-$130,991,791	-$178,354,663	-$18,650,284	-$20,908,608
Risk-based, 12-month Inspections	$32,508,008	$44,261,970	$4,628,409	$5,188,853
Risk-based, Method 1 48-month Inspections, @30 Percent	-$163,499,799	-$222,616,634	-$23,278,693	-$26,097,461
Risk-based, Method 1 48-month Inspections, @65 percent	-$354,249,564	-$482,336,040	-$50,437,168	-$56,544,498
Section 650.313 - Inspection Procedures	$1,892,479	$2,381,975	$269,446	$279,240
Initial and Routine Inspections for Bridges with Phased Const. or Temp. Bridges	$420,428	$572,442	$59,859	$67,108
Written Policies for Closing Bridges	$988,956	$1,151,764	$140,805	$135,022
Critical Findings Reporting and Tracking	$483,095	$657,769	$68,782	$77,111
Section 315 - Inventory	$1,080,341	$1,470,962	$153,816	$172,442
Bridge Inventory for Tribal Governments	$1,080,341	$1,470,962	$153,816	$172,442
Section 315 - SNBI	$111,021,713	$146,617,401	$15,806,994	$17,188,032
Inventory Software Upgrades	$20,521,881	$23,900,302	$2,921,854	$2,801,844
Updated Inspection Manuals	$311,521	$362,806	$44,354	$42,532
Additional Inspection Costs from SNBI	$57,127,326	$81,852,423	$8,133,646	$9,595,601
Additional One-time Inspection Costs for ELI	$23,491,928	$27,359,293	$3,344,722	$3,207,344
Additional Recurring Inspection Costs for ELI	$8,795,938	$12,242,185	$1,252,344	$1,435,158
Inspector Training for SNBI	$773,119	$900,394	$110,075	$105,554
Total Cost of Proposed Rule, @30 percent	-$4,613,474	-$11,630,210	-$656,855	-$1,363,415
Total Cost of Proposed Rule, @65 percent	-$195,363,239	-$271,349,616	-$27,815,330	-$31,810,453
BENEFITS				
NBIS	Not Quantified			
SNBI	Not Quantified			
NET BENEFITS				
All Provisions	Not Quantified			

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Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612), FHWA has evaluated the effects of this final rule on small entities. Because these regulations are primarily intended for States and Federal agencies, FHWA has determined that the action is not anticipated to have a significant economic impact on a substantial number of small entities. States and Federal agencies are not included in the definition of small entity set forth in 5 U.S.C. 601. Therefore, FHWA certifies that the action will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

FHWA has determined that this final rule will not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995, 109 Stat. 48). The NBIS is needed to ensure safety for the users of the Nation's bridges and to help protect Federal infrastructure investment. As discussed above, FHWA finds that this regulatory action will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $155,000,000 or more in any one year (2 U.S.C. 1532). In addition, the definition of ''Federal mandate'' in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or Tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The Federal-aid highway program permits this type of flexibility.

Executive Order 13132 (Federalism Assessment)

FHWA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132. FHWA has determined that this action will not have sufficient federalism implications to warrant the preparation of a federalism assessment. FHWA has also determined that this action will not preempt any State law or State regulation or affect the States' ability to discharge traditional State governmental functions.

Executive Order 12372 (Intergovernmental Review)

The regulations implementing E.O. 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program. Local entities should refer to the Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction, for further information.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct, sponsor, or require through regulations. The first data collection in the SNBI format will be in March 2026, which will be discussed in the 2024 notice. Until then, annual data collection will continue under the current notice.

This action contains a collection of information requirement under the PRA that is covered under existing OMB Control number 2125–0501.

National Environmental Policy Act

The Department has analyzed this action for the purpose of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*), and has determined that this action would not have a significant effect on the quality of the environment and qualifies for the categorical exclusion at 23 CFR 771.117(c)(20).

Executive Order 13175 (Tribal Consultation)

In accordance with E.O. 13175, FHWA identified potential effects on federally recognized Indian Tribes that might result from this rule. Accordingly, during the development of the NPRM, FHWA conducted a webinar on August 7, 2014, in furtherance of its duty to consult with Tribal governments under E.O. 13175 ''Consultation and Coordination With Indian Tribal Governments.'' The webinar dealt with the NBIS and mentioned that FHWA was planning to publish an NPRM sometime in the future that would include requirements for bridges owned by Tribal governments. The date and time of the webinar had been announced to the Tribal governments through the seven Tribal Technical Assistance Program centers. A total of 35 connections were on the webinar with one or more persons on each connection. Two Tribal governments were identified on the connections and at least one consultant that works with the Tribes was on the webinar. A number of the personnel on the webinar were from BIA and FHWA.

The webinar was conducted by three bridge engineers and one attorney all from FHWA. The PowerPoint presentation and narrative covered the history of the NBIS, the NBIS general requirements based on the current NBIS, and a final section considering the impacts on the Tribal governments caused by the 23 U.S.C. 144(h)(2) amendments to the NBIS. There was a question and answer period after the presentation where general questions about the NBIS were discussed as well as impacts to bridges owned by Tribal governments. Issues discussed included why a NPRM was needed, if trail bridges and pedestrian bridges were subject to the NBIS, and what funding was available for the bridge inspections. The webinar lasted for nearly an hour and was terminated when no more questions were asked. The webinar was recorded and uploaded onto the Tribal Transportation Program Bridge website [20] maintained by FHWA.

Tribal governments did not submit any comments in response to the NPRM. FHWA continues to work closely with Tribal governments on the implementation of the NBIS program through BIA coordination.

Executive Order 12898 (Environmental Justice)

E.O. 12898 requires that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. FHWA has determined that this final rule does not raise any environmental justice issues.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 650

Bridges, Grant programs—transportation, Highways and roads, Incorporation by reference, Reporting and recordkeeping requirements.

Issued in Washington, DC, under authority delegated in 49 CFR 1.85(a)(1).

Stephanie Pollack,

Deputy Administrator, Federal Highway Administration.

In consideration of the foregoing, FHWA amends title 23, Code of Federal Regulations, part 650, as set forth below:

[20] *https://flh.fhwa.dot.gov/programs/ttp/bridges/bip.htm.*

PART 650—BRIDGES, STRUCTURES, AND HYDRAULICS

■ 1. The authority citation for part 650 continues to read as follows:

Authority: 23 U.S.C. 119, 144, and 315.

■ 2. Revise subpart C to read as follows:

Subpart C—National Bridge Inspection Standards (NBIS)

Sec.
650.301 Purpose.
650.303 Applicability.
650.305 Definitions.
650.307 Bridge inspection organization responsibilities.
650.309 Qualification of personnel.
650.311 Inspection interval.
650.313 Inspection procedures.
650.315 Inventory.
650.317 Incorporation by reference.

Subpart C—National Bridge Inspection Standards (NBIS)

§ 650.301 Purpose.

This subpart sets the national minimum standards for the proper safety inspection and evaluation of all highway bridges in accordance with 23 U.S.C. 144(h) and the requirements for preparing and maintaining an inventory in accordance with 23 U.S.C. 144(b).

§ 650.303 Applicability.

The National Bridge Inspection Standards (NBIS) in this subpart apply to all structures defined as highway bridges located on all public roads, on and off Federal-aid highways, including tribally-owned and federally-owned bridges, private bridges that are connected to a public road on both ends of the bridge, temporary bridges, and bridges under construction with portions open to traffic.

§ 650.305 Definitions.

The following terms used in this subpart are defined as follows:

AASHTO Manual. The term ''AASHTO Manual'' means the American Association of State Highway and Transportation Officials (AASHTO) ''Manual for Bridge Evaluation'', including Interim Revisions, excluding the 3rd paragraph in Article 6B.7.1, incorporated by reference in § 650.317.

Attribute. Characteristic of the design, loading, conditions, and environment that affect the reliability of a bridge or bridge member.

Bridge. A structure including supports erected over a depression or an obstruction, such as water, highway, or railway, and having a track or passageway for carrying traffic or other moving loads, and having an opening measured along the center of the roadway of more than 20 feet between under copings of abutments or spring lines of arches, or extreme ends of openings for multiple boxes; it includes multiple pipes, where the clear distance between openings is less than half of the smaller contiguous opening.

Bridge inspection experience. Active participation in bridge inspections in accordance with the this subpart, in either a field inspection, supervisory, or management role. Some of the experience may come from relevant bridge design, bridge load rating, bridge construction, and bridge maintenance experience provided it develops the skills necessary to properly perform a NBIS bridge inspection.

Bridge inspection refresher training. The National Highway Institute [1] (NHI) ''Bridge Inspection Refresher Training Course'' or other State, federally, or tribally developed instruction aimed to improve quality of inspections, introduce new techniques, and maintain consistency in the inspection program.

Bridge Inspector's Reference Manual or *the BIRM.* A comprehensive FHWA manual on procedures and techniques for inspecting and evaluating a variety of in-service highway bridges. This manual is available at the following URL: *www.fhwa.dot.gov/bridge/nbis.cfm.* This manual may be purchased from the Government Publishing Office, Washington, DC 20402 and from National Technical Information Service, Springfield, VA 22161.

Complex feature. Bridge component(s) or member(s) with advanced or unique structural members or operational characteristics, construction methods, and/or requiring specific inspection procedures. This includes mechanical and electrical elements of moveable spans and cable-related members of suspension and cable-stayed superstructures.

Comprehensive bridge inspection training. Training that covers all aspects of bridge inspection and enables inspectors to relate conditions observed on a bridge to established criteria (see the BIRM for the recommended material to be covered in a comprehensive training course).

Consequence. A measure of impacts to structural safety and serviceability in a hypothetical scenario where a deterioration mode progresses to the point of requiring immediate action. This may include costs to restore the bridge to safe operating condition or other costs.

Critical finding. A structural or safety related deficiency that requires immediate action to ensure public safety.

Damage inspection. An unscheduled inspection to assess structural damage resulting from environmental factors or human actions.

Deterioration mode. Typical deterioration or damage affecting the condition of a bridge member that may affect the structural safety or serviceability of the bridge.

Element level bridge inspection data. Quantitative condition assessment data, collected during bridge inspections, that indicates the severity and extent of defects in bridge elements.

End-of-course assessment. A comprehensive examination given to students after the completion of the delivery of a training course.

Hands-on inspection. Inspection within arm's length of the member. Inspection uses visual techniques that may be supplemented by nondestructive evaluation techniques.

Highway. The term ''highway'' is defined in 23 U.S.C. 101.

In-depth inspection. A close-up, detailed inspection of one or more bridge members located above or below water, using visual or nondestructive evaluation techniques as required to identify any deficiencies not readily detectable using routine inspection procedures. Hands-on inspection may be necessary at some locations. In-depth inspections may occur more or less frequently than routine inspections, as outlined in bridge specific inspection procedures.

Initial inspection. The first inspection of a new, replaced, or rehabilitated bridge. This inspection serves to record required bridge inventory data, establish baseline conditions, and establish the intervals for other inspection types.

Inspection date. The date on which the field portion of the bridge inspection is completed.

Inspection due date. The last inspection date plus the current inspection interval.

Inspection report. The document which summarizes the bridge inspection findings, recommendations, and identifies the team leader responsible for the inspection and report.

Internal redundancy. A redundancy that exists within a primary member cross-section without load path redundancy, such that fracture of one component will not propagate through the entire member, is discoverable by the applicable inspection procedures, and will not cause a portion of or the entire bridge to collapse.

Inventory data. All data reported to the National Bridge Inventory (NBI) in accordance with the § 650.315.

[1] The NHI training may be found at the following URL: *www.nhi.fhwa.dot.gov/.*

Legal load. The maximum load for each vehicle configuration, including the weight of the vehicle and its payload, permitted by law for the State in which the bridge is located.

Legal load rating. The maximum permissible legal load to which the structure may be subjected with the unlimited numbers of passages over the duration of a specified bridge evaluation period. Legal load rating is a term used in Load and Resistance Factor Rating method.

Load path redundancy. A redundancy that exists based on the number of primary load-carrying members between points of support, such that fracture of the cross section at one location of a member will not cause a portion of or the entire bridge to collapse.

Load posting. Regulatory signs installed in accordance with 23 CFR 655.601 and State or local law which represent the maximum vehicular live load which the bridge may safely carry.

Load rating. The analysis to determine the safe vehicular live load carrying capacity of a bridge using bridge plans and supplemented by measurements and other information gathered from an inspection.

Nationally certified bridge inspector. An individual meeting the team leader requirements of § 650.309(b).

Nonredundant Steel Tension Member (NSTM). A primary steel member fully or partially in tension, and without load path redundancy, system redundancy or internal redundancy, whose failure may cause a portion of or the entire bridge to collapse.

NSTM inspection. A hands-on inspection of a nonredundant steel tension member.

NSTM inspection training. Training that covers all aspects of NSTM inspections to relate conditions observed on a bridge to established criteria.

Operating rating. The maximum permissible live load to which the structure may be subjected for the load configuration used in the load rating. Allowing unlimited numbers of vehicles to use the bridge at operating level may shorten the life of the bridge. Operating rating is a term used in either the Allowable Stress or Load Factor Rating method.

Private bridge. A bridge open to public travel and not owned by a public authority as defined in 23 U.S.C. 101.

Procedures. Written documentation of policies, methods, considerations, criteria, and other conditions that direct the actions of personnel so that a desired end result is achieved consistently.

Probability. Extent to which an event is likely to occur during a given interval. This may be based on the frequency of events, such as in the quantitative probability of failure, or on degree of belief or expectation. Degrees of belief about probability can be chosen using qualitative scales, ranks, or categories such as, remote, low, moderate, or high.

Professional engineer (PE). An individual, who has fulfilled education and experience requirements and passed examinations for professional engineering and/or structural engineering license that, under State licensure laws, permits the individual to offer engineering services within areas of expertise directly to the public.

Program manager. The individual in charge of the program, that has been assigned the duties and responsibilities for bridge inspection, reporting, and inventory, and has the overall responsibility to ensure the program conforms with the requirements of this subpart. The program manager provides overall leadership and is available to inspection team leaders to provide guidance.

Public road. The term ''public road'' is defined in 23 U.S.C. 101.

Quality assurance (QA). The use of sampling and other measures to assure the adequacy of QC procedures in order to verify or measure the quality level of the entire bridge inspection and load rating program.

Quality control (QC). Procedures that are intended to maintain the quality of a bridge inspection and load rating at or above a specified level.

Rehabilitation. The major work required to restore the structural integrity of a bridge as well as work necessary to correct major safety defects.

Risk. The exposure to the possibility of structural safety or serviceability loss during the interval between inspections. It is the combination of the probability of an event and its consequence.

Risk assessment panel (RAP). A group of well experienced panel members that performs a rigorous assessment of risk to establish policy for bridge inspection intervals.

Routine inspection. Regularly scheduled comprehensive inspection consisting of observations and measurements needed to determine the physical and functional condition of the bridge and identify changes from previously recorded conditions.

Routine permit load. A live load, which has a gross weight, axle weight, or distance between axles not conforming with State statutes for legally configured vehicles, authorized for unlimited trips over an extended period of time to move alongside other heavy vehicles on a regular basis.

Safe load capacity. A live load that can safely utilize a bridge repeatedly over the duration of a specified inspection interval.

Scour. Erosion of streambed or bank material due to flowing water; often considered as being localized around piers and abutments of bridges.

Scour appraisal. A risk-based and data-driven determination of a bridge's vulnerability to scour, resulting from the least stable result of scour that is either observed, or estimated through a scour evaluation or a scour assessment.

Scour assessment. The determination of an existing bridge's vulnerability to scour which considers stream stability and scour potential.

Scour critical bridge. A bridge with a foundation member that is unstable, or may become unstable, as determined by the scour appraisal.

Scour evaluation. The application of hydraulic analysis to estimate scour depths and determine bridge and substructure stability considering potential scour.

Scour plan of action (POA). Procedures for bridge inspectors and engineers in managing each bridge determined to be scour critical or that has unknown foundations.

Service inspection. An inspection to identify major deficiencies and safety issues, performed by personnel with general knowledge of bridge maintenance or bridge inspection.

Special inspection. An inspection scheduled at the discretion of the bridge owner, used to monitor a particular known or suspected deficiency, or to monitor special details or unusual characteristics of a bridge that does not necessarily have defects.

Special permit load. A live load, which has a gross weight, axle weight, or distance between axles not conforming with State statutes for legally configured vehicles and routine permit loads, typically authorized for single or limited trips.

State transportation department. The term ''State transportation department'' is defined in 23 U.S.C. 101.

System redundancy. A redundancy that exists in a bridge system without load path redundancy, such that fracture of the cross section at one location of a primary member will not cause a portion of or the entire bridge to collapse.

Team leader. The on-site, nationally certified bridge inspector in charge of an inspection team and responsible for planning, preparing, performing, and reporting on bridge field inspections.

Temporary bridge. A bridge which is constructed to carry highway traffic until the permanent facility is built, repaired, rehabilitated, or replaced.

Underwater bridge inspection diver. The individual performing the inspection of the underwater portion of the bridge.

Underwater Bridge Inspection Manual. A comprehensive FHWA manual on the procedures and techniques for underwater bridge inspection. This manual is available at the following URL: *www.fhwa.dot.gov/bridge/nbis.cfm.* This manual may be purchased from the Government Publishing Office, Washington, DC 20402 and from National Technical Information Service, Springfield, VA 22161.

Underwater bridge inspection training. Training that covers all aspects of underwater bridge inspection to relate the conditions of underwater bridge members to established criteria (see Underwater Bridge Inspection Manual and the BIRM section on underwater inspection for the recommended material to be covered in an underwater bridge inspection training course).

Underwater inspection. Inspection of the underwater portion of a bridge substructure and the surrounding channel, which cannot be inspected visually at low water or by wading or probing, and generally requiring diving or other appropriate techniques.

Unknown Foundations. Foundations of bridges over waterways where complete details are unknown because either the foundation type and depth are unknown, or the foundation type is known, but its depth is unknown, and therefore cannot be appraised for scour vulnerability.

§ 650.307 Bridge inspection organization responsibilities.

(a) Each State transportation department must perform, or cause to be performed, the proper inspection and evaluation of all highway bridges that are fully or partially located within the State's boundaries, except for bridges that are owned by Federal agencies or Tribal governments.

(b) Each Federal agency must perform, or cause to be performed, the proper inspection and evaluation of all highway bridges that are fully or partially located within the respective Federal agency's responsibility or jurisdiction.

(c) Each Tribal government, in consultation with the Bureau of Indian Affairs (BIA) or FHWA, must perform, or cause to be performed, the proper inspection and evaluation of all highway bridges that are fully or partially located within the respective Tribal government's responsibility or jurisdiction.

(d) Where a bridge crosses a border between a State transportation department, Federal agency, or Tribal government jurisdiction, all entities must determine through a joint written agreement the responsibilities of each entity for that bridge under this subpart, including the designated lead State for reporting NBI data.

(e) Each State transportation department, Federal agency, and Tribal government must include a bridge inspection organization that is responsible for the following:

(1) Developing and implementing written Statewide, Federal agencywide, or Tribal governmentwide bridge inspection policies and procedures;

(2) Maintaining a registry of nationally certified bridge inspectors that are performing the duties of a team leader in their State or Federal agency or Tribal government that includes, at a minimum, a method to positively identify each inspector, inspector's qualification records, inspector's current contact information, and detailed information about any adverse action that may affect the good standing of the inspector;

(3) Documenting the criteria for inspection intervals for the inspection types identified in these standards;

(4) Documenting the roles and responsibilities of personnel involved in the bridge inspection program;

(5) Managing bridge inspection reports and files;

(6) Performing quality control and quality assurance activities;

(7) Preparing, maintaining, and reporting bridge inventory data;

(8) Producing valid load ratings and when required, implementing load posting or other restrictions;

(9) Managing the activities and corrective actions taken in response to a critical finding;

(10) Managing scour appraisals and scour plans of action; and

(11) Managing other requirements of these standards.

(f) Functions identified in paragraphs (e)(3) through (11) of this section may be delegated to other individuals, agencies, or entities. The delegated roles and functions of all individuals, agencies, and entities involved must be documented by the responsible State transportation department, Federal agency, or Tribal government. Except as provided below, such delegation does not relieve the State transportation department, Federal agency, or Tribal government of any of its responsibilities under this subpart. A Tribal government may, with BIA's or FHWA's concurrence via a formal written agreement, delegate its functions and responsibilities under this subpart to the BIA or FHWA.

(g) Each State transportation department, Federal agency, or Tribal government bridge inspection organization must have a program manager with the qualifications defined in § 650.309(a). An employee of the BIA or FHWA having the qualification of a program manager as defined in § 650.309(a) may serve as the program manager for a Tribal government if the Tribal government delegates this responsibility to the BIA or FHWA in accordance with paragraph (f) of this section.

§ 650.309 Qualifications of personnel.

(a) A program manager must, at a minimum:

(1) Be a registered Professional Engineer, or have 10 years of bridge inspection experience;

(2) Complete an FHWA-approved comprehensive bridge inspection training course as described in paragraph (h) of this section and score 70 percent or greater on an end-of-course assessment (completion of FHWA-approved comprehensive bridge inspection training under FHWA regulations in this subpart in effect before June 6, 2022, satisfies the intent of the requirement in this paragraph (a));

(3) Complete a cumulative total of 18 hours of FHWA-approved bridge inspection refresher training over each 60 month period;

(4) Maintain documentation supporting the satisfaction of paragraphs (a)(1) through (3) of this section; and

(5) Satisfy the requirements of this paragraph (a) within 24 months from June 6, 2022, if serving as a program manager who was qualified under prior FHWA regulations in this subpart.

(b) A team leader must, at a minimum:

(1) Meet one of the four qualifications listed in paragraphs (b)(1)(i) through (iv) of this section:

(i) Be a registered Professional Engineer and have 6 months of bridge inspection experience;

(ii) Have 5 years of bridge inspection experience;

(iii) Have all of the following:

(A) A bachelor's degree in engineering or engineering technology from a college or university accredited by or determined as substantially equivalent by the Accreditation Board for Engineering and Technology; and

(B) Successfully passed the National Council of Examiners for Engineering

and Surveying Fundamentals of Engineering examination; and

(C) Two (2) years of bridge inspection experience; or

(iv) Have all of the following:

(A) An associate's degree in engineering or engineering technology from a college or university accredited by or determined as substantially equivalent by the Accreditation Board for Engineering and Technology; and

(B) Four (4) years of bridge inspection experience;

(2) Complete an FHWA-approved comprehensive bridge inspection training course as described in paragraph (h) of this section and score 70 percent or greater on an end-of-course assessment (completion of FHWA-approved comprehensive bridge inspection training under FHWA regulations in this subpart in effect before June 6, 2022, satisfies the intent of the requirement in this paragraph (b));

(3) Complete a cumulative total of 18 hours of FHWA-approved bridge inspection refresher training over each 60 month period;

(4) Provide documentation supporting the satisfaction of paragraphs (b)(1) through (3) of this section to the program manager of each State transportation department, Federal agency, or Tribal government for which they are performing bridge inspections; and

(5) Satisfy the requirements of this paragraph (b) within 24 months from June 6, 2022, if serving as a team leader who was qualified under prior FHWA regulations in this subpart.

(c) Team leaders on NSTM inspections must, at a minimum:

(1) Meet the requirements in paragraph (b) of this section;

(2) Complete an FHWA-approved training course on the inspection of NSTMs as defined in paragraph (h) of this section and score 70 percent or greater on an end-of-course assessment (completion of FHWA-approved NSTM inspection training prior to June 6, 2022, satisfies the intent of the requirement in this paragraph (c)); and

(3) Satisfy the requirements of this paragraph (c) within 24 months from June 6, 2022.

(d) Load ratings must be performed by, or under the direct supervision of, a registered professional engineer.

(e) An Underwater Bridge Inspection Diver must complete FHWA-approved underwater bridge inspection training as described in paragraph (h) of this section and score 70 percent or greater on an end-of-course assessment (completion of FHWA-approved comprehensive bridge inspection training or FHWA-approved underwater bridge inspection training under FHWA regulations in this subpart in effect before June 6, 2022, satisfies the intent of the requirement in this paragraph (e)).

(f) State transportation departments, Federal agencies, and Tribal governments must establish documented personnel qualifications for Damage and Special Inspection types.

(g) State transportation departments, Federal agencies, and Tribal governments that establish risk-based routine inspection intervals that exceed 48 months under § 650.311(a)(2) must establish documented personnel qualifications for the Service Inspection type.

(h) The following are considered acceptable bridge inspection training:

(1) *National Highway Institute training.* Acceptable NHI courses include:

(i) Comprehensive bridge inspection training, which must include topics of importance to bridge inspection; bridge mechanics and terminology; personal and public safety issues associated with bridge inspections; properties and deficiencies of concrete, steel, timber, and masonry; inspection equipment needs for various types of bridges and site conditions; inspection procedures, evaluations, documentation, data collection, and critical findings for bridge decks, superstructures, substructures, culverts, waterways (including underwater members), joints, bearings, drainage systems, lighting, signs, and traffic safety features; nondestructive evaluation techniques; load path redundancy and fatigue concepts; and practical applications of the concepts listed in this paragraph (h)(1)(i);

(ii) Bridge inspection refresher training, which must include topics on documentation of inspections, commonly miscoded items, recognition of critical inspection findings, recent events impacting bridge inspections, and quality assurance activities;

(iii) Underwater bridge inspection training, which must include topics on the need for and benefits of underwater bridge inspections; typical defects and deterioration in underwater members; inspection equipment needs for various types of bridges and site conditions; inspection planning and hazard analysis; and underwater inspection procedures, evaluations, documentation, data collection, and critical findings; and

(iv) NSTM inspection training, which must include topics on the identification of NSTMs and related problematic structural details; the recognition of areas most susceptible to fatigue and fracture; the evaluation and recording of defects on NSTMs; and the application of nondestructive evaluation techniques.

(2) *FHWA approval of alternate training.* A State transportation department, Federal agency, or Tribal government may submit to FHWA a training course as an alternate to any of the NHI courses listed in paragraph (h)(1) of this section. An alternate must include all the topics described in paragraph (h)(1) and be consistent with the related content. FHWA must approve alternate course materials and end-of-course assessments for national consistency and certification purposes. Alternate training courses must be reviewed by the program manager every 5 years to ensure the material is current. Updates to approved course materials and end-of-course assessments must be resubmitted to FHWA for approval.

(3) *FHWA-approved alternate training under prior regulations.* Agencies that have alternate training courses approved by FHWA prior to June 6, 2022, have 24 months to review and update training materials to satisfy requirements as defined in § 650.305 and paragraph (h)(1) of this section and resubmit to FHWA for approval.

§ 650.311 Inspection interval.

(a) *Routine inspections.* Each bridge must be inspected at regular intervals not to exceed the interval established using one of the risk-based methods outlined in paragraph (a)(1) or (2) of this section.

(1) *Method 1.* Inspection intervals are determined by a simplified assessment of risk to classify each bridge into one of three categories with an inspection interval as described below.

(i) *Regular intervals.* Each bridge must be inspected at regular intervals not to exceed 24 months, except as required in paragraph (a)(1)(ii) of this section and allowed in paragraphs (a)(1)(iii) of this section.

(ii) *Reduced intervals.* (A) State transportation departments, Federal agencies, or Tribal governments must develop and document criteria used to determine when intervals must be reduced below 24 months. Factors to consider include structure type, design, materials, age, condition ratings, scour, environment, annual average daily traffic and annual average daily truck traffic, history of vehicle impact damage, loads and safe load capacity, and other known deficiencies.

(B) Certain bridges meeting any of the following criteria as recorded in the National Bridge Inventory (NBI) (see § 650.315) must be inspected at intervals not to exceed 12 months:

(*1*) One or more of the deck, superstructure, or substructure, or culvert components is rated in serious or worse condition, as recorded by the Deck, Superstructure, or Substructure Condition Rating items, or the Culvert Condition Rating item, coded three (3) or less; or

(*2*) The observed scour condition is rated serious or worse, as recorded by the Scour Condition Rating item coded three (3) or less.

(C) Where condition ratings are coded three (3) or less due to localized deficiencies, a special inspection limited to those deficiencies, as described in § 650.313(h), can be used to meet this requirement in lieu of a routine inspection. In such cases, a complete routine inspection must be conducted in accordance with paragraph (a)(1)(i) of this section.

(iii) *Extended intervals.* (A) Certain bridges meeting all of the following criteria as recorded in the NBI (see § 650.315) may be inspected at intervals not to exceed 48 months:

(*1*) The deck, superstructure, and substructure, or culvert, components are all rated in satisfactory or better condition, as recorded by the Deck, Superstructure, and Substructure Condition Rating items, or the Culvert Condition Rating item coded six (6) or greater;

(*2*) The channel and channel protection are rated in satisfactory or better condition, as recorded by the Channel Condition and Channel Protection Condition items coded six (6) or greater;

(*3*) The inventory rating is greater than or equal to the standard AASHTO HS–20 or HL–93 loading and routine permit loads are not restricted or not carried/issued, as recorded by the Inventory Load Rating Factor item coded greater than or equal to 1.0 and the Routine Permit Loads item coded A or N;

(*4*) A steel bridge does not have Category E or E' fatigue details, as recorded by the Fatigue Details item coded N;

(*5*) All roadway vertical clearances are greater than or equal to 14′-0″, as recorded in the Highway Minimum Vertical Clearance item;

(*6*) All superstructure materials limited to concrete and steel and all superstructure types limited to certain arches, box girders/beams, frames, girders/beams, slabs, and culverts, as recorded by the Span Material items coded C01–C05 or S01–S05, and the Span Type items coded A01, B02–B03, F01–F02, G01–G08, S01–S02, or P01–P02; and

(*7*) Stable for potential scour and observed scour condition is rated satisfactory or better, as recorded by the Scour Vulnerability item coded A or B and the Scour Condition Rating item coded six (6) or greater.

(B) State transportation departments, Federal agencies, or Tribal governments that implement paragraph (a)(1)(iii)(A) of this section must develop and document an extended interval policy and must notify FHWA in writing prior to implementation. Factors to consider include structure type, design, materials, age, condition ratings, scour, environment, annual average daily traffic and annual average daily truck traffic, history of vehicle impact damage, loads and safe load capacity, and other known deficiencies.

(2) *Method 2.* Inspection intervals are determined by a more rigorous assessment of risk to classify each bridge, or a group of bridges, into one of four categories, with inspection intervals not to exceed 12, 24, 48, or 72 months. The risk assessment process must be developed by a Risk Assessment Panel (RAP) and documented as a formal policy. The RAP must be comprised of not less than four people, at least two of which are professional engineers, with collective knowledge in bridge design, evaluation, inspection, maintenance, materials, and construction, and include the NBIS program manager. The policy and criteria which establishes intervals, including subsequent changes, must be submitted by the State transportation department, Federal agency, or Tribal government for FHWA approval. The request must include the items in paragraphs (a)(2)(i) through (vi) of this section:

(i) Endorsement from a RAP, which must be used to develop a formal policy.

(ii) Definitions for risk factors, categories, and the probability and consequence levels that are used to define the risk for each bridge to be assessed.

(iii) Deterioration modes and attributes that are used in classifying probability and consequence levels, depending on their relevance to the bridge being considered. A system of screening, scoring, and thresholds are defined by the RAP to assess the risks. Scoring is based on prioritizing attributes and their relative influence on deterioration modes.

(A) A set of screening criteria must be used to determine how a bridge should be considered in the assessment and to establish maximum inspection intervals. The screening criteria must include:

(*1*) Requirements for flexure and shear cracking in concrete primary load members;

(*2*) Requirements for fatigue cracking and corrosion in steel primary load members;

(*3*) Requirements for other details, loadings, conditions, and inspection findings that are likely to affect the safety or serviceability of the bridge or its members;

(*4*) Bridges classified as in poor condition cannot have an inspection interval greater than 24 months; and

(*5*) Bridges classified as in fair condition cannot have an inspection interval greater than 48 months.

(B) The attributes in each assessment must include material properties, loads and safe load capacity, and condition.

(C) The deterioration modes in each assessment must include:

(*1*) For steel members: Section loss, fatigue, and fracture;

(*2*) For concrete members: Flexural cracking, shear cracking, and reinforcing and prestressing steel corrosion;

(*3*) For superstructure members: Settlement, rotation, overload, and vehicle/vessel impact; and

(*4*) For substructure members: Settlement, rotation, and scour.

(D) A set of criteria to assess risk for each bridge member in terms of probability and consequence of structural safety or serviceability loss in the time between inspections.

(iv) A set of risk assessment criteria, written in standard logical format amenable for computer programming.

(v) Supplemental inspection procedures and data collection that are aligned with the level of inspection required to obtain the data to apply the criteria.

(vi) A list classifying each bridge into one of four risk categories with a routine inspection interval not to exceed 12, 24, 48, or 72 months.

(3) *Service inspection.* A service inspection must be performed during the month midway between routine inspections when a risk-based, routine inspection interval exceeds 48 months.

(4) *Additional routine inspection interval eligibility.* Any new, rehabilitated, or structurally modified bridge must receive an initial inspection, be in service for 24 months, and receive its next routine inspection before being eligible for inspection intervals greater than 24 months.

(b) *Underwater inspections.* Each bridge must be inspected at regular intervals not to exceed the interval established using one of the risk-based methods outlined in paragraph (b)(1) or (2) of this section.

(1) *Method 1.* Inspection intervals are determined by a simplified assessment

of risk to classify each bridge into one of three categories for an underwater inspection interval as described in this section.

(i) *Regular intervals.* Each bridge must be inspected at regular intervals not to exceed 60 months, except as required in paragraph (b)(1)(ii) of this section and allowed in paragraph (b)(1)(iii) of this section.

(ii) *Reduced intervals.* (A) State transportation departments, Federal agencies, or Tribal governments must develop and document criteria used to determine when intervals must be reduced below 60 months. Factors to consider include structure type, design, materials, age, condition ratings, scour, environment, annual average daily traffic and annual average daily truck traffic, history of vehicle/vessel impact damage, loads and safe load capacity, and other known deficiencies.

(B) Certain bridges meeting at least any of the following criteria as recorded in the NBI (see § 650.315) must be inspected at intervals not to exceed 24 months:

(*1*) The underwater portions of the bridge are in serious or worse condition, as recorded by the Underwater Inspection Condition item coded three (3) or less;

(*2*) The channel or channel protection is in serious or worse condition, as recorded by the Channel Condition and Channel Protection Condition items coded three (3) or less; or

(*3*) The observed scour condition is three (3) or less, as recorded by the Scour Condition Rating item.

(C) Where condition ratings are coded three (3) or less due to localized deficiencies, a special inspection of the underwater portions of the bridge limited to those deficiencies, as described in § 650.313(h), can be used to meet this requirement in lieu of a complete underwater inspection. In such cases, a complete underwater inspection must be conducted in accordance with paragraph (b)(1)(i) of this section.

(iii) *Extended intervals.* (A) Certain bridges meeting all of the following criteria as recorded in the NBI (see § 650.315) may be inspected at intervals not to exceed 72 months:

(*1*) The underwater portions of the bridge are in satisfactory or better condition, as recorded by the Underwater Inspection Condition item coded six (6) or greater;

(*2*) The channel and channel protection are in satisfactory or better condition, as indicated by the Channel Condition and Channel Protection Condition items coded six (6) or greater;

(*3*) Stable for potential scour, Scour Vulnerability item coded A or B, and Scour Condition Rating item is satisfactory or better, coded six (6) or greater.

(B) State transportation departments, Federal agencies, or Tribal governments that implement paragraph (b)(1)(iii)(A) of this section must develop and document an underwater extended interval policy and must notify FHWA in writing prior to implementation. Factors to consider include structure type, design, materials, age, condition ratings, scour, environment, annual average daily traffic and annual average daily truck traffic, history of vehicle/vessel impact damage, loads and safe load capacity, and other known deficiencies.

(2) Method 2. Inspection intervals are determined by a more rigorous assessment of risk. The policy and criteria which establishes intervals, including subsequent changes, must be submitted by the State transportation department, Federal agency, or Tribal government for FHWA approval. The process and criteria must be similar to that outlined in paragraph (a)(2) of this section except that each bridge must be classified into one of three risk categories with an underwater inspection interval not to exceed 24, 60, and 72 months.

(c) *NSTM inspections.* NSTMs must be inspected at regular intervals not to exceed the interval established using one of the risk-based methods outlined in paragraph (c)(1) or (2) of this section.

(1) *Method 1.* Inspection intervals are determined by a simplified assessment of risk to classify each bridge into one of three risk categories with an interval not to exceed 12, 24, or 48 months.

(i) *Regular intervals.* Each NSTM must be inspected at intervals not to exceed 24 months except as required in paragraph (c)(1)(ii) of this section and allowed in paragraph (c)(1)(iii) of this section.

(ii) *Reduced intervals.* (A) State transportation departments, Federal agencies, or Tribal governments must develop and document criteria to determine when intervals must be reduced below 24 months. Factors to consider include structure type, design, materials, age, condition, environment, annual average daily traffic and annual average daily truck traffic, history of vehicle impact damage, loads and safe load capacity, and other known deficiencies.

(B) Certain NSTMs meeting the following criteria as recorded in the NBI (see § 650.315) must be inspected at intervals not to exceed 12 months:

(*1*) The NSTMs are rated in poor or worse condition, as recorded by the NSTM Inspection Condition item, coded 4 or less; or

(*2*) [Reserved].

(iii) *Extended intervals.* (A) Certain NSTMs meeting all of the following criteria may be inspected at intervals not to exceed 48 months:

(*1*) Bridge was constructed after 1978 as recorded in the NBI (see § 650.315) Year Built item and fabricated in accordance with a fracture control plan;

(*2*) All NSTMs have no fatigue details with finite life;

(*3*) All NSTMs have no history of fatigue cracks;

(*4*) All NSTMs are rated in satisfactory or better condition, as recorded in the NBI (see § 650.315) by the NSTM Inspection Condition item, coded 6 or greater; and

(*5*) The bridge's inventory rating is greater than or equal to the standard AASHTO HS–20 or HL–93 loading and routine permit loads are not restricted or not carried/issued, as recorded in the NBI (*see* § 650.315) by the Inventory Load Rating Factor item coded greater than or equal to 1.0 and the Routine Permit Loads item coded A or N;

(*6*) All NSTMs do not include pin and hanger assemblies.

(B) State transportation departments, Federal agencies, or Tribal governments that implement paragraph (c)(1)(iii)(A) of this section must develop and document an extended interval policy, and notify FHWA in writing prior to implementation. Factors to consider include structure type, design, materials, age, condition, environment, annual average daily traffic and annual average daily truck traffic, history of vehicle impact damage, loads and safe load capacity, and other known deficiencies.

(2) Method 2. Inspection intervals are determined by a more rigorous assessment of risk. The policy and criteria which establishes intervals, including subsequent changes must be submitted by the State transportation department, Federal agency, or Tribal government for FHWA approval. The process and criteria must be similar to that outlined in paragraph (a)(2) of this section except that each bridge must be classified into one of three risk categories with a NSTM inspection interval not to exceed 12, 24, or 48 months.

(d) *Damage, in-depth, and special inspections.* A State transportation department, Federal agency, or Tribal government must document the criteria to determine the level and interval for these inspections in its bridge inspection policies and procedures.

(e) *Bridge inspection interval tolerance.* (1) The acceptable tolerance for intervals of less than 24 months for the next inspection is up to two (2) months after the month in which the inspection was due.

(2) The acceptable tolerance for intervals of 24 months or greater for the next inspection is up to three (3) months after the month in which the inspection was due.

(3) Exceptions to the inspection interval tolerance due to rare and unusual circumstances must be approved by FHWA in advance of the inspection due date plus the tolerance in paragraphs (e)(1) and (2) of this section.

(f) *Next inspection.* Establish the next inspection interval for each inspection type based on results of the inspection and requirements of this section.

(g) *Implementation.* (1) The requirements of paragraphs (a)(1)(ii), (b)(1)(ii), and (c)(1)(ii) of this section must be satisfied within 24 months from June 6, 2022.

(2) Prior FHWA approved extended inspection interval policies will be rescinded 24 months after June 6, 2022.

§ 650.313 Inspection procedures.

(a) *General.* Inspect each bridge to determine condition, identify deficiencies, and document results in an inspection report in accordance with the inspection procedures in Section 4.2, AASHTO Manual (incorporated by reference, *see* § 650.317). Special equipment or techniques, and/or traffic control are necessary for inspections in circumstances where their use provide the only practical means of accessing and/or determining the condition of the bridge. The equipment may include advanced technologies listed in the BIRM.

(b) *Initial inspection.* Perform an initial inspection in accordance with Section 4.2, AASHTO Manual (incorporated by reference, *see* § 650.317) for each new, replaced, rehabilitated, and temporary bridge as soon as practical, but within 3 months of the bridge opening to traffic.

(c) *Routine inspection.* Perform a routine inspection in accordance with Section 4.2, AASHTO Manual (incorporated by reference, *see* § 650.317).

(d) *In-depth inspection.* Identify the location of bridge members that need an in-depth inspection and document in the bridge files. Perform in-depth inspections in accordance with the procedures developed in paragraph (g) of this section.

(e) *Underwater inspection.* Identify the locations of underwater portions of the bridge in the bridge files that cannot be inspected using wading and probing during a routine inspection. Perform underwater inspections in accordance with the procedures developed in paragraph (g) of this section. Perform the first underwater inspection for each bridge and for each bridge with portions underwater that have been rehabilitated as soon as practical, but within 12 months of the bridge opening to traffic.

(f) *NSTM inspection.* (1) Identify the locations of NSTMs in the bridge files.

(i) A State transportation department, Federal agency, or Tribal government may choose to demonstrate a member has system or internal redundancy such that it is not considered an NSTM. The entity may develop and submit a formal request for FHWA approval of procedures using a nationally recognized method to determine that a member has system or internal redundancy. FHWA will review the procedures for approval based upon conformance with the nationally recognized method. The request must include:

(A) Written policy and procedures for determining system or internal redundancy.

(B) Identification of the nationally recognized method used to determine system or internal redundancy. Nationally recognized means developed, endorsed and disseminated by a national organization with affiliates based in two or more States; or currently adopted for use by one or more State governments or by the Federal Government; and is the most current version.

(C) Baseline condition of the bridge(s) to which the policy is being applied.

(D) Description of design and construction details on the member(s) that may affect the system or internal redundancy.

(E) Routine inspection requirements for bridges with system or internally redundant members.

(F) Special inspection requirements for the members with system or internal redundancy.

(G) Evaluation criteria for when members should be reviewed to ensure they still have system and internal redundancy.

(ii) Inspect the bridge using the approved methods outlined in paragraphs (f)(1)(i)(E) and (F) of this section.

(2) Perform hands-on inspections of NSTMs in accordance with the procedures developed in paragraph (g) of this section.

(3) Perform the first NSTM inspection for each bridge and for each bridge with rehabilitated NSTMs as soon as practical, but within 12 months of the bridge opening to traffic.

(g) *NSTM, underwater, in-depth, and complex feature inspection procedures.* Develop and document inspection procedures for bridges which require NSTM, underwater, in-depth, and complex feature inspections in accordance with Section 4.2, AASHTO Manual (incorporated by reference, *see* § 650.317). State transportation departments, Federal agencies, and Tribal governments can include general procedures applicable to many bridges in their procedures manual. Specific procedures for unique and complex structural features must be developed for each bridge and contained in the bridge file.

(h) *Special inspection.* For special inspections used to monitor conditions as described in paragraphs (a)(1)(ii) and (b)(1)(ii) of this section, develop and document procedures in accordance with Section 4.2, AASHTO Manual (incorporated by reference, *see* § 650.317).

(i) *Service inspection.* Perform a service inspection when the routine inspection interval is greater than 48 months. Document the inspection date and any required follow up actions in the bridge file.

(j) *Team leader.* Provide at least one team leader at the bridge who meets the minimum qualifications stated in § 650.309 and actively participates in the inspection at all times during each initial, routine, in-depth, NSTM, underwater inspection, and special inspection described in paragraph (h) of this section.

(k) *Load rating.* (1) Rate each bridge as to its safe load capacity in accordance with the incorporated articles in Sections 6 and 8, AASHTO Manual (incorporated by reference, *see* § 650.317).

(2) Develop and document procedures for completion of new and updated bridge load ratings. Load ratings must be completed as soon as practical, but no later than 3 months after the initial inspection and when a change is identified that warrants a re-rating such as, but not limited to, changes in condition, reconstruction, new construction, or changes in dead or live loads.

(3) Analyze routine and special permit loads for each bridge that these loads cross to verify the bridge can safely carry the load.

(l) *Load posting.* (1) Implement load posting or restriction for a bridge in accordance with the incorporated articles in Section 6, AASHTO Manual (incorporated by reference, *see* § 650.317), when the maximum

unrestricted legal loads or State routine permit loads exceed that allowed under the operating rating, legal load rating, or permit load analysis.

(2) Develop and document procedures for timely load posting based upon the load capacity and characteristics such as annual average daily traffic, annual average daily truck traffic, and loading conditions. Posting shall be made as soon as possible but not later than 30 days after a load rating determines a need for such posting. Implement load posting in accordance with these procedures.

(3) Missing or illegible posting signs shall be corrected as soon as possible but not later than 30 days after inspection or other notification determines a need.

(m) *Closed bridges.* Develop and document criteria for closing a bridge which considers condition and load carrying capacity for each legal vehicle. Bridges that meet the criteria must be closed immediately. Bridges must be closed when the gross live load capacity is less than 3 tons.

(n) *Bridge files.* Prepare and maintain bridge files in accordance with Section 2.2, AASHTO Manual (incorporated by reference, *see* § 650.317).

(o) *Scour.* (1) Perform a scour appraisal for all bridges over water, and document the process and results in the bridge file. Re-appraise when necessary to reflect changing scour conditions. Scour appraisal procedures should be consistent with Hydraulic Engineering Circulars (HEC) 18 and 20. Guidance for scour evaluations is located in HEC 18 and 20, and guidance for scour assessment is located in HEC 20.

(2) For bridges which are determined to be scour critical or have unknown foundations, prepare and document a scour POA for deployment of scour countermeasures for known and potential deficiencies, and to address safety concerns. The plan must address a schedule for repairing or installing physical and/or hydraulic scour countermeasures, and/or the use of monitoring as a scour countermeasure. Scour plans of actions should be consistent with HEC 18 and 23.

(3) Execute action in accordance with the plan.

(p) *Quality control and quality assurance.* (1) Assure systematic QC and QA procedures identified in Section 1.4, AASHTO Manual (incorporated by reference, *see* § 650.317) are used to maintain a high degree of accuracy and consistency in the inspection program.

(2) Document the extent, interval, and responsible party for the review of inspection teams in the field, inspection reports, NBI data, and computations, including scour appraisal and load ratings. QC and QA reviews are to be performed by personnel other than the individual who completed the original report or calculations.

(3) Perform QC and QA reviews and document the results of the QC and QA process, including the tracking and completion of actions identified in the procedures.

(4) Address the findings of the QC and QA reviews.

(q) *Critical findings.* (1) Document procedures to address critical findings in a timely manner. Procedures must:

(i) Define critical findings considering the location and the redundancy of the member affected and the extent and consequence of a deficiency. Deficiencies include, but are not limited to scour, damage, corrosion, section loss, settlement, cracking, deflection, distortion, delamination, loss of bearing, and any condition posing an imminent threat to public safety. At a minimum, include findings which warrant the following:

(A) Full or partial closure of any bridge;

(B) An NSTM to be rated in serious or worse condition, as defined in the NBI (*see* § 650.315) by the NSTM Inspection item, coded three (3) or less;

(C) A deck, superstructure, substructure, or culvert component to be rated in critical or worse condition, as defined in the NBI (*see* § 650.315) by the Deck, Superstructure, or Substructure Condition Rating items, or the Culvert Condition Rating item, coded two (2) or less;

(D) The channel condition or scour condition to be rated in critical or worse condition as defined in the NBI (*see* § 650.315) by the Channel Condition Rating or Scour Condition Rating items, coded critical (2) or less; or

(E) Immediate load restriction or posting, or immediate repair work to a bridge, including shoring, in order to remain open.

(ii) Develop and document timeframes to address critical findings identified in paragraph (q)(1)(i) of this section.

(2) State transportation departments, Federal agencies, and Tribal governments must inform FHWA of all critical findings and actions taken, underway, or planned to resolve critical findings as follows:

(i) Notify FHWA within 24 hours of discovery of each critical finding on the National Highway System (NHS) as identified in paragraphs (q)(1)(i)(A) and (B) of this section;

(ii) Provide monthly, or as requested, a written status report for each critical finding as identified in paragraph (q)(1)(i) of this section until resolved. The report must contain:

(A) Owner;

(B) NBI Structure Number;

(C) Date of finding;

(D) Description and photos (if available) of critical finding;

(E) Description of completed, temporary and/or planned corrective actions to address critical finding;

(F) Status of corrective actions: Active/Completed;

(G) Estimated date of completion if corrective actions are active; and

(H) Date of completion if corrective actions are completed.

(r) *Review of compliance.* Provide information annually or as required in cooperation with any FHWA review of compliance with this subpart.

§ 650.315 Inventory.

(a) Each State transportation department, Federal agency, or Tribal government must prepare and maintain an inventory of all bridges subject to this subpart. Inventory data, as defined in § 650.305, must be collected, updated, and retained by the responsible State transportation department, Federal agency, or Tribal government and submitted to FHWA on an annual basis or whenever requested. For temporary bridges open to traffic greater than 24 months, inventory data must be collected and submitted per this section. Inventory data must include element level bridge inspection data for bridges on the NHS collected in accordance with the ''Manual for Bridge Element Inspection'' (incorporated by reference, *see* § 650.317). Specifications for collecting and reporting this data are contained in the ''Specifications for the National Bridge Inventory'' (incorporated by reference, *see* § 650.317).

(b) For all inspection types, enter changes to the inventory data into the State transportation department, Federal agency, or Tribal government inventory within 3 months after the month when the field portion of the inspection is completed.

(c) For modifications to existing bridges that alter previously recorded inventory data and for newly constructed bridges, enter the inventory data into the State transportation department, Federal agency, or Tribal government inventory within 3 months after the month of opening to traffic.

(d) For changes in load restriction or closure status, enter the revised inventory data into the State transportation department, Federal agency, or Tribal government inventory within 3 months after the month the change in load restriction or closure status of the bridge is implemented.

(e) Each State transportation department, Federal agency, or Tribal government must establish and document a process that ensures the time constraint requirements of paragraphs (b) through (d) of this section are fulfilled.

§ 650.317 Incorporation by reference .

Certain material is incorporated by reference (IBR) into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the U.S. Department of Transportation (DOT) and the National Archives and Records Administration (NARA). Contact DOT at: U.S. Department of Transportation Library, 1200 New Jersey Avenue SE, Washington, DC 20590 in Room W12–300, (800) 853–1351, *www.ntl.bts.gov/ntl.* For information on the availability of this material at NARA email: *fr.inspection@nara.gov* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.* The material may be obtained from the following sources:

(a) AASHTO. American Association of State Highway and Transportation Officials, 555 12th Street NW, Suite 1000, Washington, DC 20004; 1–800–231–3475; *https://store.transportation.org.*

(1) MBE–3. ''The Manual for Bridge Evaluation,'' Third Edition, 2018; IBR approved for § 650.305 and 650.313.:

(2) MBE–3–I1–OL. The Manual for Bridge Evaluation, 2019 Interim Revisions [to 2018 Third Edition], copyright 2018; IBR approved for § 650.305 and 650.313.

(3) MBE–3–I2. The Manual for Bridge Evaluation, 2020 Interim Revisions [to 2018 Third Edition], copyright 2020; IBR approved for § 650.305 and 650.313.

(4) MBEI–2: Manual for Bridge Element Inspection, Second Edition, 2019, IBR approved for § 650.315.

(b) FHWA. Federal Highway Administration, 1200 New Jersey Avenue SE, Washington, DC 20590: 1–202–366–4000; *www.fhwa.dot.gov/bridge/nbi.cfm.*

(1) FHWA–HIF–22–017: Specifications for the National Bridge Inventory, March, 2022, IBR approved for § 650.315.

(2) [Reserved].

Subpart D—[Removed and Reserved]

■ 3. Remove and reserve subpart D.

Subpart G—[Removed and Reserved]

■ 4. Remove and reserve subpart G.

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